

ELITE PHARMACEUTICALS INC /DE/

Form 10-Q

November 15, 2010

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended

September 30, 2010

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):

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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 November 12, 2010 the issuer had outstanding 97,949,973 shares of common stock, \$0.001 par value (exclusive of 100,000 shares held in treasury).

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## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

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## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

|   | September 30,<br>2010<br>(Unaudited) | March 31,<br>2010<br>(Audited) |
|---|--------------------------------------|--------------------------------|
| <b>ASSETS</b>   |                                      |                                |
| <b>CURRENT ASSETS</b>   |                                      |                                |
| Cash and cash equivalents   | \$ 593,853                           | \$ 578,187                     |
| Accounts receivable (net of allowance for doubtful accounts of -0-)   | 441,330                              | 404,961                        |
| Inventories (net of reserve of \$494,425 and \$494,425, respectively)                                       | 1,331,173                            | 1,371,292                      |
| Prepaid expenses and other current assets   | 100,639                              | 131,507                        |
| Total Current Assets  | 2,466,995                            | 2,485,947                      |
| <b>PROPERTY AND EQUIPMENT, net of accumulated depreciation of \$3,954,837 and \$3,840,279, respectively</b> |                                      |                                |
|   | 3,910,418                            | 4,095,814                      |
| <b>INTANGIBLE ASSETS – net of accumulated amortization of \$-0- and \$76,434, respectively</b>              |                                      |                                |
|   | 554,872                              | 96,407                         |
| <b>OTHER ASSETS</b>   |                                      |                                |
| Investment in Novel Laboratories, Inc.  | 3,329,322                            | 3,329,322                      |
| Security deposits   | 28,377                               | 14,652                         |
| Restricted cash – debt service for EDA bonds  | 292,416                              | 294,836                        |
| EDA bond offering costs, net of accumulated amortization of 71,832 and 64,767, respectively                 | 282,619                              | 289,685                        |
| Total Other Assets  | 3,932,734                            | 4,024,902                      |
| <b>TOTAL ASSETS</b>   | <b>\$ 10,865,019</b>                 | <b>\$ 10,606,663</b>           |

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

## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

|   | September 30,<br>2010<br>(Unaudited) | March 31,<br>2010<br>(Audited) |
|---|--------------------------------------|--------------------------------|
| <b>LIABILITIES AND STOCKHOLDERS DEFICIT</b>   |                                      |                                |
| <b>CURRENT LIABILITIES</b>  |                                      |                                |
| EDA bonds payable   | \$ 3,385,000                         | \$ 3,385,000                   |
| Short term loans and current portion of long-term debt  | 12,335                               | 82,302                         |
| Accounts payable and accrued expenses   | 1,342,094                            | 986,777                        |
| Preferred share derivative interest payable   | 306,439                              | 306,440                        |
| Total Current Liabilities   | 5,045,868                            | 4,760,519                      |
| <b>LONG TERM LIABILITIES</b>  |                                      |                                |
| Deferred revenues   | 198,889                              | —                              |
| Long term debt, less current portion  | 56,173                               | 19,823                         |
| Derivative liability - preferred shares   | 12,595,402                           | 7,924,763                      |
| Derivative liability – warrants   | 5,775,676                            | 8,499,423                      |
| Total Long Term Liabilities   | 18,626,140                           | 16,444,009                     |
| <b>TOTAL LIABILITIES</b>  | <b>23,672,008</b>                    | <b>21,204,528</b>              |
| <b>STOCKHOLDERS DEFICIT</b>   |                                      |                                |
| Common stock – par value \$0.001, Authorized 355,516,558 Issued and outstanding – 92,656,745 shares and 83,950,168 shares, respectively | 92,657                               | 83,950                         |
| Additional paid-in-capital  | 91,591,236                           | 90,903,896                     |
| Accumulated deficit   | (104,184,041)                        | (101,278,870)                  |
| Treasury stock at cost (100,000 common shares)  | (306,841)                            | (306,841)                      |
| <b>TOTAL STOCKHOLDERS DEFICIT</b>   | <b>(12,806,989)</b>                  | <b>(10,597,865)</b>            |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS DEFICIT</b>   | <b>\$ 10,865,019</b>                 | <b>\$ 10,606,663</b>           |

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<br>SEPTEMBER 30, |                | SIX MONTHS ENDED<br>SEPTEMBER 30, |                |
|--|-------------------------------------|----------------|-----------------------------------|----------------|
|  | 2010                                | 2009           | 2010                              | 2009           |
| <b>REVENUES</b>  |                                     |                |                                   |                |
| Manufacturing Fees   | \$ 767,341                          | \$ 538,941     | \$ 1,334,410                      | \$ 1,204,005   |
| Royalties  | 169,901                             | 237,275        | 350,935                           | 386,086        |
| Lab Fee Revenues   | 57,404                              | —              | 141,221                           | —              |
| Total Revenues   | 994,646                             | 776,216        | 1,826,566                         | 1,590,091      |
| Costs of Revenues  | 565,624                             | 453,029        | 977,295                           | 1,315,029      |
| Gross Profit   | 429,022                             | 323,187        | 849,271                           | 275,062        |
| <b>OPERATING EXPENSES</b>  |                                     |                |                                   |                |
| Research and Development   | 150,436                             | 259,326        | 315,444                           | 510,418        |
| General and Administrative   | 379,104                             | 392,100        | 635,345                           | 788,637        |
| Non-cash compensation through issuance of stock options                      | 10,329                              | 29,190         | 25,687                            | 84,553         |
| Depreciation and amortization  | 25,960                              | 49,230         | 104,291                           | 174,772        |
| Total Operating Expenses   | 565,829                             | 729,846        | 1,080,767                         | 1,558,380      |
| LOSS FROM OPERATIONS   | (136,807)                           | (406,659)      | (231,496)                         | (1,283,318)    |
| <b>OTHER INCOME (EXPENSES)</b>   |                                     |                |                                   |                |
| Interest expense, net  | (57,737)                            | (61,208)       | (115,806)                         | (131,188)      |
| Change in fair value of warrant derivatives                                  | 900,047                             | (1,520,822)    | 2,723,747                         | (1,366,496)    |
| Change in fair value of preferred share derivatives                          | 1,505,333                           | (1,383,231)    | (4,569,005)                       | 1,178,296      |
| Interest expense attributable to preferred share derivatives                 | (306,440)                           | (299,352)      | (670,359)                         | (658,373)      |
| Discount in Series E issuance attributable to beneficial conversion features | (39,132)                            | —              | (39,132)                          | (258,700)      |
| Total Other Income (Expense)   | 2,002,071                           | (3,264,613)    | (2,670,555)                       | (1,236,461)    |
| INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES                              | 1,865,264                           | (3,671,272)    | (2,902,051)                       | (2,519,779)    |
| Provision for income taxes   | 1,040                               | 1,040          | 3,120                             | 1,040          |
| NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS                        | \$ 1,864,224                        | \$ (3,672,312) | \$ (2,905,171)                    | \$ (2,520,819) |
| <b>NET INCOME (LOSS) PER SHARE</b>   |                                     |                |                                   |                |
| Basic  | \$ 0.02                             | \$ (0.05)      | \$ (0.03)                         | \$ (0.04)      |
| Diluted  | \$ 0.01                             | \$ (0.05)      | \$ (0.03)                         | \$ (0.04)      |
| <b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>                  |                                     |                |                                   |                |
| Basic  | 92,367,680                          | 74,075,307     | 89,760,532                        | 70,232,854     |
| Diluted  | 299,999,783                         | 74,075,307     | 89,760,532                        | 70,232,854     |

