

ELITE PHARMACEUTICALS INC /DE/
Form 10-Q
February 12, 2010

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, 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

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

Yes No The registrant is not yet subject to this requirement.

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

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

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

Yes No

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date. As of February 10, 2010 the issuer had outstanding 83,746,168 shares of common stock, \$0.001 par value (exclusive of 100,000 shares held in treasury).

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX

| | Page No. |
|--------------------------------|---|
| PART I - FINANCIAL INFORMATION | |
| Item 1. | Financial Statements |
| | Condensed Consolidated Balance Sheets as of December 31, 2009 (unaudited) and March 31, 2009 (audited) |
| | F-1 – F-2 |
| | Condensed Consolidated Statements of Operations for the three and nine months ended December 31, 2009 (unaudited) and December 31, 2008 (unaudited) |
| | F-3 |
| | Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended December 31, 2009 (unaudited) |
| | F-4 – F-5 |
| | Condensed Consolidated Statements of Cash Flows for the nine months ended December 31, 2009 (unaudited) and December 31, 2008 (unaudited) |
| | F-6 |
| | Notes to Condensed Consolidated Financial Statements |
| | F-7 |
| Item 2. | Management's Discussion and Analysis of Financial Condition and Results of Operations |
| | 1 |
| Item 3. | Quantitative and Qualitative Disclosures about Market Risk |
| | 9 |
| Item 4T. | Controls and Procedures |
| | 9 |
| PART II - OTHER INFORMATION | |
| Item 1. | Legal Proceedings |
| | 9 |
| Item 1A. | Risk Factors |
| | 10 |
| Item 2 | Unregistered Sales of Equity Securities and Use of Proceeds |
| | 10 |
| Item 3. | Defaults upon Senior Securities |
| | 10 |
| Item 4. | Submission of Matters to a Vote of Security Holders |
| | 10 |
| Item 5. | Other Information |
| | 11 |
| Item 6. | Exhibits |
| | 11 |
| SIGNATURES | 14 |

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

| | ASSETS | |
|---|----------------------------------|-----------------------------|
| | December 31, 2009 (Unaudited) | March 31, 2009 (Audited) |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 867,388 | \$ 282,578 |
| Accounts receivable, (net of allowance for doubtful accounts of zero) | 413,303 | 1,177 |
| Inventories (net of allowance of \$494,425 and \$zero, respectively) | 1,395,795 | 1,703,766 |
| Prepaid expenses and other current assets | 61,758 | 331,622 |
| Total current assets | 2,378,244 | 2,319,143 |
| PROPERTY AND EQUIPMENT , net of accumulated depreciation and amortization of \$3,720,455 and \$3,360,606 | 4,215,638 | 4,575,487 |
| INTANGIBLE ASSETS – net of accumulated amortization of \$137,324 and \$131,677 | 22,096 | 27,743 |
| OTHER ASSETS | | |
| Accrued interest receivable | 9,916 | 8,539 |
| Deposit on equipment | — | 14,073 |
| Investment in related party | 3,329,322 | 3,329,322 |
| Security deposits | 14,652 | 13,488 |
| Restricted cash – debt service for EDA bonds | 278,812 | 327,435 |
| EDA Bond offering costs, net of accumulated amortization of \$61,234 and \$49,534 | 293,218 | 304,918 |
| Total other assets | 3,925,920 | 3,997,775 |
| TOTAL ASSETS | \$ 10,901,898 | \$ 10,920,148 |

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

| | December 31, 2009 (Unaudited) | March 31, 2009 (Audited) |
|--|-------------------------------------|-----------------------------|
| CURRENT LIABILITIES | | |
| Current portion of EDA Bonds | \$ 225,000 | \$ 210,000 |
| Short term loans and current portion of long-term debt | 35,432 | 10,788 |
| Accounts payable and accrued expenses | 1,306,126 | 981,058 |
| Preferred share derivative interest payable | 350,009 | — |
| Dividends payable | — | 358,621 |
| Total Current Liabilities | 1,916,567 | 1,560,467 |
| LONG TERM LIABILITIES | | |
| EDA bonds – net of current portion | 3,160,000 | 3,385,000 |
| Long-term debt, less current portion | 22,871 | 31,600 |
| Derivative Liability – Preferred Shares | 9,787,965 | — |
| Derivative Liability – Warrants | 11,855,657 | — |
| Total Long-Term Liabilities | 24,826,493 | 3,416,600 |
| Total Liabilities | 26,743,060 | 4,977,067 |

COMMITMENTS AND CONTINGENCIES:

STOCKHOLDERS (DEFICIT) EQUITY

| | | |
|---|---|-----|
| 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 December 31, 2009 and March 31, 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 April 1, 2009 | — | 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 April 1, 2009 | — | 137 |
| Authorized 30,000 Series D convertible Preferred Stock – issued and outstanding 9,008 and 9,154 shares, respectively – Reclassified as a liability as of April 1, 2009 | — | 91 |
| Common Stock – par value of \$0.001 and \$0.01 as of December 31, 2009 and March 31, 2009, respectively | | |

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

Authorized 355,516,558 and 210,000,000 shares as of December 31, 2009 and March 31, 2009, respectively

