

ELITE PHARMACEUTICALS INC /NV/  
Form 10-Q  
February 14, 2012

**U.S. SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2011

or

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

For the transition period ended \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-15697

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

Nevada 22-3542636  
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

165 Ludlow Avenue, Northvale, New Jersey 07647  
(Address of principal executive offices) (Zip Code)

(201) 750-2646

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(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 S 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 S No

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

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

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

Yes  No S

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of January 30, 2012 the issuer had outstanding 267,981,747 shares of common stock, \$0.001 par value (exclusive of 100,000 shares held in treasury).

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

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

|   | December 31,<br>2011<br>(Unaudited) | March 31,<br>2011<br>(Audited) |
|---|-------------------------------------|--------------------------------|
| <b>ASSETS</b>   |                                     |                                |
| <b><u>CURRENT ASSETS</u></b>  |                                     |                                |
| Cash and cash equivalents   | \$ 568,691                          | \$ 1,825,858                   |
| Accounts receivable (net of allowance for doubtful accounts of -0-)   | 483,311                             | 571,667                        |
| Inventories (net of reserve of \$93,338 and \$1,047,456, respectively)  | 431,400                             | 616,362                        |
| Prepaid expenses and other current assets   | 58,798                              | 133,472                        |
| <br>Total Current Assets  | <br>1,542,200                       | <br>3,147,359                  |
| <br><b><u>PROPERTY AND EQUIPMENT</u></b> , net of accumulated depreciation of \$4,542,590 and \$4,189,618, respectively | <br>4,234,604                       | <br>4,118,274                  |
| <br><b><u>INTANGIBLE ASSETS</u></b> – net of accumulated amortization of \$-0- and \$-0-, respectively                  | <br>629,963                         | <br>597,556                    |
| <br><b><u>OTHER ASSETS</u></b>  |                                     |                                |
| Investment in Novel Laboratories, Inc.  | 3,329,322                           | 3,329,322                      |
| Security deposits   | 14,913                              | 28,377                         |
| Restricted cash – debt service for EDA bonds  | 333,246                             | 291,420                        |
| EDA bond offering costs, net of accumulated amortization of \$89,497 and \$78,898, respectively                         | 264,955                             | 275,554                        |
| <br>Total Other Assets  | <br>3,942,436                       | <br>3,924,673                  |
| <br><b>TOTAL ASSETS</b>   | <br><b>\$ 10,349,203</b>            | <br><b>\$ 11,787,862</b>       |

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

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

|  | December 31,<br>2011<br>(Unaudited) | March 31,<br>2011<br>(Audited) |
|--|-------------------------------------|--------------------------------|
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                                     |                                |
| <b><u>CURRENT LIABILITIES</u></b>  |                                     |                                |
| EDA bonds payable  | \$3,385,000                         | \$3,385,000                    |
| Short term loans and current portion of long-term debt   | 10,257                              | 13,105                         |
| Accounts payable and accrued expenses  | 1,227,152                           | 935,797                        |
| Customer Deposits  | —                                   | 39,400                         |
| Deferred revenues – current  | 13,333                              | 13,333                         |
| Preferred share derivative interest payable  | 86,326                              | 282,680                        |
| <b>Total Current Liabilities</b>   | <b>4,722,068</b>                    | <b>4,669,315</b>               |
| <b><u>LONG TERM LIABILITIES</u></b>  |                                     |                                |
| Deferred revenues  | 168,891                             | 178,890                        |
| Other long term liabilities  | 78,379                              | 75,463                         |
| Derivative liability – preferred shares  | 10,646,711                          | 14,192,329                     |
| Derivative liability – warrants  | 9,043,464                           | 10,543,145                     |
| <b>Total Long Term Liabilities</b>   | <b>19,937,445</b>                   | <b>24,989,827</b>              |
| <b>TOTAL LIABILITIES</b>   | <b>24,659,513</b>                   | <b>29,659,142</b>              |
| <b><u>STOCKHOLDERS' DEFICIT</u></b>  |                                     |                                |
| Common stock – par value \$0.001, Authorized 355,516,558 shares Issued and outstanding – 264,830,735 shares and 180,545,657 shares, respectively | 264,831                             | 180,546                        |
| Additional paid-in-capital   | 108,645,839                         | 97,116,044                     |
| Accumulated deficit  | (122,914,139)                       | (114,861,029)                  |
| Treasury stock at cost (100,000 common shares)   | (306,841 )                          | (306,841 )                     |
| <b>TOTAL STOCKHOLDERS' DEFICIT</b>   | <b>(14,310,310 )</b>                | <b>(17,871,280 )</b>           |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   | <b>\$10,349,203</b>                 | <b>\$11,787,862</b>            |

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

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

|  | THREE MONTHS ENDED<br>December 31, |            | NINE MONTHS ENDED<br>December 31, |             |
|--|------------------------------------|------------|-----------------------------------|-------------|
|  | 2011                               | 2010       | 2011                              | 2010        |
| <b>REVENUES</b>  |                                    |            |                                   |             |
| Manufacturing Fees   | \$170,099                          | \$901,653  | \$847,832                         | \$2,236,064 |
| Royalties & Profit Splits  | 20,127                             | 231,742    | 430,228                           | 582,677     |
| Lab Fee Revenues   | 319,712                            | 92,902     | 495,987                           | 234,123     |
| Total Revenues   | 509,938                            | 1,226,297  | 1,774,047                         | 3,052,864   |
| <b>COSTS OF REVENUES</b>   |                                    |            |                                   |             |
| Gross Profit   | 353,348                            | 584,773    | 1,115,758                         | 1,434,044   |
| <b>OPERATING EXPENSES</b>  |                                    |            |                                   |             |
| Research and Development   | 386,430                            | 179,525    | 1,030,141                         | 494,968     |
| General and Administrative   | 288,416                            | 315,537    | 1,089,909                         | 947,761     |
| Non-cash compensation through issuance of stock options                      | 6,113                              | 7,580      | 18,340                            | 33,268      |
| Depreciation and Amortization  | 103,339                            | 9,200      | 336,454                           | 113,490     |
| Total Operating Expenses   | 784,298                            | 511,842    | 2,474,844                         | 1,589,487   |
| <b>PROFIT / (LOSS) FROM OPERATIONS</b>                                       | (430,950 )                         | 72,931     | (1,359,086 )                      | (155,443 )  |
| <b>OTHER INCOME / (EXPENSES)</b>   |                                    |            |                                   |             |
| Interest expense, net  | (57,138 )                          | (58,059 )  | (172,438 )                        | (173,867 )  |
| Change in fair value of warrant derivatives                                  | 4,586,076                          | 2,064,745  | 1,499,682                         | 4,788,493   |
| Change in fair value of preferred share derivatives                          | 4,749,332                          | 4,156,097  | (7,665,268 )                      | (412,908 )  |
| Interest expense attributable to preferred share derivatives                 | (86,325 )                          | (306,440 ) | (353,500 )                        | (976,799 )  |
| Discount in Series E issuance attributable to beneficial conversion features | —                                  | —          | —                                 | (39,132 )   |
| Total Other Income / (Expense)   | 9,191,945                          | 5,856,343  | (6,691,524 )                      | 3,185,787   |
|  | 8,760,995                          | 5,929,274  | (8,050,610 )                      | 3,030,344   |