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

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## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(Unaudited)

|   | Common Stock |           | Additional<br>Paid-In<br>Capital | Treasury Stock |              | Accumulated<br>Deficit | Stockholders'<br>Deficit |
|---|--------------|-----------|----------------------------------|----------------|--------------|------------------------|--------------------------|
|   | Shares       | Amount    |                                  | Shares         | Amount       |                        |                          |
| Balance at<br>March 31, 2010  | 83,950,168   | \$ 83,950 | \$ 90,903,896                    | 100,000        | \$ (306,841) | \$ (101,278,870)       | \$ (10,597,865)          |
| Net Income  |              |           |                                  |                |              | (2,905,171)            | (2,905,171)              |
| Common shares<br>issued in lieu of<br>cash in payment<br>of preferred<br>share derivative<br>interest expense | 8,706,577    | 8,707     | 661,653                          |                |              |                        | 670,360                  |
| Non-cash<br>compensation<br>through the<br>issuance of<br>stock options                                       |              |           | 25,687                           |                |              |                        | 25,687                   |
| Balance at<br>September 30,<br>2010   | 92,656,745   | \$ 92,657 | \$ 91,591,236                    | 100,000        | \$ (306,841) | \$ (104,184,041)       | \$ (12,806,989)          |

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



## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

|  | SIX MONTHS ENDED SEPTEMBER 30, |                    |
|--|--------------------------------|--------------------|
|  | 2010                           | 2009               |
|  | (Unaudited)                    | (Unaudited)        |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |                                |                    |
| Net Loss   | \$ (2,905,171)                 | \$ (2,520,819)     |
| Adjustments to reconcile net loss to cash used in operating activities :             |                                |                    |
| Depreciation and amortization  | 241,626                        | 251,936            |
| Inventory adjustment   | —                              | 311,986            |
| Change in fair value of warrant derivative liability                                 | (2,723,747)                    | 1,366,496          |
| Change in fair value of preferred share derivative liability                         | 4,569,005                      | (1,178,296)        |
| Discount in Series E issuance attributable to embedded beneficial conversion feature | 39,132                         | 258,700            |
| Preferred share derivative interest satisfied by the issuance of common stock        | 670,360                        | 658,373            |
| Non-cash compensation satisfied by the issuance of common stock and options          | 25,687                         | 84,553             |
| Non-cash lease accretion   | 298                            | —                  |
| Changes in assets and liabilities :  |                                |                    |
| Accounts receivable  | (36,372)                       | (357,348)          |
| Inventories  | 40,120                         | (63,109)           |
| Prepaid expenses and other current assets  | 30,868                         | 12,211             |
| Security deposit   | (13,725)                       | 12,909             |
| Accounts payable, accrued expenses and other current liabilities                     | 217,817                        | 105,224            |
| Deferred Revenues  | 198,889                        | —                  |
| <b>NET CASH PROVIDED BY / (USED IN) OPERATING ACTIVITIES</b>                         | <b>354,788</b>                 | <b>(1,057,184)</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |                                |                    |
| Purchases of property and equipment  | (23,779)                       | —                  |
| Cost of capital leasehold improvements   | (35,610)                       | —                  |
| Costs incurred for intellectual property assets                                      | (258,464)                      | —                  |
| Proceeds from sale of retired equipment  | 30,000                         | —                  |
| Withdrawals from restricted cash, net  | 2,420                          | 214,002            |
| <b>NET CASH PROVIDED BY / (USED IN) INVESTING ACTIVITIES</b>                         | <b>(285,433)</b>               | <b>214,002</b>     |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |                                |                    |
| Other loan payments  | (53,689)                       | (48,953)           |
| NJEDA bond principal payments  | —                              | (210,000)          |
| Proceeds from issuance of Series E Convertible Preferred Stock and Warrants          | —                              | 1,000,000          |
| <b>NET CASH PROVIDED BY / (USED IN) FINANCING ACTIVITIES</b>                         | <b>(53,869)</b>                | <b>741,047</b>     |

|   |            |            |
|---|------------|------------|
| NET CHANGE IN CASH AND CASH EQUIVALENTS                 | 15,666     | (102,135)  |
| CASH AND CASH EQUIVALENTS – beginning of period         | 578,187    | 282,578    |
| CASH AND CASH EQUIVALENTS – end of period               | \$ 593,853 | \$ 180,443 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION       |            |            |
| Cash paid for interest                                  | 115,524    | 133,200    |
| Cash paid for taxes                                     | 3,120      | 1,040      |
| SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES |            |            |
| Non-Cash acquisition of Naltrexone ANDA                 | \$ 200,000 | —          |

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 SIX MONTHS ENDED SEPTEMBER 30, 2010 AND 2009  
(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION AND LIQUIDITY

The information in this quarterly report on Form 10-Q includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the "Company") for the three and six months ended September 30, 2010 and 2009. The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and Exchange Commission in accordance with accounting principles generally accepted for interim financial statement presentation. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America ("GAAP") for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the condensed consolidated financial position, results of operations and cash flows of the Company for the periods presented have been included.