Issued and outstanding – 80,126,234 shares and 60,839,374 shares, as of December 31, 2009 and March 31, 2009, respectively

| | | |
|--|----------------------|----------------------|
| | 80,126 | 608,394 |
| Subscription receivable | (75,000) | (75,000) |
| Additional paid-in capital | 90,489,114 | 95,718,082 |
| Accumulated deficit | (106,028,561) | (90,001,793) |
| Treasury stock, at cost (100,000 shares) | (306,841) | (306,841) |
| Total Stockholders Equity / (Deficit) | (15,841,162) | 5,493,081 |
| TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY | \$ 10,901,898 | \$ 10,920,148 |

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

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

| | THREE MONTHS ENDED DECEMBER 31, | | NINE MONTHS ENDED DECEMBER 31, | |
|--|------------------------------------|--------------|-----------------------------------|--------------|
| | 2009 | 2008 | 2009 | 2008 |
| REVENUES | | | | |
| Manufacturing Fees | 744,948 | 162,558 | 1,948,952 | \$1,255,850 |
| Royalties | 172,435 | 74,222 | 558,522 | 232,800 |
| Total Revenues | 917,383 | 236,780 | 2,507,474 | 1,488,650 |
| Costs of Revenues | | | | |
| Inventory Adjustment | — | — | 311,986 | — |
| Gross Profit | 307,967 | 77,129 | 583,029 | 327,503 |
| COST OF OPERATIONS | | | | |
| Research and development | 247,773 | 600,680 | 758,190 | 3,144,370 |
| General and administrative | 498,884 | 467,487 | 1,288,565 | 1,741,760 |
| Non-cash compensation through issuance of stock options and warrants | 28,488 | 246,858 | 113,041 | 839,031 |
| Depreciation and amortization | 39,715 | 130,257 | 214,487 | 390,771 |
| Total Cost of Operations | 814,860 | 1,445,282 | 2,374,283 | 6,115,932 |
| LOSS FROM OPERATIONS | (506,893) | (1,368,153) | (1,791,254) | (5,788,429) |
| OTHER INCOME / (EXPENSES) | | | | |
| Interest income | — | 8,482 | 2,012 | 38,583 |
| Interest expense | (67,342) | (61,437) | (200,541) | (190,691) |
| Change in fair value of outstanding warrant derivatives | (5,086,610) | — | (6,453,107) | — |
| Change in fair value of preferred share derivatives | (3,325,418) | — | (2,147,122) | — |
| Interest expense attributable to dividends accrued to preferred share derivative liabilities | (350,010) | — | (1,008,383) | — |
| Discount in Series E issuance attributable to beneficial conversion features | (254,212) | — | (512,912) | — |
| Total Other Income / (Expense) | (9,083,592) | (52,955) | (10,320,053) | (152,108) |
| INCOME / (LOSS) BEFORE PROVISION FOR INCOME TAXES | (9,590,485) | (1,421,108) | (12,111,307) | (5,940,537) |
| Provision for Income Taxes | — | — | — | (3,120) |
| NET INCOME / (LOSS) | (9,590,485) | (1,421,108) | (12,111,307) | (5,943,657) |
| Preferred Stock Dividends | — | (659,562) | — | (1,771,751) |

| | | | | |
|---|----------------|----------------|-----------------|----------------|
| NET INCOME / (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS | \$(9,590,485) | \$(2,080,670) | \$(12,111,307) | \$(7,715,408) |
| BASIC AND DILUTED LOSS PER COMMON SHARE | \$(0.12) | \$(0.07) | \$(0.17) | \$(0.30) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING – BASIC | 78,620,207 | 29,799,888 | 73,018,708 | 25,886,117 |

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

F - 3

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT)EQUITY
(page 1 of 2)

| | Series B | | Series C | | Series D | | Common Stock | |
|--|---------------------------|--------|---------------------------|--------|---------------------------|--------|--------------|-----------|
| | Preferred Stock Shares | Amount | Preferred Stock Shares | Amount | Preferred Stock Shares | Amount | Shares | Amount |
| Balance at March 31, 2009 | 1,046 | 11 | 13,705 | 137 | 9,154 | 91 | 60,839,374 | 608,394 |
| Cumulative effect of reclassification of preferred stock and warrants | | (11) | | (137) | | (91) | — | — |
| Proceeds received in exchange for beneficial conversion features embedded in Series E preferred shares | — | — | — | — | — | — | — | — |
| Conversion of Series B, Series C and Series D preferred shares into common | (150) | | (8,827) | | (146) | | 5,383,010 | 53,830 |
| Costs associated with raising capital | — | — | — | — | — | — | — | — |
| Non-cash compensation through Issuance of stock options and warrants | — | — | — | — | — | — | — | — |
| Net Income for the six months ended September 30, 2009 | — | — | — | — | — | — | — | — |
| Dividends | — | — | — | — | — | — | 4,006,339 | 40,063 |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expense | — | — | — | — | — | — | 8,988,420 | 89,884 |
| Reduction in Par Value | — | — | — | — | — | — | — | (721,136) |
| | — | — | — | — | — | — | 909,091 | 9,091 |

Common shares issued
in lieu of cash in
payment of legal
expenses

| | | | | | | | | |
|---------------------------------|-----|---|-------|---|-------|---|------------|--------|
| Balance at December 31, 2009 | 896 | — | 5,418 | — | 9,008 | — | 80,126,234 | 80,126 |
|---------------------------------|-----|---|-------|---|-------|---|------------|--------|