INCOME (LOSS) BEFORE PROVISION FOR  
INCOME TAXES

|  |             |             |                |             |
|--|-------------|-------------|----------------|-------------|
| PROVISION FOR INCOME TAXES                               | —           | 1,062       | 2,500          | 7,302       |
| NET INCOME (LOSS) ATTRIBUTABLE TO<br>COMMON SHAREHOLDERS | \$8,760,995 | \$5,928,212 | \$(8,053,110 ) | \$3,023,042 |
| NET INCOME (LOSS) PER SHARE                              |             |             |                |             |
| Basic  | \$0.03      | \$0.06      | \$(0.03 )      | \$0.03      |
| Diluted  | \$0.02      | \$0.02      | \$(0.03 )      | \$0.03      |
| WEIGHTED AVERAGE NUMBER OF COMMON<br>SHARES OUTSTANDING  |             |             |                |             |
| Basic  | 262,067,348 | 96,873,523  | 247,443,617    | 92,196,433  |
| Diluted  | 427,037,498 | 307,830,425 | 247,443,617    | 264,110,230 |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT***(Unaudited)*

|   | Common Stock |            |                                  | Treasury Stock |             | Accumulated<br>Deficit | Stockholders'<br>Deficit |
|---|--------------|------------|----------------------------------|----------------|-------------|------------------------|--------------------------|
|   | Shares       | Amount     | Additional<br>Paid-In<br>Capital | Shares         | Amount      |                        |                          |
| Balance at Mar 31,<br>2011  | 180,545,657  | \$ 180,546 | \$97,116,044                     | 100,000        | \$(306,841) | \$(114,861,029)        | \$(17,871,280)           |
| Net Loss  |              |            |                                  |                |             | (8,053,110 )           | (8,053,110 )             |
| Common shares<br>issued in lieu of<br>cash in payment of<br>preferred share<br>derivative interest<br>expense | 7,259,361    | 7,259      | 542,595                          |                |             |                        | 549,854                  |
| Conversion of<br>Series B Preferred<br>Shares into<br>Common Shares   | 660,000      | 660        | 71,940                           |                |             |                        | 72,600                   |
| Conversion of<br>Series C Preferred<br>Shares into<br>Common Shares   | 15,346,670   | 15,347     | 1,387,320                        |                |             |                        | 1,402,667                |
| Conversion of<br>Series D Preferred<br>Shares into<br>Common Shares   | 58,042,857   | 58,043     | 9,415,672                        |                |             |                        | 9,473,715                |
| Conversion of<br>Series E Preferred<br>Shares into<br>Common Shares   | 2,976,190    | 2,976      | 383,929                          |                |             |                        | 386,905                  |
| Non-cash<br>compensation  |              |            | 18,339                           |                |             |                        | 18,339                   |

through the  
issuance of stock  
options

|   |            |            |
|---|------------|------------|
| Commitment fee<br>relating to the<br>commitment of<br>Socius to purchase<br>Series F Preferred<br>Stock | (250,000 ) | (250,000 ) |
|---|------------|------------|

|  |           |           |
|--|-----------|-----------|
| Costs associated<br>with raising capital | (40,000 ) | (40,000 ) |
|--|-----------|-----------|

|                                 |             |           |               |         |             |                 |                |
|---------------------------------|-------------|-----------|---------------|---------|-------------|-----------------|----------------|
| Balance at<br>December 31, 2011 | 264,830,735 | \$264,831 | \$108,645,839 | 100,000 | \$(306,841) | \$(122,914,139) | \$(14,310,310) |
|---------------------------------|-------------|-----------|---------------|---------|-------------|-----------------|----------------|