The financial results for the interim periods are not necessarily indicative of the results to be expected for the full year or future interim periods.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended March 31, 2010. There have been no changes in significant accounting policies since March 31, 2010.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2011; therefore a current provision for income tax was not established for the three and six months ended September 30, 2010. Only the minimum liability required for state corporation taxes was considered.

The accompanying unaudited condensed consolidated financial statements were prepared on the assumption that the Company will continue as a going concern. As of September 30, 2010, the Company had a working capital deficit of \$2.6 million, losses from operations totaling \$0.2 million for the six months ended September 30, 2010, other expenses totaling \$2.7 million for the six months ended and a net loss of \$2.9 million for the six months ended September 30, 2010.

In addition, the Company has received Notice of Default from the Trustee of the NJED Bonds as a result of the utilization of the debt service reserve being used to pay interest payments due on September 1, 2009, March 1, 2010 and September 1, 2010 totaling \$121k, \$113k and \$113k, respectively, and principal payments due on September 1, 2009 totaling \$210k. The debt service reserve was utilized to make such payments as a result of the Company's not having sufficient funds available to make such payments when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$200k and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$200k was not made.

The Company has requested a postponement of principal payments due on September 1, 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. Resolution of the Company's default on the NJEDA Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future.

Please refer to Note 5 to our financial statements for a more detailed discussion of the NJEDA Bonds and Notice of Default. Please also note that the working capital deficit of \$2.6 million as of September 30, 2010, includes the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million was first classified as a current liability as of March 31, 2010, due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds.

As of September 30, 2010, we had cash reserves of \$593,853. 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 Hydromorphone 8mg and Naltrexone 50mg recently acquired pursuant to asset purchase agreements with Mikah Pharma LLC, 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, June 5, 2009 and July 1, 2010, which disclosures are incorporated herein by reference.

## NOTE 2 - CASH AND CASH EQUIVALENTS

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

## NOTE 3 - INVENTORIES

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

## NOTE 4 - INTANGIBLE ASSETS

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

As of September 30, 2010, the following costs were recorded as intangible assets on the Company’s balance sheet:

|   |         |
|---|---------|
| Intangible assets at March 31, 2010 (audited)                                     |         |
| Patent application costs  | 96,407  |
| ANDA acquisitions   | —       |
| Intangible asset costs capitalized during the six months ended September 30, 2010 |         |
| Patent application costs  | 33,465  |
| ANDA acquisition costs  | 425,000 |
| Amortization of intangible assets during the six months ended September 30, 2010  |         |
| Patent application costs  | —       |
| ANDA acquisition costs  | —       |
| Intangible assets at September 30, 2010 (unaudited)                               |         |
| Patent application costs  | 129,872 |
| ANDA acquisition costs  | 425,000 |

|       |    |         |
|-------|----|---------|
| Total | \$ | 554,872 |
|-------|----|---------|

The costs incurred in patent applications totaling \$16,753 and \$33,465 for the three and six months ended September 30, 2010, respectively, were all related to our abuse resistant and extended release opioid product lines. The Company is continuing its efforts to achieve approval of such patents. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

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The ANDA acquisition costs of \$425,000 incurred during the six months ended September 30, 2010, are related to our acquisition of the ANDA's for Hydromorphone 8mg and Naltrexone 50mg. Please refer to the current reports on Form 8-K filed with the SEC on May 24, 2010 for the Hydromorphone ANDA acquisition and September 1, 2010 for the Naltrexone ANDA acquisition, such filings being herein incorporated by this reference for further details on this acquisition. In addition, please refer to exhibits 10.4 and 10.5 of the quarterly report on Form 10-Q filed with the SEC on November 15, 2010 for the purchase agreements for Hydromorphone and Naltrexone, respectively, such filings being herein incorporated by this reference. The Company is in the process of complying with all FDA and DEA requirements which are a prerequisite to achieving our manufacture and commercialization of the Hydromorphone 8mg ANDA. Amortization of the costs incurred to acquire the ANDA is to commence upon the Company's commercialization of such.

NOTE 5

- NJEDA BONDS

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products.

Interest is payable semiannually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a \$415,500 Debt Service Reserve Fund consisting of \$366,000 from the Series A Notes proceeds and \$49,500 from the Series B Notes proceeds. The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets. \$1,274,311 of the proceeds had been deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company's facility. As of September 30, 2010, 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 issuance costs amounted to \$3,533 and \$7,065 for the three and six months ended September 30, 2010, respectively. Amortization of bond issuance costs amounted to \$3,533 and \$7,065 for the three and six months ended September 30, 2009, respectively.

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

The interest payments due on September 1, 2009, March 31, 2010 and September 1, 2010, totaling \$120,775, \$113,075 and \$113,075, respectively were paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make such payments when due.

The principal payment due on September 1, 2009, totaling \$210,000 was paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make the payment when due. The Company did not have sufficient funds available to make the principal payments due on September 1, 2010 totaling \$200,000, and requested the Trustee to withdraw the funds from debt service reserve held in the restricted cash account and to utilize such funds to make the principal payment due. The Company's request was denied by the Trustee. Accordingly, the principal payment due on September 1, 2010, totaling \$200,000 was not made.

Pursuant to the terms of the NJED Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on September 1, 2009, March 1, 2010 and September 1, 2010. The Company is required to make four additional monthly payments of \$19,330 during the period November 15, 2010 through February 15, 2011, in order to fully replenish the September 1, 2010 withdrawal from the debt service reserve.



The Company does not expect to have sufficient available funds to make the interest payment of \$113,075 due on March 1, 2011 as well as the principal payment of \$200,000 which was due, but not paid, on September 1, 2010

The Company has received Notice of Default from the Trustee of the NJED Bonds in relation to the withdrawals from the debt service reserve, and has requested a postponement of principal payments due on September 1st of 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. Resolution of the Company's default under the NJED Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future.