Schedule continues on next page

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

F - 4

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
 CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT) EQUITY
 (page 2 of 2)

(schedule continued from preceding page)

| | Subscription Receivable | Additional Paid in Capital | Treasury Stock Shares | Treasury Stock Amount | Accumulated Deficit | Stockholders (Deficit) Equity |
|---|----------------------------|----------------------------------|--------------------------|--------------------------|------------------------|-------------------------------------|
| Balance at March 31, 2009 | (75,000) | 95,718,092 | (100,000) | (306,841) | (90,001,793) | 5,943,081 |
| Cumulative effect of reclassification of preferred stock and warrants | — | (7,144,131) | — | — | (3,915,462) | (11,059,593) |
| Proceeds received in exchange for beneficial conversion features embedded in Series E preferred shares | — | 512,912 | — | — | — | 512,912 |
| Conversion of Series B, Series C and Series D preferred shares into common | — | 14,400 | — | — | — | 68,230 |
| Costs associated with raising capital | — | (359,264) | — | — | — | (359,264) |
| Non-cash compensation through Issuance of stock options and warrants | — | 113,041 | — | — | — | 113,041 |
| Net Income for the nine months ended December 31, 2009 | — | — | — | — | (12,111,307) | (12,111,307) |
| Dividends | — | 318,958 | — | — | — | 359,021 |
| Common shares issued in lieu of cash in payment of preferred share derivative interest | — | 503,062 | — | — | — | 592,946 |

expense

| | | | | | | |
|---|----------|------------|-----------|-----------|----------------|---------------|
| Reduction in Par Value | | 721,136 | | | | — |
| Common shares issued in lieu of cash in payment of legal expenses | | 90,909 | | | | 100,000 |
| Balance at December 31, 2009 | (75,000) | 90,489,114 | (100,000) | (306,841) | (106,028,561) | (15,841,162) |

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

F - 5

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

| | NINE MONTHS ENDED DECEMBER | |
|---|----------------------------|---------------------|
| | 31, | |
| | 2009 | 2008 |
| | (Unaudited) | (Unaudited) |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net Loss | \$ (12,111,307) | \$ (4,522,549) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 377,196 | 260,514 |
| Inventory adjustment | 311,986 | — |
| Change in fair value of warrant derivative liability | 6,453,107 | — |
| Change in fair value of preferred shares derivative liability | 2,147,122 | — |
| Discount in Series E issuance attributable to embedded beneficial conversion feature | 512,912 | — |
| Preferred shares derivative interest accrued | 1,008,383 | — |
| Legal expenses satisfied by the issuance of common stock | 100,000 | |
| Non-cash compensation satisfied by the issuance of common stock, options and warrants | 113,041 | 592,173 |
| Changes in assets and liabilities: | | |
| Accounts and interest receivable | (413,503) | (258,419) |
| Inventories | (4,015) | 410,905 |
| Prepaid expenses and other current assets | 72,374 | 52,296 |
| Security deposit | 12,909 | — |
| Accounts payable, accrued expenses and other current liabilities | 275,643 | 190,827 |
| NET CASH USED IN OPERATING ACTIVITIES | (1,144,152) | (3,274,253) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchases of property and equipment | — | (75,558) |
| (Deposits) to / Withdrawals from restricted cash | 48,623 | (3,326) |
| NET CASH PROVIDED BY /(USED IN) INVESTING ACTIVITIES | 48,623 | (78,884) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Dividends paid | — | (126,603) |
| Proceeds from issuance of Series D 8% Convertible Preferred Stock and Warrants | — | 1,777,000 |
| Proceeds from issuance of Series E Preferred Stock and Warrants | 2,000,000 | — |
| NJEDA bond principal payments | (210,000) | (200,000) |
| Other loan payments | (109,661) | (4,821) |
| Costs associated with raising capital | — | (263,753) |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 1,680,339 | 1,181,823 |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | 584,810 | (2,171,314) |
| CASH AND CASH EQUIVALENTS – beginning of period | 282,578 | 3,702,615 |
| CASH AND CASH EQUIVALENTS – end of period | \$ 867,388 | \$ 1,531,301 |

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

| | | |
|----------------------------|---------|---------|
| Cash paid for interest | 145,287 | 130,472 |
| Cash paid for income taxes | — | 3,120 |

SCHEDULE OF NON-CASH INVESTING AND FINANCING
ACTIVITIES

| | | |
|--|-----------|--------|
| Accrued dividends | — | 36,800 |
| Common shares issued in lieu of cash in payment of preferred share | | |
| derivative interest expense | 8,988,420 | — |
| Accrued preferred share derivative interest expense | 1,008,383 | — |

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2009 AND 2008
(UNAUDITED)

NOTE
1 - BASIS OF PRESENTATION

The information in this quarterly report on Form 10-Q includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the “Registrant”) including its wholly-owned subsidiaries, Elite Laboratories, Inc. (“Elite Labs”) and Elite Research, Inc. (“ERI”) for the three and nine months ended December 31, 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 the fiscal year ending March 31, 2010; therefore a current provision for income tax was not established for the three and nine months ended December 31, 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. As of December 31, 2009, we had cash and cash equivalents of \$867,388. We believe that our existing cash and cash equivalents plus revenues from the sale of our Lodrane 24® and Lodrane 24D® products, will be sufficient to fund our anticipated operating expenses and capital requirements through December 2010. We will require additional funding in order to continue to operate thereafter. If the third closing of the transactions contemplated by the Epic Strategic Alliance Agreement is not completed 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 third closing 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 third closing 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.