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

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

|  | NINE MONTHS ENDED<br>DECEMBER 30, |                   |
|--|-----------------------------------|-------------------|
|  | 2011                              | 2010              |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |                                   |                   |
| Net (Loss) Income  | \$(8,053,110)                     | \$3,023,042       |
| Adjustments to reconcile net loss to cash used in operating activities:              |                                   |                   |
| Depreciation and amortization  | 363,542                           | 362,381           |
| Change in fair value of warrant derivative liability                                 | (1,499,682)                       | (4,788,493)       |
| Change in fair value of preferred share derivative liability                         | 7,665,268                         | 412,908           |
| Discount in Series E issuance attributable to embedded beneficial conversion feature | —                                 | 39,132            |
| Preferred share derivative interest satisfied by the issuance of common stock        | 549,854                           | 897,680           |
| Non-cash compensation satisfied by the issuance of common stock and options          | 18,339                            | 33,268            |
| Non-cash rent expense  | 8,686                             | 22,584            |
| Non-cash lease accretion   | 949                               | 601               |
| <b>Changes in Assets and Liabilities</b>   |                                   |                   |
| Accounts receivable  | 88,356                            | (221,280 )        |
| Inventories  | 184,963                           | 69,151            |
| Prepaid and other current assets   | 74,671                            | 76,239            |
| Security deposits  | 13,464                            | (13,725 )         |
| Accounts payable, accrued expenses and other current liabilities                     | 41,355                            | 90,892            |
| Deferred revenues and Customer deposits  | (49,399 )                         | 234,956           |
| Derivative interest payable  | (196,354 )                        | 79,120            |
| <b>NET CASH (USED IN) / PROVIDED BY OPERATING ACTIVITIES</b>                         | <b>(789,098 )</b>                 | <b>318,456</b>    |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |                                   |                   |
| Purchases of property and equipment  | (78,427 )                         | (35,398 )         |
| Cost of leasehold improvements   | (390,845 )                        | (176,645 )        |
| Costs incurred for intellectual property assets                                      | (32,406 )                         | (191,274 )        |
| Proceeds from sale of retired equipment  | —                                 | 30,000            |
| Deposits to restricted cash, net   | (41,826 )                         | (51,464 )         |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>   | <b>(543,504 )</b>                 | <b>(424,781 )</b> |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |                                   |                   |
| Proceeds from issuance of Series E Convertible Preferred Stock                       | 125,000                           |                   |
| Other loan payments  | (9,565 )                          | (56,669 )         |
| Costs associated with raising capital  | (40,000 )                         |                   |
| <b>NET CASH PROVIDED BY / (USED IN) FINANCING ACTIVITIES</b>                         | <b>75,435</b>                     | <b>(56,669 )</b>  |

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|  |             |            |
|--|-------------|------------|
| NET CHANGE IN CASH AND CASH EQUIVALENTS                                    | (1,257,167) | (162,994 ) |
| CASH AND CASH EQUIVALENTS – beginning of period                            | 1,825,858   | 578,187    |
| CASH AND CASH EQUIVALENTS – end of period                                  | \$568,691   | \$415,193  |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION                          |             |            |
| Cash paid for interest   | 172,439     | 114,950    |
| Cash paid for taxes  | 2,500       | 4,182      |
| SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES                    |             |            |
| Non-Cash acquisition of Naltrexone ANDA                                    | —           | 275,000    |
| Commitment fee relating to commitment to purchase Series F Preferred Stock | 250,000     | —          |

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**THREE AND NINE MONTHS ENDED DECEMBER 31, 2011 AND 2010**

**(UNAUDITED)**

**NOTE 1 - BASIS OF PRESENTATION AND LIQUIDITY**

The information in this quarterly report on Form 10-Q includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the “Company” or “Elite”) for the three and nine months ended December 31, 2011 and 2010. The accompanying unaudited condensed consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and Exchange Commission in accordance with accounting principles generally accepted for interim financial statement presentation. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America (“GAAP”) for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the condensed consolidated financial position, results of operations and cash flows of the Company for the periods presented have been included.

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

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K for the year ended March 31, 2011. There have been no changes in significant accounting policies since March 31, 2011.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2012; therefore a current provision for income tax was not established for the three and nine months ended December 31, 2011. Only the minimum liability required for state corporation taxes was considered.

The accompanying unaudited condensed consolidated financial statements were prepared on the assumption that the Company will continue as a going concern. As of December 31, 2011, the Company had a working capital deficit of \$3.2 million, losses from operations totaling \$1.4 million for the nine months ended December 31, 2011, other expenses totaling \$6.7 million for the nine months ended December 31, 2011, and a net loss of \$8.1 million for the nine months ended December 31, 2011. The financial statements do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should the Company be unable to continue in operation.

Please note that revenues and operating profits for the foreseeable future are expected to be significantly and adversely effected by the U.S. Food and Drug Administration’s (“FDA”) removal of the Lodrane® extended release

product line from the market. The Lodrane® extended release products, which constituted approximately 97% of the Company's revenues at the time of FDA's directive, were included on a list of approximately 500 cough/cold and allergy products which are being removed from the U.S. market pursuant to a directive from the FDA issued on March 4, 2011. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 and the Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, such filings being herein incorporated by reference.

In addition, the Company has received Notice of Default from the Trustee of the NJED Bonds as a result of the utilization of the debt service reserve being used to pay semi-annual interest payments due on September 1<sup>st</sup> and March 1<sup>st</sup> of each year. The debt service reserve was first used to make such semi-annual interest payments on March 1, 2009 and has been utilized for all semi-annual interest payments due since September 1, 2009. As of December 31, 2011, there have been 6 separate interest payments, totaling \$694k for which 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 \$225k 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 \$225k was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470k, with such amount including the principal payments due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$470k 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 \$3.2 million as of December 31, 2011, includes the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million was first classified as a current liability as of March 31, 2010, due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds.

As of December 31, 2011, we had cash reserves of \$0.6 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that Elite will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement, we still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under "Epic Strategic Alliance Agreement" in Item 7 of Part II of our Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009, June 5, 2009, July 1, 2010 and June 29, 2011, such disclosures being herein incorporated by reference.

On December 30, 2011, Elite entered into a securities purchase agreement (the "Socius Agreement") with Socius CG II, Ltd. ("Socius"), under which, subject to the terms of the Socius Agreement, Elite may sell up to \$5 million on non-convertible Series F preferred stock (the "Series F Preferred Stock") to Socius. Such terms include, without limitation, the filing and effectiveness of a registration, as a prerequisite of any sales of Series F Preferred Stock to Socius. There can be no assurance that Elite will be able to meet the terms and conditions representing such prerequisites of any sales of Series F Preferred Stock to Socius. Even if Elite were to sell to Socius up to \$5 million



of Series F Preferred Stock, it still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all. For additional information on the Socius Agreement, please refer to the Current Report on Form 8-K filed with the SEC on January 5, 2012, with such filing being herein incorporated by reference.

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Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50mg have occurred as a result of a notification received from the FDA reclassifying to a Prior Approval Supplement, the Company's Changes Being Effected in 30 Days Supplement ("CBE-30") related to a change in the manufacturing and packaging site this product.