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

## NOTE 6

## - DERIVATIVE LIABILITIES

Accounting Standard Codification "ASC" 815 – Derivatives and Hedging, which provides guidance on determining what types of instruments or embedded features in an instrument issued by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. These requirements can affect the accounting for warrants and convertible preferred instruments issued by the Company. As the conversion features within, and the detachable warrants issued with the Company's Series B, Series C, Series D and Series E Preferred Stock, do not have fixed settlement provisions because their conversion and exercise prices may be lowered if the Company issues securities at lower prices in the future, we have concluded that the instruments are not indexed to the Company's stock and are to be treated as derivative liabilities.

## Preferred Stock Derivative Liabilities

|  | Series B  | Series C   | Series D     | Series E     | Total         |
|--|-----------|------------|--------------|--------------|---------------|
| Preferred shares Outstanding                               | 896       | 5,418      | 9,008        | 2,062.5      | 17,384.5      |
| Underlying common shares into which Preferred may convert  | 574,076   | 3,365,217  | 128,692,014  | 77,292,061   | 209,923,369   |
| Closing price on valuation date                            | \$ 0.06   | \$ 0.06    | \$ 0.06      | \$ 0.06      | \$ 0.06       |
| Preferred stock derivative liability at September 30, 2010 | \$ 34,445 | \$ 201,913 | \$ 7,721,521 | \$ 4,637,524 | \$ 12,595,402 |
| Preferred stock derivative liability at June 30, 2010      | \$ 39,037 | \$ 228,835 | \$ 8,751,057 | \$ 4,980,172 | \$ 13,999,102 |
| Preferred stock derivative liability at March 31, 2010     | \$ 48,796 | \$ 286,043 | \$ 3,828,587 | \$ 3,761,761 | \$ 7,925,187  |

|  |                |
|--|----------------|
| Change in preferred stock derivative liability for the three months ended September 20, 2010 | \$ (1,505,333) |
|--|----------------|

|  |              |
|--|--------------|
| Change in preferred stock derivative liability for the six months ended September 20, 2010 | \$ 4,569,005 |
|--|--------------|

#### 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:

|                          | March 31<br>2010 | June 30<br>2010 | September 30<br>2010 |
|--------------------------|------------------|-----------------|----------------------|
| Risk-Free interest rate  | 2.4% - 3.3%      | 0.3% - 2.4%     | 0.3% - 1.6%          |
| Expected volatility      | 126% - 214%      | 120% - 210%     | 135% - 194%          |
| Expected life (in years) | 0.5 - 6.6        | 0.3 - 6.3       | 0.0 - 6.1            |
| Expected dividend yield  | —                | —               | —                    |
| Number of warrants       | 125,299,740      | 125,299,740     | 125,116,392          |

|   |              |              |              |
|---|--------------|--------------|--------------|
| Fair value – Warrant Derivative Liability | \$ 8,499,423 | \$ 6,675,722 | \$ 5,775,676 |
|---|--------------|--------------|--------------|

|   |                |              |
|---|----------------|--------------|
| Change in warrant derivative liability for the three months ended | \$ (1,823,701) | \$ (900,046) |
|---|----------------|--------------|

|   |                |
|---|----------------|
| Change in warrant derivative liability for the six months ended | \$ (2,723,747) |
|---|----------------|

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 Company's share price for periods equal to the expected life of the outstanding warrants at each valuation date. The expected dividend rate was based on the fact that the Company has not historically paid dividends on common stock and does not expect to pay dividends on common stock in the future.

#### NOTE 7 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE

Preferred share derivative interest payable as of September 30, 2010 consisted of \$306,440 in derivative interest accrued as of September 30, 2010. The full amount of derivative interest payable as of September 30, 2010 was paid via the issuance of 5,293,228 shares of common stock in October 2010.

#### NOTE 8 - OPERATING LEASES

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

This property requires significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use. It is expected that approximately 3,500 square feet of this property will be constructed and qualified as suitable for use for storage of pharmaceutical finished goods, raw materials, equipment and documents on or before the expiration of the lease for the current warehouse at 80 Oak Street.

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

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

|                                     |            |
|-------------------------------------|------------|
| Fiscal year ended March 31, 2011    | \$ 19,689  |
| Fiscal year ended March 31, 2012    | 79,248     |
| Fiscal year ended March 31, 2013    | 81,228     |
| Fiscal year ended March 31, 2014    | 83,259     |
| Fiscal year ended March 31, 2015    | 85,344     |
| Total Minimum 5 year lease payments | \$ 348,768 |

\* Minimum lease payments are exclusive of additional expenses related to certain expenses incurred in the operation and maintenance of the premises, including, without limitation, real estate taxes and common area charges which may be due under the terms and conditions of the lease, but which are not quantifiable at the time of filing of this quarterly report on Form 10-Q.

Rent expense relating to the operating lease is recorded using the straight line method, and is summarized as follows:

|  | Three<br>Months<br>Ended<br>Sept 30,<br>2010 | Six Months<br>Ended<br>Sept 30,<br>2010 |
|--|--|---|
| Rent Expense   | \$ 22,584                                    | \$ 22,584                               |
| Change in deferred rent liability                        | 22,584                                       | 22,584                                  |
| Balance of deferred rent liability (long-term liability) | 22,584                                       | 22,584                                  |

#### NOTE 9 - DEFERRED REVENUES

Deferred revenue in the amount of \$198,889 represents the unamortized amount of a \$200,000 advance payment received for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license.

#### NOTE 10 - STOCKHOLDERS' EQUITY

##### Common Stock

During the three months ended September 30, 2010, the Company issued 4,482,629 shares of common stock in lieu of cash in payment of interest expense, totaling \$306,440 due and owing as of June 30, 2010 to holders of the Company's Series B, Series C and Series D Preferred Share derivative instruments.

During the six months ended September 30, 2010, the Company issued 8,706,577 shares of common stock in lieu of cash in payment of interest expense, totaling \$612,880, to holders of the Company's Series B, Series C and Series D Preferred Share derivative instruments.