F - 7

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. “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.

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 are 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 |
| Preferred stock derivative liability at April 1, 2009 | \$ 87,130 | \$ 1,106,615 | \$ 5,950,386 | \$ — | \$ 7,144,131 |

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 in accordance with generally accepted accounting principles, is recognized as an adjustment in the opening accumulated deficit balance.

PREFERRED STOCK DERIVATIVE LIABILITY AS OF DECEMBER 31, 2009

| | Series B | Series C | Series D | Series E | Total |
|--|--------------|---------------|---------------|--------------|--------------|
| Preferred shares Outstanding | 896 | 5,418 | 9,008 | 2,000 | 17,322 |
| Underlying common shares into which Preferred may convert | 574,076 | 3,365,217 | 45,042,205 | 40,000,000 | 88,981,499 |
| Closing price on valuation date | \$ 0.11 | \$ 0.11 | \$ 0.11 | \$ 0.11 | \$ 0.11 |
| Preferred stock derivative liability at December 31, 2009 | \$ 63,148 | \$ 370,174 | \$ 4,954,643 | \$ 4,400,000 | \$ 9,787,965 |
| Series E liability at issue date (related to beneficial conversion option) | | | | 512,912 | 512,912 |
| Change in preferred stock derivative liability for the nine months ended December 31, 2009 | \$ (23,982) | \$ (736,441) | \$ (979,543) | \$ 3,887,088 | \$ 2,147,122 |

| | | | | | |
|---|-----------|-----------|------------|--------------|--------------|
| Change in preferred stock derivative liability for the three months ended December 31, 2009 | \$ 11,481 | \$ 67,304 | \$ 900,845 | \$ 2,345,788 | \$ 3,325,418 |
|---|-----------|-----------|------------|--------------|--------------|

The change of \$3,325,418 and \$2,147,122 in value of the preferred stock derivative liability occurring during the three and nine months ended December 31, 2009, respectively, is included in the amount reported in the "Other Income / (Expense)" section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

F - 9

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:

| | Apr 1 2009 | Jun 30 2009 | Sept 30 2009 | Dec 31 2009 |
|--|---------------|----------------------------------|-----------------------------------|----------------------------------|
| Risk-Free interest rate | 2% | 2% | 2% | 2.545% |
| Expected volatility | 118% - 137% | 116% - 153% | 120% - 165% | 125% - 184% |
| Expected life (in years) | 3.2 – 5.2 | 3.0 – 7.0 | 2.7 – 6.7 | 2.5 – 6.8 |
| Expected dividend yield | — | — | — | — |
| Number of warrants | 45,469,740 | 85,469,740 | 85,469,740 | 125,469,740 |
| Fair value – Warrant Derivative Liability | \$ 3,915,462 | 4,502,436 | \$ 6,023,258 | \$ 11,855,657 |
| | | 3 Months Ended Jun 30 2009 | 6 Months Ended Sept 30 2009 | 9 Months Ended Dec 31 2009 |
| Initial derivative warrant value for those warrants existing at the beginning of the fiscal year | | 3,915,462 | 3,915,462 | 3,915,462 |
| Cumulative initial value of warrants issued during the fiscal year | | 741,300 | 741,300 | 1,487,088 |
| Year-to-Date Change in Warrant Derivative Liability | | (154,326) | 1,366,496 | 6,453,107 |
| Fair Value – Warrant Derivative Liability | | \$ 4,502,436 | \$ 6,023,258 | \$ 11,855,657 |
| Change in Warrant Derivative Value for the Quarter Ended | | \$ (154,326) | \$ 1,520,822 | \$ 5,086,610 |

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 increase of \$5,086,610 and \$6,453,107 in value of the warrant derivative liability occurring during the three and nine months ended December 31, 2009, respectively, is reported in the "Other Income (Expenses)" section of the statement of operations.

F - 10

Beneficial Conversion Features of Series E Preferred Shares

The Series E Preferred shares include 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 and \$0.08 for the issuances of Series E Preferred shares at the first and second closings of the Epic Strategic Alliance Agreement (the “First and Second Closings”), respectively. The differences of \$0.04 and \$.03 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 beneficial conversion feature was valued at \$258,700 and \$254,212, for the First and Second closings, respectively, calculated using the relative fair value method, as required by FAS 14, allocating the proceeds of \$1 million from each issuance of the Series E Preferred shares to the conversion option and detachable warrants included with such issuance as follows:

| | First Closing (Jun 2009) | | Second Closing (Oct 2009) | |
|--|--------------------------------|---|---------------------------------|---|
| Allocation % attributable to the Preferred shares conversion option | | | | |
| Proceeds from Issuance of Series E Preferred Shares | \$ 1,000,000 | | \$ 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 | | 2,933,727 | |
| Total of proceeds plus warrants | 3,865,486 | | 3,933,727 | |
| Allocation % attributable to Preferred Shares conversion option (quotient of the proceeds divided by the proceeds plus warrants) | 25.9 | % | 25.4 | % |
| Amount of proceeds attributed to conversion option | 258,700 | | 254,212 | |
| Gross value of beneficial conversion feature | | | | |
| Share price as of issue date | \$ 0.09 | | \$.08 | |
| Conversion option price | \$ 0.05 | | \$.05 | |
| Beneficial conversion feature per share | \$ 0.04 | | \$.03 | |
| Number of common shares | 20,000,000 | | 20,000,000 | |
| Gross value of beneficial conversion feature | \$ 800,000 | | \$ 600,000 | |
| Beneficial conversion option recorded (lesser of the gross value or the amount of proceeds attributed to the conversion option) | \$ 258,700 | | \$ 254,212 | |