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

NOTE  
2 - CASH AND CASH EQUIVALENTS

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

NOTE  
3 - INVENTORIES

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

NOTE  
4 - INTANGIBLE ASSETS

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

As of December 31, 2011, the following costs were recorded as intangible assets on the Company's balance sheet:

|  |         |
|--|---------|
| <u>Intangible assets at March 31, 2011 (audited)</u>                                     |         |
| Patent application costs   | 147,556 |
| ANDA acquisitions  | 450,000 |
| Total Intangible Assets at March 31, 2011 (audited)                                      | 597,556 |
| <u>Intangible asset costs capitalized during the nine months ended December 31, 2011</u> |         |
| Patent application costs   | 32,407  |
| ANDA acquisition costs   | —       |

Amortization of intangible  
assets during the nine  
months ended December  
31, 2011

|                          |   |
|--------------------------|---|
| Patent application costs | — |
| ANDA acquisition costs   | — |

Intangible assets at  
December 31, 2011  
(unaudited)

|  |         |
|--|---------|
| Patent application costs                                       | 179,963 |
| ANDA acquisitions costs  | 450,000 |
| Total Intangible Assets at<br>December 31, 2011<br>(unaudited) | 629,963 |

The costs incurred in patent applications totaling \$32,407 for the nine months ended December 31, 2011, were related to our abuse resistant opioid product lines. The Company is continuing its efforts to achieve approval of such patents. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

NOTE  
5 - NJEDA BONDS

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of December 31, 2011, all of the proceeds were utilized by the Company for such stated purposes.

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

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$3,533 and \$10,598 for the three and nine months ended December 31, 2011.

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

The interest payments due on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011 and September 1, 2011 totaling \$120,775, \$120,775, \$113,075, \$113,075, \$113,075, and \$113,075, respectively were paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make such payments when due.

The principal payment due on September 1, 2009, totaling \$210,000 was paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make the payment when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$225k 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 \$225k was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470k, with such amount including the principal payments due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$470k was not made.

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15<sup>th</sup> of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15<sup>th</sup> 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 March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011 and September 1, 2011.

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The Company does not expect to have sufficient available funds as of September 1, 2012, to make principal payments, totaling \$730,000, and consisting of \$260,000 due on September 1, 2012, \$245,000 which was due on September 1, 2011 and not paid and \$225,000 which was due on September 1, 2010 and not paid.

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

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

NOTE  
6 - PREFERRED STOCK DERIVATIVE LIABILITIES

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

Preferred Stock Derivative Liability as of December 31, 2011

|  | Series B  | Series C    | Series D    | Series E     | Total        |
|--|-----------|-------------|-------------|--------------|--------------|
| Preferred shares Outstanding                               | 796.6     | 3,116       | —           | 3,112.5      | 7,025.1      |
| Underlying common shares into which Preferred may convert  | 5,310,393 | 20,773,333  | —           | 126,012,146  | 152,095,872  |
| Closing price on valuation date                            | \$0.07    | \$0.07      | n/a         | \$0.07       | \$0.07       |
| Preferred stock derivative liability at December 31, 2011  | \$371,728 | \$1,454,133 | \$—         | \$8,820,850  | \$10,646,711 |
| Preferred stock derivative liability at September 30, 2011 | \$536,350 | \$2,958,627 | \$—         | \$12,677,200 | \$16,172,177 |
| Preferred stock derivative liability at June 30, 2011      | \$97,593  | \$572,087   | \$—         | \$20,659,722 | \$21,329,402 |
|  | \$56,961  | \$333,906   | \$4,527,343 | \$9,274,119  | \$14,192,329 |

Preferred stock derivative liability at March  
31, 2011

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## CHANGE IN VALUE OF PREFERRED STOCK DERIVATIVE LIABILITY

|  | Three months ended Dec 31 |                | Nine months ended Dec 31, |            |
|--|---------------------------|----------------|---------------------------|------------|
|  | 2011                      | 2010           | 2011                      | 2010       |
| Change in Preferred Stock Derivative Liability | \$(4,749,332 )            | \$(4,156,097 ) | \$ 7,665,268              | \$ 412,908 |

Please note that on August 12, 2011, the Holders of in excess of 50% of the Company's outstanding shares of Series B 8% Convertible Preferred Stock, par value US \$0.01 per share ("Series B Preferred Stock"), and shares of Series C 8% Convertible Preferred Stock, par value US \$ 0.01 per share ("Series C Preferred Stock"), voting as one class (collectively the "Preferred Stock"), consented to amendments to the Amended Certificates of Designations of the Series B Preferred Stock and the Series C Preferred Stock (the "Amended Certificates"). The Certificates of Designations for each of the Series B Preferred Stock and the Series C Preferred Stock are the same in all respects except where specifically noted.

Pursuant to the terms of the Amended Certificates, the terms of the Series B Preferred and the Series C Preferred Stock have been amended as follows, with the amendment to the Conversion Price, as detailed below, resulting in a significant increase in the underlying common shares into which the Series B Preferred Stock and Series C Preferred may convert, and accordingly a significant effect on the preferred stock derivative liability related to the Series B Preferred Stock and Series C Preferred Stock.

Dividends : The Preferred Stock continues to accrue dividends at the rate of 8% per annum on their stated value of US \$1,000 per share, payable quarterly on January 1, April 1, July 1 and October 1 and such rate shall not increase to 15% per annum as previously provided in the respective Certificates of Designations of the Preferred Stock.

Conversion Price : The conversion price of the Series B Preferred Stock was reduced from \$1.23 to \$0.15 per share and the conversion price of the Series C Preferred Stock was reduced from \$1.27 per share to \$0.15 per share (subject to adjustments as provided in the Amended Certificates).