##### Options

At September 30, 2010, the Company had 1,666,999 options fully vested and outstanding with exercise prices ranging from \$0.06 to \$3.00 per share; each option representing the right to purchase one share of common stock. In addition, there are 1,390,001 options issued pursuant to the Company's 2004 Stock Option Plan which are outstanding and not vested, with exercise prices ranging from \$0.06 to \$2.50 per share. These options are scheduled to vest in equal annual increments on January 18, 2011, 2012 and 2013 or upon the occurrence of certain defined events and require that employees awarded such options be employed by the Company on the vesting date.

#### NOTE 11 - PER SHARE INFORMATION

Basic earnings per share of common stock ("Basic EPS") is computed by dividing the net (loss) income by the weighted-average number of shares of common stock outstanding. Diluted earnings per share of common stock ("Diluted EPS") is computed by dividing the net (loss) income by the weighted-average number of shares of common stock, and dilutive common stock equivalents and convertible securities then outstanding. GAAP requires the presentation of both Basic and Diluted EPS, if such Diluted EPS is not anti-dilutive, on the face of Company's Condensed Statements of Operations. Diluted earnings per share is not presented for the six months ended September 30, 2010, because the effect of the Company's common stock equivalents is anti-dilutive.

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|   | For the<br>Three Months<br>Ended<br>September 30, 2010 | For the<br>Six months<br>Ended<br>September 30, 2010 |
|---|--|--|
| <b>Numerator</b>  |  |  |
| Net Income (loss) attributable to common shareholders                 | \$ 1,864,224   | \$ (2,905,171)                                       |
| <b>Denominator</b>  |  |  |
| Weighted-average shares of common stock outstanding                   | 92,367,680   | 89,760,532   |
| Dilutive effect of stock options, warrants and convertible securities | 207,632,103  |  |
| <b>Net (loss) income per share</b>                                    |  |  |
| Basic   | \$ 0.02  | \$ (0.03)  |
| Diluted   | \$ 0.01  |  |

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NOTE 12

- SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through November 15, 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 September 30, 2010 were paid during October 2010 through the issuance of 5,293,228 shares of common stock.

Approval of NOL Sale application by the New Jersey Economic Development Authority ("NJ-EDA")

The Company has been notified that its application to the NJ-EDA for sale of New Jersey net-operating losses under the Technology Business Tax Certificate Transfer Program has been approved. At the time of filing of this quarterly report on Form 10-Q, the amount of net-operating losses approved for sale has not yet been communicated to the Company. The Company anticipates that such amount will be known prior to the end of the current fiscal year and that the actual sale of such net-operating losses approved for sale will also occur prior to the end of the current fiscal year.

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

THREE AND SIX MONTH PERIODS ENDED SEPTEMBER 30, 2010  
COMPARED TO THE  
THREE AND SIX MONTH PERIOD ENDED SEPTEMBER 30, 2009  
(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

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology and generic pharmaceuticals. Our strategy includes improving off-patent drug products for life cycle management and developing generic versions of controlled-release drug products with high barriers to entry. Our technology is applicable to the development of delayed-, sustained- or targeted-release pellets, capsules, tablets, granules and powders.

We have two products, Lodrane 24® and Lodrane 24D®, currently being sold commercially. We also have an approved generic methadone product developed with our partner, The PharmaNetwork. We are pursuing a sales and distribution agreement for this product. A sales and distribution agreement is a prerequisite for the launch of this product and must be mutually agreed upon by Elite and our development partner. Elite has purchased two approved generic products: a generic hydromorphone product and a generic naltrexone product. In addition, Elite has purchased a generic product for which an ANDA has been previously filed but not yet approved by the FDA. The manufacturing process transfer for all three recently acquired products from the previous ANDA holders and filers to our facilities in Northvale, New Jersey, is currently on-going. Elite also executed a License Agreement with Precision Dose, Inc. ("Precision Dose") to market and sell the Elite products in the United States, Puerto Rico, and Canada through its wholly-owned subsidiary, TAGI Pharma Inc. ("TAGI"). TAGI will market the two approved and on approval-pending product recently purchased by the Company as well as additional products and dosage strengths that have or will be filed for approval with the FDA. The Company also has a pipeline of additional generic drug candidates under active development. Additionally, the Company is developing ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-daily oxycodone product. Elite's facility in Northvale, New Jersey operates under Current Good Manufacturing

Practice (“cGMP”) and is a United States Drug Enforcement Agency (“DEA”) registered facility for research, development and manufacturing.

### Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite’s pain management products, (ii) manufacturing of Lodrane 24® and Lodrane 24D® products; (iii) set up and launch of approved generic products; (iv) the development of the other products in our pipeline including the eight products pursuant to the Epic Strategic Alliance Agreement; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations, and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.



Elite is focusing on the development of various types of drug products, including branded drug products which require new drug applications (“NDAs”) under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Drug Price Competition Act”) as well as generic drug products which require abbreviated new drug applications (“ANDAs”).

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

#### Commercial Products

Elite manufactures two once-daily allergy products, Lodrane 24® and Lodrane 24D®, that were co-developed with our partner, ECR Pharmaceuticals (“ECR”). Elite entered into development agreements for these two products with ECR in June 2001 whereby Elite agreed to commercially develop two products in exchange for development fees, certain payments, royalties and manufacturing rights. The products are being marketed by ECR which also has the responsibility for regulatory matters. In addition to receiving revenues for the manufacture of these products, Elite receives a royalty on in-market sales.

Lodrane 24®, was first commercially offered in November 2004 and Lodrane 24D® was first commercially offered in December 2006. Elite’s revenues for manufacturing these products and a royalty on sales for the quarters ended September, 2010 and 2009 aggregated \$937,242 and, \$776,216, respectively. Elite’s revenues for manufacturing these products and a royalty on sales for the six month periods ended September, 2010 and 2009 aggregated \$1,826,566 and, \$1,590,091, respectively.

Since January, 2010, the Company has performed laboratory stability studies of Lodrane and Lodrane 24D, for ECR, on a contract basis. Elite’s revenues from such contract laboratory services for the six months ended September 30, 2010 were \$141,221.