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

| | First Closing (June 2009) | Second Closing (Oct 2009) |
|--------------------------|------------------------------------|---------------------------------|
| Risk-free interest rate | 2.000% | 2.980% |
| Expected volatility | 115.2% | 122.5% |
| Expected life (in years) | 7 | 7 |
| | 40 million | 40 million |

| | |
|-----------------|------------------------|
| N u m b e r o f | |
| warrants | |
| Fair value | \$2,865,486\$2,933,727 |

A beneficial conversion option is required to 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.

F - 11

Summary of effects of derivatives on the financial statements

| | Derivative Liabilities | Accumulated Deficit and Paid-in Capital | Other Income / (Expense) |
|---|---------------------------|--|--------------------------------|
| 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 | — | 512,912 | — |
| Warrants issued with Series E | 1,487,088 | — | — |
| Amortization of beneficial conversion of Series E as interest expense | 512,912 | — | (512,912) |
| Change in value of preferred stock derivative liability | 2,147,122 | — | (2,147,122) |
| Change in value of warrants derivative liability | 6,453,107 | — | (6,453,107) |
| Preferred stock derivatives converted into common shares | (16,200) | (16,200) | — |
| Net Effect of Derivatives | 21,643,622 | (10,562,881) | (9,113,141) |

NOTE
3 - INVENTORIES

Inventories are recorded at the lower of cost or market. As of December 31, 2009 the Company had inventory valuation reserve totaling \$494,425 resulting in a charge to operations of \$311,986 during the nine months ended December 31, 2009.

NOTE
4 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE

Preferred share derivative interest payable as of December 31, 2009 consisted of \$350,019 in derivative interest accrued as of December 31, 2009. The full amount of derivative interest payable as of December 31, 2009 was paid via the issuance of 3,619,745 shares of common stock in January 2010.

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 were \$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 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 was deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company's facility. As of December 31, 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 \$10,598 and \$10,638 for the nine months ended December 31, 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 December 31, 2009, the Registrant had 2,287,000 options outstanding with exercise prices ranging from \$0.06 to \$3.00 per share; each option representing the right to purchase one share of Common Stock. Subsequent to December 31, 2009, the Registrant's Compensation Committee made a determination to grant Incentive Stock Options to current employees in accordance with the Registrant's 2009 Equity Incentive Plan, as adopted November 24, 2009. Such options, when awarded, will be in addition to those outstanding as of December 31, 2009. Please refer to Note 8 of this quarterly report for details of this determination made by the Compensation Committee.

NOTE
7 - PER SHARE INFORMATION

Basic earnings per share of common stock ("Basic EPS") is computed by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding. Diluted earnings per share of common stock ("Diluted EPS") is computed by dividing the net (loss) income by the weighted-average number of shares of common stock, and dilutive common stock equivalents and convertible securities then outstanding. 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 Condensed Statements of Operations. Diluted earnings per share is not presented because the effect of the Company's common stock equivalents is anti-dilutive.

| | For the Three Months Ended December 31, 2009 | For the Nine Months Ended December 31, 2008 |
|---|---|---|
| Numerator | | |
| Net Income (loss) attributable to common shareholders | \$ (9,590,485) | \$ (12,111,307) |
| Denominator | | |
| Weighted-average shares of common stock outstanding | 78,620,207 | 73,018,708 |
| Net (loss) income per share | | |
| Basic | \$ (0.12) | \$ (0.17) |

NOTE
8 - SUBSEQUENT EVENTS

The Registrant has evaluated subsequent events from the balance sheet date through February 12, 2010, the date the accompanying financial statements were issued. The following are material subsequent events:

Common shares issued in lieu of cash in payment of derivative interest expense
Derivative interest expense related to the Preferred Share derivatives due and payable as of December 31, 2009 were paid during January 2010 through the issuance of 3,619,745 shares of common stock.

Changes in the Registrant's Certifying Accountant

The Audit Committee of the Board of Directors of Elite Pharmaceuticals, Inc ("Company") regularly reviews the selection of the Company's independent registered public accounting firm. On January 14, 2010, after an extensive evaluation process the Audit Committee engaged Demetrius & Company, LLC ("Demetrius") as its new independent registered public accounting firm and dismissed Rosen Seymour Shapss Martin & Company LLP ("Rosen") as the Company's independent registered public accounting firm.

The reports of Rosen on the Company's consolidated financial statements for the fiscal year ended March 31, 2009 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no disagreements with Rosen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Rosen's satisfaction, would have caused Rosen to make reference to the subject matter of the disagreement in connection with its report. During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K.