Automatic Monthly Conversions : On each Monthly Conversion Date (as defined below), a number of shares of the Preferred Stock equal to each Holder's pro rata portion (based on the number of shares of Preferred Stock held by each Holder on August 1, 2011) of the Monthly Conversion Amount (as defined below) will automatically convert into shares of the Company's Common Stock at the then effective conversion price (each such conversion, a "Monthly Conversion"). Notwithstanding the foregoing, the Company will not be permitted to effect a Monthly Conversion on a Monthly Conversion Date unless (i) the Common Stock shall be listed or quoted for trading on a trading market, (ii) there is a sufficient number of authorized shares of Common Stock for issuance of all Common Stock to be issued upon such Monthly Conversion, (iii) as to any Holder of the Preferred Stock, the issuance of shares will not cause a breach of the ownership limitations set forth in the Amended Certificates, (iv) if requested by a Holder of the Preferred Stock and a customary Rule 144 representation letter relating to all shares of Common Stock to be issued upon each Monthly Conversion is provided by such Holder after request from the Company, the shares of Common Stock issued upon such Monthly Conversion are delivered electronically through the Depository Trust Company or another established clearing corporation performing similar functions("DTC"), may be sold by such Holder pursuant to an exemption under the Securities Act of 1933 and are otherwise free of restrictive legends and trading restrictions on such holder, (v) there has been no public announcement of a pending or proposed Fundamental Transaction or



Change of Control Transaction (as such terms are defined in the Amended Certificates) that has not been consummated, (vi) the applicable Holder of Preferred Stock is not in possession of any information provided to such holder by the Company that constitutes material non-public information, and (vii) the average VWAP (as defined in the Amended Certificates) for the 20 trading days immediately prior to the applicable Monthly Conversion Date equals or exceeds the then effective conversion price of the Preferred stock. As used herein, the following terms have the following meanings: (i) "Monthly Conversion Date" means the first day of each month, commencing on September 1, 2011, and terminating on the date the Preferred Stock is no longer outstanding; (ii) "Monthly Conversion Amount" means an aggregate Stated Value of the Preferred Stock among all Holders that is equal to 35% of aggregate dollar trading volume of the Common Stock during the 20 Trading Days immediately prior to the applicable Monthly Conversion Date (such 20 Trading Day period, the "Measurement Period"), increasing to 50% of the aggregate dollar trading volume during the Measurement Period if the average VWAP during such Measurement Period equals or exceeds US \$0.20 (subject to adjustment for forward and reverse stock splits and the like that occur after August 1, 2011) and further increasing to 70% of the aggregate dollar trading volume during such Measurement Period if the average VWAP during such Measurement Period equals or exceeds \$0.25 (subject to adjustment for forward and reverse stock splits and the like that occur after August 1, 2011). All shares of Common Stock issued on a Monthly Conversion Date shall be delivered otherwise in accordance with the procedures and time frames set forth in Section 6 of the Amended Certificates. Upon the request of the Company, each Holder shall provide to the Company, a customary Rule 144 representation letter relating to all shares of Common Stock to be issued upon each Monthly Conversion. As of December 31, 2011, the Company does not meet certain of the requirements for Automatic Monthly Conversions.

For further details, please refer to the Current Reports on Form 8-K filed with the SEC on August 12, 2011 and August 31, 2011, such filings being herein incorporated by reference.

#### 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:

#### FAIR VALUE OF WARRANT DERIVATIVE LIABILITY

|  | March 31<br>2011 | June 30<br>2011 | Sept 30<br>2011 | Dec 31<br>2011 |
|--|------------------|-----------------|-----------------|----------------|
| Risk-Free interest rate                    | 0.09% - 2.9%     | 0.3% - 2.5%     | 0.02% - 1.3%    | 0.02% - 1.09%  |
| Expected volatility                        | 138% - 194%      | 153% - 217%     | 133% - 196%     | 100% - 175%    |
| Expected life (in years)                   | 0.3 – 7.0        | 0.0 – 6.8       | 0.2 – 6.5       | 0.3 – 6.3      |
| Expected dividend yield                    | —                | —               | —               | —              |
| Number of warrants                         | 155,325,048      | 154,334,659     | 154,153,308     | 153,674,610    |
| Fair Value of Warrant Derivative Liability | \$ 10,543,145    | \$ 24,126,576   | \$ 13,629,540   | \$ 9,043,464   |

#### CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY

|  | Three months ended Dec 31,<br>2011 | Nine months ended Dec 31,<br>2010 | Three months ended Dec 31,<br>2011 | Nine months ended Dec 31,<br>2010 |
|--|------------------------------------|-----------------------------------|------------------------------------|-----------------------------------|
| Change in Warrant Derivative Liability | \$(4,586,076 )                     | \$(2,064,745 )                    | \$(1,499,682 )                     | \$(4,788,493 )                    |

The risk free interest rate was based on rates established by the US Treasury Department. The expected volatility was based on the historical volatility of the Company's share price for periods equal to the expected life of the outstanding warrants at each valuation date. The expected dividend rate was based on the fact that the Company has not historically paid dividends on common stock and does not expect to pay dividends on common stock in the future.

NOTE  
7 -PREFERRED SHARE DERIVATIVE INTEREST PAYABLE

Preferred share derivative interest payable as of December 31, 2011 consisted of \$86,236 in derivative interest accrued and owing as of December 31, 2011. The full amount of derivative interest payable as of December 31, 2011, was paid via the issuance of 1,151,013 shares of common stock in January 2012.

NOTE  
8 -OPERATING LEASES

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

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

Leasehold improvements and qualification as suitable for manufacturing and packaging 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 this property will ever achieve qualification for intended future utilization.