#### Approved Products

On November 25, 2009, the Company and ThePharmaNetwork, LLC (“TPN”) were notified of the approval of an Abbreviated New Drug Application 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.

On May 18, 2010, Elite executed an asset purchase agreement with Mikah Pharma LLC. Under that agreement we completed the acquisition from Mikah of an Abbreviated New Drug Application (Hydromorphone Hydrochloride Tablets USP, 8 mg) for aggregate consideration of \$225,000, comprised of an initial payment of \$150,000, which was made on May 18, 2010. A second payment of \$75,000 was due to be paid to Mikah on June 15, 2010 and is recorded in accounts payable as of September 30, 2010. The Company may, at its election, make this payment in cash or by issuing to Mikah 937,500 shares of the Company’s common stock. Elite is transferring the process to the Facility in Northvale, NJ where it intends to manufacture the product. A current report on form 8-K was filed on May 24, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

On August 27, 2010, Elite executed the Naltrexone Asset Purchase Agreement with Mikah pursuant to which Elite acquired from Mikah the Abbreviated New Drug Application number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto (the “ANDA”), that have to date been filed with the FDA seeking

authorization and approval to manufacture, package, ship and sell the products described in the ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of \$200,000. In lieu of cash, Mikah agreed to accept from Elite product development services to be performed by Elite, as described below under Product Development Agreement heading. A current report on form 8-K was filed on August 27, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

#### Products Pending FDA Approval of Previously Filed ANDA

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement with Epic Pharma LLC (the “Seller”) for the purpose of acquiring from the seller an Abbreviated New Drug Application (“ANDA”) for a generic product. The ANDA has been filed with the FDA and seeks authorization and approval to manufacture, package, ship and sell the product. The acquisition of the ANDA will close on the later of 60 days from the date of the Purchase Agreement or upon receipt of FDA approval of the ANDA. Upon the closing, Elite will pay a portion of the purchase price. The remainder of the purchase price will be paid in quarterly installments over a period of three years, beginning at the end of the first full quarter following the closing. A current report on form 8-K was filed on September 10, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

#### Licensing Agreement

On September 10, 2010, Elite Pharmaceuticals Inc. (“Elite”) executed a License Agreement with Precision Dose, Inc. (“Precision Dose”) to market and sell four Elite generic products, consisting of Hydromorphone, Naltrexone, and two generic products for which ANDA’s have been filed but not yet approved by the FDA., through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada. Precision Dose will have the exclusive right to market the products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the License Agreement. The milestone payments will be paid in 6 installments. The first installment was paid upon execution of the License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years. A current report on form 8-K was filed on September 10, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

#### Products Under Development

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

#### ELI-154 and ELI-216

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

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

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

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

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has currently chosen to develop these products itself but expects to license these products at a later date to a third party who could provide funding for the remaining clinical studies, including a Phase III study, and who could provide sales and distribution for the product. The drug delivery technology underlying ELI-154 was originally developed under a joint venture with Elan which terminated in 2002.

According to the Elan Termination Agreement, Elite acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including ELI-154. Upon licensing or commercialization of ELI-154, Elite will pay a royalty to Elan pursuant to the Termination Agreement. If Elite were to sell the product itself, Elite will pay a 1% royalty to Elan based on the product's net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite's net revenues from this product. (Elite's net product revenues would include license fees, royalties, manufacturing profits and milestones) Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

#### Epic Strategic Alliance Agreement

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

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

For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under "Epic Strategic Alliance Agreement" in Item 7 of Part II of this Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which are incorporated herein by reference.

#### Product Development Agreement

On August 27, 2010, Elite Pharmaceuticals Inc. ("Elite") executed an agreement with Mikah Pharma, LLC ("Mikah") to undertake and perform development work to facilitate the preparation of a regulatory filing for a product under development (the "Product Development Agreement"). The product will be formulated with a previously approved drug substance and will be designed to be delivered in a unique delivery profile. Among other responsibilities, Elite will provide formulation, analytical development, clinical batch manufacture and validation work for the product. The parties agreed that, in lieu of cash, the transfer to Elite of the Naltrexone product in accordance with the terms of the Naltrexone Asset Purchase Agreement (see discussion at Item 2.01 below), which they valued at \$200,000, constituted

the consideration for the development services being performed by Elite under the Product Development Agreement. Mikah will also pay to Elite, on a quarterly basis, a royalty in the amount of 5% of net sales of the product. The royalty will be due and payable for the duration of the period beginning on the date that the product is approved by the United States Food and Drug Administration (the "FDA") and ending on the date of the introduction into the market of an equivalent generic product. Upon approval of the new drug application by the FDA, Elite will manufacture the product and the parties will negotiate in good faith a manufacturing and supply agreement for the product. The Product Development Agreement has a term of 10 years. There is no guarantee that the product will receive approval from the FDA. A current report on form 8-K was filed on September 1, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

## Novel Labs Investment

At the end of 2006, Elite entered into an agreement with VGS Pharma, LLC (“VGS”) and created Novel Laboratories, Inc. (“Novel”), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite owns approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel. To date, Elite has received no distributions or dividends from this investment.

## Critical Accounting Policies and Estimates

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe is more likely than not to be realized. We assess the recoverability of long-lived assets and intangible assets whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. We assess our exposure to current commitments and contingencies. It should be noted that actual results may differ from these estimates under different assumptions or conditions.

## Results of Consolidated Operations

### Three Months Ended September 30, 2010 Compared to Three Months Ended September 30, 2009

Our revenues for the three months ended September 30, 2010 were \$994,646, an increase of \$218,430 or approximately 28% over revenues for the comparable period of the prior year, and consisted of \$767,341 in manufacturing fees, \$57,404 in lab fees and \$169,901 in royalty fees. Revenues for the three months ended September 30, 2009, consisted of \$538,941 in manufacturing fees and \$237,275 in royalty fees. Manufacturing fees increased by approximately 42% due to timing of orders and shipments and growing demand for the Lodrane products. Royalty revenues for the quarter ended September 30, 2010 decreased by \$67,374, when compared to royalty revenues for the same quarter of the prior year. This decrease is due to a timing difference in the prior year and is not an indicator of decreased overall Lodrane market sales.