The Company requested Rosen to furnish a letter addressed to the Securities and Exchange Commission stating whether Rosen agrees with the above statements. A copy of that letter, dated January 14, 2010, is filed as Exhibit 16.2 to the Form 8-K filed with the SEC on January 14, 2010, such filing being incorporated herein by this reference.

During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, the Company did not consult Demetrius with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements.

Determination by Compensation Committee to grant Incentive Stock Options (ISO)

On January 18, 2010, the Compensation Committee made a determination to grant Incentive Stock Options to current employees in accordance with the Equity Incentive Plan as adopted November 24, 2009 (the "Equity Incentive Plan"). A total of 1,000,000 incentive stock options are to be awarded, with each option representing the right to purchase one share of common stock, with an exercise price equal to the fair market value of the shares on the date of the grant.

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2009 COMPARED TO THE
THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 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". 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. In addition, approval for a generic pain management product, co-developed with our partner, The PharmaNetwork was received in November 2009, and the Company also has a pipeline of 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'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 has scaled 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 worldwide.

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 estimate 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® and Lodrane 24D® products; (iii) launch of the recently approved generic pain product; (iv) the development of the other products in Elite's pipeline; (v) development of the eight products pursuant to the Epic Strategic Alliance Agreement and (vi) 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.

FDA Approval for generic Methadone tablets

On December 2, 2009, the Registrant and ThePharmaNetwork, LLC (“TPN”) announced the approval of an Abbreviated New Drug Application (“ANDA”) for methadone hydrochloride 10mg tablets by the U.S. Food and Drug Administration (“FDA”). Elite and TPN co-developed the product and the ANDA was filed under the TPN name.

A current report on form 8-K was filed on December 2, 2009 in relation to this announcement, such filing being incorporated herein by this reference.

Epic Strategic Alliance Agreement

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a wholly-owned subsidiary of Epic Pharma, LLC (collectively “Epic”) entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009), 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.

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 (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.

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 would 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

In order to provide Elite with the additional capital necessary for the product development and synergies presented by the strategic relationship with Epic, Epic agreed to invest \$3.75 million in Elite through the purchase of Elite's Series E Preferred Stock and common stock warrants. 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 Epic, 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 Epic'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. Epic 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 Epic's consent was not required under the Epic Strategic Alliance Agreement, at a price less than the then applicable Exercise Price of the Initial Warrant. Epic 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 Epic 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 Epic at the Initial Closing.

On October 30, 2009, Elite completed the second closing of the Strategic Alliance Agreement with Epic. Epic paid to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, and a warrant to purchase an additional 40,000,000 shares of Common Stock. The warrant is to be exercisable until the date that is the seventh anniversary of the Second Closing Date and is to have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, without limitation, dividends, stock splits, combinations and the like.

On the first trading day following the first anniversary of the Initial Closing Date, it is anticipated that 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, if such closing is held, 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 shares will be convertible, as described above, 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 is to be exercisable until the date that is the seventh anniversary of the Third Closing Date and is to 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 is to 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 Epic'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 Epic, work towards securing licensing arrangements for such pain products.

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 December 31, 2009 Compared to Three Months Ended December 31, 2008

Our revenues for the three months ended December 31, 2009 were \$917,383 an increase of \$680,603 or approximately 287% over revenues for the comparable period of the prior year, and consisted of \$744,948 in manufacturing fees and \$172,435 in royalty fees. Revenues for the three months ended December 31, 2008, consisted of \$162,558 in manufacturing fees and \$74,222 in royalty fees. Manufacturing fees increased by approximately 358% due to increased orders resulting in large part from increased marketing efforts being made by the distributor of the products for whom we manufacture on a contract basis and due to timing of orders. Royalties increased by approximately 132% due to growth of product sales.

Research and development costs for the three months ended December 31, 2009, were \$247,773, a decrease of \$352,907 or approximately 59% from \$600,680 of such costs for the comparable period of the prior year. Decreases were attributed to decreases in employee costs and consulting fees associated with the development of products and lower active pharmaceutical ingredient ("API") costs for product development. To conserve cash, we have reduced the number of our employees from 17 full time employees in December 2008, to 13 full-time and 3 part-time employees as of December 31, 2009.

General and administrative expenses for the three months ended December 31, 2009, were \$498,884, an increase of \$31,397, or approximately 7% from \$467,487 of general and administrative expenses for the comparable period of the prior year. The increase was primarily attributable to legal fees incurred as part of the Registrant's defense of *Midsummer Investments Ltd., et al. v Elite Pharmaceuticals, Inc.* Please refer to Part II, Item 1 of this current report on Form 10-Q for further details of these legal proceedings.

Depreciation and amortization for the three months ended December 31, 2009 was \$39,715, a decrease of \$90,542, or approximately 70%, from \$130,257 for the comparable period of the prior year. The decrease was due to the

implementation of a manufacturing cost accounting system as of July 1, 2009 which more accurately allocates depreciation expense among manufacturing and other operations.