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

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

\* 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:

RENT EXPENSE

|                                   | Three<br>Months<br>Ended<br>Dec 31, 2011 | Three<br>Months<br>Ended<br>Dec 31,<br>2010 | Nine<br>Months<br>Ended<br>Dec 31, 2011 | Nine<br>Months<br>Ended<br>Dec 31, 2010 |
|-----------------------------------|--|---|---|---|
| Rent Expense                      | \$ 22,584                                | \$22,584                                    | \$ 67,753                               | \$ 45,169                               |
| Change in deferred rent liability | \$ 2,895                                 | \$22,584                                    | \$ 8,686                                | \$ 45,169                               |

DEFERRED RENT LIABILITY (LONG-TERM LIABILITY)

|                                    | March 31<br>2011 | June 30<br>2011 | September 30<br>2011 | December 31<br>2011 |
|------------------------------------|------------------|-----------------|----------------------|---------------------|
| Balance of Deferred Rent Liability | \$48,064         | \$50,960        | \$ 53,855            | \$ 56,748           |

NOTE  
9 - DEFERRED REVENUES

Deferred revenues totaling \$182,224 represents the unamortized amount of a \$200,000 advance payment received from Precision Dose Inc. for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license. The current portion of deferred revenues, totaling \$13,333 represents the revenue that will be recognized over the 12 months immediately subsequent to December 31, 2011. The long term portion of deferred revenues, totaling \$168,891, represents the revenue that will be recognized during the period that begins more than twelve months subsequent to December 31, 2011. Please refer to exhibit 10.9 of the quarterly report on form 10-Q filed on November 15, 2010 for further details on the Precision Dose Manufacturing Agreement, with such exhibit being herein incorporated by this reference.

NOTE  
10 - STOCKHOLDERS' EQUITY

## Common Stock

During the nine months ended December 31, 2011, the Company issued a total of 84,285,078 shares of Common Stock, with such issuances of Common Stock being summarized as follows:

| Description   | Shares<br>Of<br>Common Stock |
|---|------------------------------|
| Common shares issued in lieu of cash in payment of preferred share derivative interest expenses totaling \$282,680 which were due and owing as of March 31, 2011 to holders of the Company's Series B, Series C and Series D Preferred Share derivative instruments | 4,775,017                    |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expenses totaling \$142,805 which were due and owing as of June 30, 2011 to holders of the Company's Series B, Series C and Series D Preferred Share derivative instruments  | 952,686                      |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expenses totaling \$124,370 which were due and owing as of December 31, 2011 to holders of the Company's Series B and Series C Preferred Share derivative instruments        | 1,531,658                    |
| Common shares issued pursuant to the conversion of Series B Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$72,600 at the time of their conversion  | 660,000                      |
| Common shares issued pursuant to the conversion of Series C Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$1,402,667 at the time of their conversion   | 15,346,670                   |
| Common shares issued pursuant to the conversion of Series D Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$9,473,715 at the time of their conversion   | 58,042,857                   |
|   | 2,976,190                    |

Common shares issued pursuant to the conversion of Series E Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$386,905 at the time of their conversion

|   |            |
|---|------------|
| Total Common Shares issued during the nine months ended December 31, 2011 | 84,285,078 |
|---|------------|

## Options

At December 31, 2011, the Company had 1,943,605 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 1,065,395 options issued pursuant to the Company's 2004 Stock Option Plan which are outstanding and not vested, with exercise prices ranging from \$0.06 to \$2.50 per share. These options are scheduled to vest in equal annual increments on January 18, 2012 and 2013 or upon the occurrence of certain defined events and require that employees awarded such options be employed by the Company on the vesting date.

NOTE  
11 **-PER SHARE INFORMATION**

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

|   | For the Three Months<br>Ended Dec 31, |             | For the Nine Months<br>Ended Dec 31, |             |
|---|---------------------------------------|-------------|--------------------------------------|-------------|
|   | 2011                                  | 2010        | 2011                                 | 2010        |
| <u>Numerator</u>  |                                       |             |                                      |             |
| Net Income (loss) attributable to common shareholders - Basic         | 8,720,994                             | \$5,928,212 | \$(8,093,110 )                       | \$3,023,043 |
| Net Income attributable to common shareholders - Diluted              | 8,807,320                             | 5,621,771   | n/a                                  | 2,046,243   |
| <u>Denominator</u>  |                                       |             |                                      |             |
| Weighted-average shares of common stock outstanding                   | 262,067,348                           | 96,873,523  | 247,443,617                          | 92,196,433  |
| Dilutive effect of stock options, warrants and convertible securities | 164,970,150                           | 210,956,902 | n/a                                  | 171,913,797 |
| <u>Net (loss) income per share</u>                                    |                                       |             |                                      |             |
| Basic   | \$0.03                                | \$0.06      | \$(0.03 )                            | \$0.03      |
| Diluted   | \$0.02                                | \$0.02      | \$(0.03 )                            | \$0.01      |

NOTE  
12 **-SUBSEQUENT EVENTS**

Common shares issued in lieu of cash in payment of derivative interest expense

Derivative interest expense related to the Preferred Share derivatives due and payable as of December 31, 2011 were paid during January 2012 through the issuance of 1,151,013 shares of common stock.

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## Reincorporation in Nevada

On January 5, 2012 (the "Effective Date"), Elite Pharmaceuticals, Inc., a Delaware corporation (the "Company" or "Elite Delaware") consummated a merger with Elite Pharmaceuticals, Inc. ("Elite Nevada"), its newly formed wholly-owned subsidiary, pursuant to the terms and conditions of an Agreement and Plan of Merger (the "Reincorporation"). As a result of the Reincorporation, the legal domicile of Company is now Nevada.

As of the Effective Date, Elite Nevada, as the surviving corporation in the Reincorporation, continues to operate the business of Elite Delaware as it existed prior to the Reincorporation. Elite Delaware's stockholders, at their Annual Meeting held on October 18, 2011, authorized the Company's Board of Directors, in its discretion, to effect a change of domicile from Delaware to Nevada. On January 5, 2012, the Board determined to effect the Reincorporation. Other than the change in the state of incorporation, the Reincorporation did not result in any change in the business, physical location, management, assets, liabilities or obligations of Elite Delaware, nor did it result in any change in location of Elite Delaware's employees, including Elite Delaware's management. Each director and officer of Elite Delaware continues to hold his respective offices with Elite Nevada.