Research and development costs for the three months ended September 30, 2010 were \$150,436, a decrease of \$108,890 or approximately 42% from \$259,326 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 costs for product development.

General and administrative expenses for the three months ended September 30, 2010, were \$379,104, a decrease of \$12,996, or approximately 3% from \$392,100 of general and administrative expenses for the comparable period of the prior year. The decrease was primarily due to continued cost reduction initiatives throughout all aspects of our operations, offset by increased rent expense related to the operating lease entered into as of July 1, 2010.

Depreciation and amortization for the three months ended September 30, 2010 was \$25,960, a decrease of \$23,540, or approximately 48%, from \$49,230 for the comparable period of the prior year. The decrease was due to the implementation of improved manufacturing cost accounting systems which more accurately allocate depreciation expense among manufacturing and other operations, as well as non-essential machinery and equipment not being replaced upon reaching retirement, full depreciation.

Non-cash compensation through the issuance of stock options and warrants for the three months ended September 30, 2010 was \$10,329, a decrease of \$18,861, or approximately 65% from \$29,190 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) for the three months ended September 30, 2010 were \$2,002,071, an increase in other income of \$5,266,684 from the net other income/(expense) of \$(3,264,613) for the comparable period of the prior year. The increase in other income/(expenses) was due to derivative income relating to changes in the fair value of our preferred shares and outstanding warrants during the quarter ended September 30, 2010 totaling \$2.4 million, as compared to a derivative expense of \$2.9 million for the comparable period of the prior year.

As a result of the foregoing, our net income for the three months ended September 30, 2010 was \$1,864,224 compared to a net loss of \$(3,672,312) for the three months ended September 30, 2009.

#### Six Months Ended September 30, 2010 Compared to Six Months Ended September 30, 2009

Our revenues for the six months ended September 30, 2010 were \$1,826,566, an increase of \$236,475 or approximately 15% over revenues for the comparable period of the prior year, and consisted of \$1,334,410 in manufacturing fees, \$141,221 in lab fees and \$350,935 in royalty fees. Revenues for the six months ended September 30, 2009, consisted of \$1,204,005 in manufacturing fees and \$386,086 in royalty fees. Manufacturing fees increased by approximately 11% due to growing demand for the Lodrane products. Royalty revenues for the quarter ended September 30, 2010 decreased by \$35,151, when compared to royalty revenues for the same period of the prior year. This decrease is due to a timing difference in the prior year and is not an indicator of decreased overall Lodrane market sales.

Research and development costs for the six months ended September 30, 2010 were \$315,444, a decrease of \$194,974 or approximately 38% from \$510,418 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 costs for product development.

General and administrative expenses for the six months ended September 30, 2010, were \$635,345, a decrease of \$153,292, or approximately 20% from \$788,637 of general and administrative expenses for the comparable period of the prior year. The decrease was primarily due to continued cost reduction initiatives throughout all aspects of our operations.

Depreciation and amortization for the six months ended September 30, 2010 was \$104,291, a decrease of \$70,481, or approximately 40%, from \$174,772 for the comparable period of the prior year. The decrease was due to the implementation of improved manufacturing cost accounting systems which more accurately allocate depreciation expense among manufacturing and other operations, as well as non-essential machinery and equipment not being replaced upon reaching retirement, full depreciation.

Non-cash compensation through the issuance of stock options and warrants for the six months ended September 30, 2010 was \$25,687, a decrease of \$58,866, or approximately 70% from \$84,553 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) for the six months ended September 30, 2010 were \$(2,670,555), a decrease in other income of \$1,434,094 from the net other income/(expense) of \$(1,236,461) for the comparable period of the prior year. The decrease in other income/(expenses) was due to derivative expense related to changes in the fair value of our preferred shares and outstanding warrants during the six months ended September 30, 2010 totaling \$1.8 million, as compared to \$0.2 million for the comparable period of the prior year.

As a result of the foregoing, our net loss for the six months ended September 30, 2010 was \$(2,905,171) compared to a net loss of \$(2,520,819) for the six months ended September 30, 2009.

#### Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), decreased to a deficit of \$2.6 million as of September 30, 2010 from a working capital deficit of \$2.3 million as of March 31, 2010, primarily due to our net loss from operations, exclusive of non-cash charges. In addition, it should be noted that current liabilities includes the entire principal amount due on the Company's NJ-EDA Bonds Payable. This amount, totaling \$3.4 million has been classified as a current liability as a result of the Company receiving a notice of default from the Trustee of the NJ-EDA Bonds. Please refer to Note 5 to our financial statements and Item 3 of this current report on Form 10-Q for further details.

We achieved a positive cash flow from operations of \$354,788 for the six months ended September 30, 2010, primarily due to deferred revenues relating to milestone payments, totaling \$200,000, received from marketing contracts signed during the period and our net income/(loss) from continuing operations of \$(2,905,171), increased by non cash charges totaling \$2,822,360, which included depreciation and amortization of \$241,626, change in fair value of warrant derivative liabilities of \$(2,723,747), change in fair value of preferred share derivative liabilities of \$4,569,005, derivative interest payments satisfied through the issuance of common shares in lieu of cash of \$670,360, and non cash compensation satisfied by the issuance of common stock and options of \$25,687.

## LIQUIDITY AND CAPITAL RESOURCES

### Going concern considerations

As of September 30, 2010, the Company had a working capital deficit of \$2.6 million, losses from operations totaling \$0.2 million for the six months ended September 30, 2010, other expenses totaling \$2.7 million for the six months ended and a net loss of \$2.9 million for the six months ended September 30, 2010.

In addition, the Company has received Notice of Default from the Trustee of the NJED Bonds as a result of the utilization of the debt service reserve being used to pay interest payments due on September 1, 2009, March 1, 2010 and September 1, 2010 totaling \$121k, \$113k and \$113k, respectively, and principal payments due on September 1, 2009 totaling \$210k. The debt service reserve was utilized to make such payments as a result of the Company's not having sufficient funds available to make such payments when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$200k and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$200k was not made.