Non-cash compensation through the issuance of stock options and warrants for the three months ended December 31, 2009 was \$28,488, a decrease of \$218,370, or approximately 88% from \$246,858 for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

Other income/(expenses) (net) for the three months ended December 31, 2009 were \$(9,083,592), a decrease in other income of \$9,030,637 from the net expense of \$(52,955) for the comparable period of the prior year. The decrease in other income/(expenses) was due to derivative expenses related to changes in the fair value of our preferred shares and outstanding warrants of \$8,412,028, derivative interest expense of \$350,010 and discount in Series E issuance attributable to beneficial conversion features of \$254,212. The derivative income and expense 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, our net loss for the three months ended December 31, 2009 was \$9,590,485 compared to a loss of \$2,080,670 for the three months ended December 31, 2008.

Nine Months Ended December 31, 2009 Compared to Nine Months Ended December 31, 2008

Our revenues for the nine months ended December 31, 2009 were \$2,507,474 an increase of \$1,018,824 or approximately 68% over revenues for the comparable period of the prior year, and consisted of \$1,948,952 in manufacturing fees and \$558,522 in royalty fees. Revenues for the nine months ended December 31, 2008, consisted of \$1,255,850 in manufacturing fees and \$232,800 in royalty fees. Manufacturing fees increased by approximately 55% due to increased orders resulting in large part from increased marketing efforts being made by the distributor of the products for whom we manufacture on a contract basis. Royalties increased by approximately 140% due to growth of product sales.

Research and development costs for the nine months ended December 31, 2009, were \$758,190, a decrease of \$2,386,180 or approximately 76% from \$3,144,370 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, we have reduced the number of our employees from 17 full time employees in December 2008, to 13 full-time and 3 part-time employees as of December 31, 2009.

General and administrative expenses for the nine months ended December 31, 2009, were \$1,288,565, a decrease of \$453,195, or approximately 26% from \$1,741,760 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 nine months ended December 31, 2009 was 214,487, a decrease of \$176,284, or approximately 45%, from \$390,771 for the comparable period of the prior year. The decrease was due to the implementation of a manufacturing cost accounting system as of July 1, 2009 which more accurately allocates depreciation expense among manufacturing and other operations.

Non-cash compensation through the issuance of stock options and warrants for the nine months ended December 31, 2009 was \$113,041, a decrease of \$725,990, or approximately 87% from \$839,031 for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

Other income/(expenses) (net) for the nine months ended December 31, 2009 were \$(10,320,053), a decrease in other income of \$10,167,945 from the net expense of \$(152,108) for the comparable period of the prior year. The decrease in other income was due to derivative expenses related to changes in the fair value of our preferred shares and outstanding warrants of \$8,600,229, derivative interest expense of \$1,008,383 and discount in Series E issuance attributable to beneficial conversion features of \$512,912. The derivative income and expense 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, our net loss for the nine months ended December 31, 2009 was \$12,111,307 compared to a loss of \$7,715,408 for the nine months ended December 31, 2008.

Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), decreased to \$461,677 as of December 31, 2009 from \$758,676 as of March 31, 2009, primarily due to our net loss from operations, exclusive of non-cash charges.

We experienced negative cash flows from operations of \$1,144,152 for the nine months ended December 31, 2009, primarily due to our net loss from continuing operations of \$12,111,306, increased by non cash charges totaling \$11,023,747, which included depreciation and amortization of \$377,196, inventory adjustments of \$311,986, change in fair value of warrant derivative liabilities of \$6,453,107, change in fair value of preferred share derivative liabilities of \$2,147,122, non cash interest expense related to the issuance of series E Preferred Stock of \$512,912, dividends accruing to preferred share derivative liabilities of \$1,008,383, non cash compensation satisfied by the issuance of common stock, options and warrants of \$113,041 and legal expenses satisfied by the issuance of common stock of \$100,000. 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 the issuance of Series E Preferred Stock.

On November 15, 2004 and on December 18, 2006, our partner, ECR Pharmaceuticals, launched Lodrane 24® and Lodrane 24D®, respectively. Under our agreement with ECR, we are currently manufacturing commercial batches of Lodrane 24® and Lodrane 24D® in exchange for manufacturing margins and royalties on product revenues. Manufacturing revenues and royalty income earned for the nine months ended December 31, 2009 and December 31, 2008 were \$2,507,474 and \$1,488,650, respectively. We expect future cash flows from manufacturing fees and royalties to provide additional cash to help fund our operations. However, no assurance can be given that we will generate any material revenues from the manufacturing fees and royalties of the Lodrane products.

LIQUIDITY AND CAPITAL RESOURCES

Going concern considerations

As of December 31, 2009, after giving effect to the initial and second closings of the Epic Strategic Alliance Agreement, we had cash reserves of \$867,000 which permits us to continue at our anticipated level of operations, including, but not limited to, the continued development of our pipeline products, through December 2010. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement, including the consummation of the third closing thereof, is expected to 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 generic methodone product co-developed with The Pharma Network and recently approved by the FDA, Elite could be profitable. In addition, the commercialization of the products developed at the Facility under the Epic Strategic Alliance Agreement is expected to add a new revenue source for Elite. However, there can be no assurances as to the growth, success of development or commercialization of these products.

Despite the successful completion of the initial and second closings of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate the third closing pursuant to the terms and conditions of the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$1.6875 million (which will include quarterly payments of \$62,500 for a period of 11 quarters). Even if we were able to successfully complete the third closing 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 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.