The Reincorporation did not alter any stockholder's percentage ownership interest or number of shares owned in Elite Delaware. As of the Effective Date, each outstanding share of Elite Delaware common stock and preferred stock automatically converted into an outstanding share of Elite Nevada common stock and preferred stock, respectively, and each outstanding option, warrant and other right to acquire shares of Elite Delaware common stock converted into an outstanding option, warrant or other right to acquire shares of Elite Nevada common stock. Stockholders are not required to undertake any exchange of stock certificates, as shares in Elite Delaware, are deemed to represent an equal number of shares in Elite Nevada. Furthermore, the Company's common stock will continue to trade on the OTC BB. As of the Effective Date, each employee benefit plan, incentive compensation plan or other similar plan of Elite Delaware converted into an employee benefit plan, incentive compensation plan or other similar plan of Elite Nevada.

In connection with the Reincorporation, as of the Effective Date, for purposes of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (i) Elite Nevada automatically inherited the Exchange Act reporting obligations of Elite Delaware, (ii) the common stock of Elite Nevada is deemed registered under Section 12(b) of the Exchange Act by operation of Exchange Act Rule 12g-3(a) and (iii) Elite Nevada is deemed to be successor issuer to Elite Delaware.

As of the Effective Date, the rights of Elite Delaware's stockholders are governed by the General Corporation Law of the State of Nevada (the "NGCL") and the Articles of Incorporation and Bylaws of Elite Nevada. The Articles of Incorporation and Bylaws of Elite Nevada include certain provisions which are required by the NGCL and may alter the rights of stockholders and powers of management.

For a description and discussion of these differences, please refer to "*Proposal 3: Reincorporation In Nevada; Differences between Delaware and Nevada Law*" Elite Delaware's proxy statement on Schedule 14A filed with the Securities and Exchange Commission on August 31, 2011, which is incorporated by reference herein.

A Current Report on Form 8-K was filed with the SEC on January 9, 2012, with such filing being herein incorporated by reference.

Methadone shipment

On January 12, 2012, Elite made the initial shipment of methadone hydrochloride 10mg tablets to ThePharmaNetwork LLC, and its wholly owned subsidiary, Ascend Laboratories, LLC under the commercial manufacturing and supply agreement dated June 23, 2011.

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The methadone hydrochloride tablets are the generic equivalent of the Dolophine® hydrochloride 10 mg tablets. The product and its equivalents had annual sales of approximately \$44 million based on September 2011 data.

Elite will be compensated at an agreed upon price for the manufacturing and packaging of the products.

A current report on Form 8-K was filed with the SEC on January 17, 2012, with such filing being herein incorporated by reference.

#### Approval of Hydromorphone 8mg

On January 23, 2012, the Company received notice from the FDA that the FDA approved the Company's supplemental application for the manufacturing and packaging of Hydromorphone Hydrochloride USP 8mg. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, Precision Dose Inc. and its wholly owned subsidiary, TAGI Pharmaceuticals Inc., which will distribute the product as part of a multi-product distribution agreement.

A current report on Form 8-K was filed with the SEC on January 27, 2012, with such filing being incorporated herein by reference

For further details on the multi-product distribution agreement with Precision Dose Inc. please refer to the Current Report on Form 8-K filed with the SEC on September 10, 2010 and the Annual Report on Form 10-K filed with SEC on June 29, 2011, with both such filings being herein incorporated by reference.

#### Sale of New Jersey State Net Operating Losses

In January 2012, the Company received final approval from the NJEDA for the sale of New Jersey net operating losses with net tax benefits equal to \$529,132 under the Technology Business Tax Certificate Transfer Program. The Company sold the net operating loss approved for sale at a transfer price equal to ninety two cents equal to every benefit dollar. The proceeds of such sale, totaling \$486,801, were received by the Company during January 2012.

**ITEM 2.**

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

**THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2011**

**COMPARED TO THE**

**THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2010**

**(UNAUDITED)**

The following discussion and analysis should be read with the financial statements and accompanying notes included elsewhere in this Form 10-Q and in the Annual Report on Form 10-K for the year ended March 31, 2011. 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. All statements other than statements of historical fact included in this Form 10-Q regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note, without limitation, that statements regarding the preliminary nature of the clinical program results and the potential for further product development, that involve known and unknown risks, delays, uncertainties and other factors not under our control, the requirement of substantial future testing, clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities prior to the commercialization of products under development, and our ability to manufacture and sell any products, gain market acceptance, earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future, are all forward-looking in nature. These risks and other factors are discussed in our filings with the Securities and Exchange Commission. 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 know-how and technology, particularly as it relates to abuse resistant products. 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.

We have three products currently being sold commercially, and one recently approved product available for commercialization, as follows:

- Phentermine 37.5mg tablets
- Lodrane D® immediate release Brompheniramine/Pseudoephedrine capsules
- Methadone Hydrochloride 10mg tablets
- Hydromorphone Hydrochloride 8mg tablets (approved for commercial production on January 23, 2012)

We have also purchased an approved generic naltrexone product, with the transfer of the manufacturing process of such product from the facilities of the previous ANDA holder to our facilities in Northvale, New Jersey (the “Northvale Facility”) being currently on-going. This transfer to the Northvale Facility has been significantly delayed, as a result of the Company being notified by the FDA of its reclassification of our CBE-30 supplement to a prior approval supplement. The transfer of the manufacturing process of naltrexone is a prerequisite to the commercial launch of this generic product. We believe that the commercial launch of this generic product will be a material event and any delays in such launch will have a significant and adverse effect on the Company’s operation and results.

Elite also executed a license agreement with Precision Dose, Inc. (the “Precision Dose Agreement”) and a manufacturing agreement with The PharmaNetwork LLC (the “TPN Agreement”). The Precision Dose Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg tablets, generic hydromorphone, generic naltrexone and a certain additional product that had been filed for approval with the FDA. Phentermine 37.5mg tablets were launched in April 2011, and the Company received approval from the FDA to manufacture and package generic hydromorphone on January 23, 2012. The TPN Agreement, executed on June 23, 2011, provides for the manufacture and packaging by the Company of The PharmaNetwork’s methadone hydrochloride, 10mg tablets (“Methadone 10mg”), with the Methadone 10mg to be marketed by TPN’s wholly owned subsidiary, Ascend Laboratories, LLC. The FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and the initial shipment of Methadone 10mg occurred during January 2012.