The Company has requested a postponement of principal payments due on September 1, 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. Resolution of the Company's default on the NJEDA Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future.

Please refer to Note 5 to our financial statements and Item 3 of this current report on Form 10-Q for a more detailed discussion of the NJEDA Bonds and Notice of Default.

As of September 30, 2010, we had cash reserves of \$593,853. 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 Hydromorphone 8mg and Naltrexone 50mg recently acquired pursuant to asset purchase agreements with Mikah Pharma LLC, 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, June 5, 2009 and July 1, 2010, which disclosures are incorporated herein by reference.

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

For the six months ended September 30, 2010, we realized approximately \$0.4 million positive cash flow from operating activities. Our working capital deficit at September 30, 2010 was approximately \$2.6 million compared with working capital surplus of approximately \$0.4 million at September 30, 2009. Please note that the working capital deficit of \$2.6 million as of September 30, 2010, includes the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million was first classified as a current liability as of March 31, 2010, due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. The working capital surplus of \$0.4 million as of September 30, 2009, does not include classification of such entire principal amount due on the NJEDA Bonds as a current liability. Please refer to Note 5 to our financial statements and Item 3 of this current report on Form 10-Q for a more detailed discussion of the NJEDA Bonds and Notice of Default.

Cash and cash equivalents at September 30, 2010, were approximately \$0.6 million, an increase of approximately \$0.4 million from the approximately \$0.2 million at September 30, 2009.

As of September 30, 2010, our principal source of liquidity was approximately \$0.6 of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. There can be no assurance that the exercise of outstanding warrants or options will generate or provide sufficient cash.

#### Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources that would be considered material to investors.

#### Effects of Inflation

We are subject to price risks arising from price fluctuations in the market prices of the products that we sell. Management does not believe that inflation risk is material to our business or our consolidated financial position, results of operations, or cash flows.

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

Not applicable

### ITEM 4 CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

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

Management has determined that, as of September 30, 2010, 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 September June 30, 2010 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.

The PharmaNetwork, LLC v. Elite Pharmaceuticals, Inc. – On or about September 3, 2010, The PharmaNetwork, LLC (“Plaintiffs”) filed a complaint against the Company in the Superior Court of New Jersey Chancery Division: Bergen County (Docket No. C-272-10), with an amendment of this complaint being filed on or about September 24, 2010 (the “TPN Complaint”). The TPN Complaint consists of two counts. The first count is for breach of contract and specific performance & injunctive relief and seeks judgment against the Company for (a) specific performance of the Product Collaboration Agreement made on or about November 26, 2006 (the “Agreement”) ; (b) injunctive relief enjoining the Company from using its assets for any purpose other than its obligations under the Agreement and the payment of the Company’s existing and continuing costs and expenses incurred in the ordinary course of business ; and (c) such other relief as the Court deems equitable and just. The second count is for breach of the implied covenant of good faith and fair dealing and seeks judgment against the Company for (a) specific performance of the Product Collaboration Agreement made on or about November 26, 2006 (the “Agreement”) ; (b) injunctive relief enjoining the Company from using its assets for any purpose other than its obligations under the Agreement and the payment of the Company’s existing and continuing costs and expenses incurred in the ordinary course of business ; and (c) such other relief as the Court deems equitable and just.

Plaintiffs requests for injunctive relief have been denied pursuant to order of the court.

The Company disputes the claims, believes the lawsuit is without merit and intends to vigorously defend against them.

On or about October 14, 2010, the Company filed its response to the TPN complaint and two counterclaims. The first counterclaim asserts TPN’s breach of contract and seeks monetary damages in the sum of an amount no less than \$1.125 million, plus interest. The second counterclaim asserts TPN’s breach of its obligation of good faith and fair dealing to the Company and seeks monetary damages in the sum of an amount no less than \$1.125 million, plus interest.

The case is presently in discovery stage.

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, 2010.

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

During the quarter ended September 30, 2010, we issued 5,303,764 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 \$306,440 in dividends earned and/or accrued during the quarter ended June 30, 2010. We did not receive any proceeds in exchange for the issuance of these securities. We relied on the exemption provided by Section 4(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.



ITEM 3.           DEFAULTS UPON SENIOR SECURITIES

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

ITEM 4.           REMOVED AND RESERVED

ITEM 5.           OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

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

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

Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.

- 3.1(k) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.

- 3.1(l) Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 3.1(m) Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 3.2 By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.2 Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.3 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.4 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.5 Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.
- 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.
- 10.1 Stipulation of Settlement and Release, dated as of June 25, 2010, by and among the Company, Midsummer Investment, Ltd., Bushido Capital Master Fund, LP, BCMF Trustees, LLC, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 10.2 Amendment Agreement, dated as of June 25, 2010, by and among the Company, and the investors signatory thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010

- 10.3 Amendment Agreement, dated as of June 2010, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 10.4 Asset Purchase Agreement dated as of May 18, 2010, by and among Mikah Pharma LLC and the Company
- 10.5 Asset Purchase Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A description of this Asset Purchase Agreement is incorporated by reference to Item 2.01 of the Current Report on Form 8-K, dated August 27, 2010 and filed with SEC on September 1, 2010
- 10.6 Master Development and License Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A description of this Asset Purchase Agreement is incorporated by reference to Item 1.01 of the Current Report on Form 8-K, dated August 27, 2010 and filed with SEC on September 1, 2010
- 10.7 Purchase Agreement, dated as of September 10, 2010, by and among Epic Pharma LLC and the Company. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A description of this Asset Purchase Agreement is incorporated by reference to Item 2.01 of the Current Report on Form 8-K, dated September 10, 2010 and filed with SEC on September 16, 2010
- 10.8 License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A description of this Asset Purchase Agreement is incorporated by reference to Item 1.01 of the Current Report on Form 8-K, dated September 10, 2010 and filed with SEC on September 16, 2010
- 10.9 Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company. Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended. A description of this Asset Purchase Agreement is incorporated by reference to Item 1.01 of the Current Report on Form 8-K, dated September 10, 2010 and filed with SEC on September 16, 2010
- 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: November 15, 2010

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

Date: November 15, 2010

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