As of December 31, 2009, we had approximately twelve months of cash available based on our current operations

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

For the nine months ended December 31, 2009, we expended \$1,144,152 in operating activities which we funded through the \$2,062,500 in gross proceeds raised through our private placement of its Series E Preferred Stock. Our working capital at December 31, 2009 was approximately \$461,677 compared with working capital of approximately \$1,191,223 at December 31, 2008. Cash and cash equivalents at December 31, 2009, were approximately \$867,388, an increase of approximately \$531,115 from the \$336,273 at December 31, 2008.

As of December 31, 2009, our principal source of liquidity was approximately \$867,388 of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. There can be no assurance that the exercise of outstanding warrants or options will generate or provide sufficient cash.

We had outstanding, as of December 31, 2009, bonds in the aggregate principal amount of \$3,385,000 consisting of \$3,140,000 of 6.5% tax exempt bonds with an outside maturity of September 1, 2030 and \$245,000 of 9.0% bonds with an outside maturity of September 1, 2012. The bonds are secured by a first lien on our 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 New Jersey Economic Development 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 our 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 Company 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, 2009, we were 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

Not applicable

ITEM 4T. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including the Chief Executive and Chief Financial Officers, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act") as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective so that that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management would not allow for timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management has determined that, as of December 31, 2009, there were material weaknesses in both the design and effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

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

Changes in Internal Controls

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15 (f) under the Exchange Act) during the quarter ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

In the ordinary course of business we may be subject to litigation from time to time. Except as follows, 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.

Midsummer Investments, Ltd., et al. v. Elite Pharmaceuticals, Inc. – On or about September 22, 2009, Midsummer Investments, Ltd. and Bushido Capital Master Fund, LP (collectively, “Plaintiffs”) filed a complaint against the Company in the United States District Court, Southern District of New York (Case No. 09 CIV 8074). The Plaintiffs asserted claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (injunctive relief and damages), and attorneys’ fees, arising out of a Securities Purchase Agreement and Certificate of Designation of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock. Plaintiffs claim that they are entitled to a reduced conversion price of their Series D Preferred Stock, as a result of the Epic Strategic Alliance Agreement. With their complaint, the Plaintiffs concurrently filed a request for preliminary injunction. A hearing was held on the Plaintiffs’ request for a preliminary injunction on October 15, 2009. At the hearing, Plaintiffs claimed that they had a substantial likelihood of succeeding on the merits of their claims and requested the delivery of 1,000,000 shares of common stock and a declaration that the conversion price of their Series D Preferred Stock is \$0.05. The Company opposed Plaintiffs’ contentions, claiming that Plaintiffs cannot establish a substantial likelihood of success, among other things. After reviewing the evidence presented at the hearing, the Court agreed with the Company’s position at the hearing. Accordingly, Plaintiffs’ request was denied pursuant to order of the Court entered on October 16, 2009. Thereafter, Plaintiffs filed an amended complaint, asserting claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (damages) and attorneys’ fees, seeking compensatory damages of \$7,455,363.00, delivery of 1,000,000 shares of common stock, a declaration that all future conversions of the Elite Series D Convertible Preferred Stock held by Plaintiffs is at a conversion price of \$0.05, attorneys’ fees, interest and costs. The Company disputes the claims, believes the lawsuit is without merit, and intends to vigorously defend against them. The case is presently in the discovery stage. The Judge has issued an order for both parties to attend a settlement conference before a United States Magistrate Judge and that conference is presently scheduled for February 9, 2010.

ITEM 1A. Risk Factors

There have been no material changes from the Risk Factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2009.

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

On October 30, 2009, Elite issued and sold to Epic Investments, LLC, an 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 October 30, 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 October 30, 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. We relied on the exemption provided by Section 4(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offeree made representations that it was an accredited investor.

During the quarter ended December 31, 2009, we issued 4,742,635 shares of our common stock to the holders of our Series B, C and D Preferred Stock. The shares were issued in satisfaction of our obligation to pay \$334,760 in dividends earned and/or accrued during the quarter ended September 30, 2009. We did not receive any proceeds in exchange for the issuance of these securities. We relied on the exemption provided by Section 4(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

10

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

Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.

- 3.1(i) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.
- 3.1(j) Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.
- 3.1(k) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.

- 3.2 By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.2 Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.3 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.4 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.5 Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.
- 4.6 Warrant to purchase 50,000 shares of Common Stock issued to Jason Lyons incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.
- 4.7 Form of Warrant to purchase shares of Common Stock issued to designees of lender with respect to financing of an equipment loan incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.
- 4.8 Form of Short Term Warrant to purchase shares of Common Stock issued to purchasers in the private placement which initially closed on October 6, 2004 (the "Series A Financing"), incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.9 Form of Long Term Warrant to purchase shares of Common Stock issued to purchasers in the Series A Financing, incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.10 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series A Financing, incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.11 Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005,

and filed with the SEC on December 20, 2005.

- 4.12 Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.
- 4.13 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.14 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.

- 4.15 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.16 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.
- 4.17 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference to Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 4.18 Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference to Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 4.19 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.20 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.21 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.22 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.23 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.24 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 4.25 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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 12, 2010

/s/ Jerry Treppel
Jerry Treppel
Chief Executive Officer
(Principal Executive Officer)

Date: February 12, 2010

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