Elite has an undisclosed generic product filed with the FDA that is awaiting review. This product is licensed to TAGI. One of the undisclosed generic products worked on under the Epic Strategic Alliance Agreement has also been filed with the FDA. In addition, Elite also has an undisclosed generic product filed with the FDA that is awaiting review and for which Elite retains all rights.

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

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

The Northvale Facility operates under Current Good Manufacturing Practice (“cGMP”) and is a United States Drug Enforcement Agency (“DEA”) registered facility for research, development and manufacturing.

## **Strategy**

Elite is focusing its efforts on the following areas: (i) development of Elite’s pain management products, including abuse resistant products, (ii) set up and launch of approved generic products; (iii) the development of the other

products in our pipeline including the eight products pursuant to the Epic Strategic Alliance Agreement; (iv) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations, and (v) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

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

### **Commercial Products**

On April 7, 2011, Elite made the initial shipment of phentermine HCl 37.5 mg tablets to TAGI. This triggered a milestone payment under the Precision Dose Agreement. Phentermine 37.5mg tablets is now a commercial product being distributed by our partner, TAGI.

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

Elite's revenue derived from phentermine 37.5mg tablets during the nine months ended December 31, 2011 was approximately \$340k, with such amount including a \$145k milestone payment triggered by the first shipment of the product, \$145k in manufacturing revenues and \$50k in royalties paid pursuant to the Precision Dose Agreement

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("ECR"), a wholly owned subsidiary of Hi-Tech Pharmacal ("Hi-Tech") announced the launch of Lodrane D®, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective, low-sedating antihistamine combined with a decongestant.

Lodrane D® is promoted and distributed in the U.S. by ECR, Hi-Tech's branded division. Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is the one of the only adult brompheniramine containing products available to the consumer at this time.

Lodrane D® is marketed under the Over-the-Counter Monograph (the "OTC Monograph") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval. Under the Federal Food Drug and Cosmetic Act ("FDCA"), FDA regulations and statements of FDA policy, certain drug products are permitted to be marketed in the U.S. without prior approval. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

Elite is manufacturing the product for ECR and will receive revenues for the manufacturing, packaging and laboratory stability study services for the product, as well as royalties on sales. The current U.S. allergy market exceeds \$3.5 billion.

A current report on Form 8-K was filed with the SEC on September 27, 2011, with such filing being herein incorporated by reference.



Elite's revenue derived from Lodrane D® during the nine months ended December 31, 2011 was approximately \$101k.

### Approved Products

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

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

The ANDA for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC ("Epic") dated September 10, 2010 (the "Phentermine Purchase Agreement"). Current reports on form 8-K were filed on September 10, 2010 and February 4, 2011 in relation to the Phentermine Purchase Agreement and the Phentermine ANDA, with such filings being incorporated herein by this reference. Please also refer to exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

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

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

Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company's commercial launch of the product, was approved by the FDA on January 23, 2012. However, please note that the completion of such transfer had been significantly delayed as a result of the FDA's reclassification of the Company's CBE-30 supplement filing to a prior approval supplement filing. As a result of the delays caused by this reclassification, the Company recorded an impairment of the Hydromorphone 8mg ANDA in an amount equal to the entire purchase price of the acquisition. A current report on Form 8-K was filed with the SEC on June 6, 2011 in relation to this issue, with such filing being herein incorporated by reference. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011 and presented in the Annual Report on Form 10-K filed with the SEC on June 29, 2011 and incorporated herein by reference. For further details on this issue, please also refer to the Current Report on Form 8-K and filed with the SEC on June 6, 2011, with such filing being herein incorporated by reference.

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

Transfer of the manufacturing process of Naltrexone 50mg to the Northvale Facility is a prerequisite of the Company's commercial launch of the product and is currently in process. However, please note that the completion of such transfer has been significantly delayed as a result of the FDA's reclassification of the Company's CBE-30 supplement filing to a prior approval supplement filing. As a result of the delays caused by this reclassification, the Company has recorded an impairment of the Naltrexone 50mg ANDA in an amount equal to the entire purchase price of the acquisition. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011 and presented in the Annual Report on Form 10-K filed with the SEC on June 29, 2011 with such filing being herein incorporated by reference.

#### **Discontinued Products - Lodrane 24® and Lodrane 24D®**

On March 3, 2011, the U.S. Food and Drug Administration ("FDA") announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The once daily allergy products manufactured by Elite, Lodrane 24® and Lodrane 24D® (the "Lodrane® Extended Release Products"), were included in the FDA list of 500 products. After this announcement by the FDA, the Company's customer for the Lodrane® Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane® Extended Release Products has ceased. The shipments made during the quarter ended June 30, 2011 consisted solely of quantities that were in production at the time ECR cancelled all outstanding orders. There were no shipments of the Lodrane Extended Release Products subsequent to those that were made during the quarter ended June 30, 2011.

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

ECR (the owner and marketer of the Lodrane® Extended Release Products) initiated a formal approval process with the FDA in 2010 regarding the Lodrane® Extended Release Products and issued a press release on March 3, 2011 stating that they will continue to actively pursue approval for the Lodrane® Extended Release Products. In addition, on April 29, 2011, ECR filed a Petition for Review with the United States Court of Appeals for the District of Columbia, petitioning such court to review and set aside the final order of the FDA with relation to the Lodrane® Extended Release Products.

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

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane® Extended Release Products. Elite's revenues for the manufacturing these products for the nine months ended December 31, 2011 and 2010 were \$251k and \$1,334k, respectively. In addition, the Company sold to ECR, at cost without markup, all raw materials related to the manufacture of the Lodrane® Extended Release Products which remained in stock subsequent to the final shipment of the Lodrane® Extended Release Products. Revenues from the sale of these raw materials totaled approximately \$221k. As manufacturing of the Lodrane® Extended Release Products has ceased, there will be no further manufacturing revenues derived from the Lodrane® Extended Release Products until such products receive the necessary approvals from the FDA. Please note that there can be no assurances that such approvals will be granted or that future manufacturing revenues will be earned by the Company from the manufacture of the Lodrane® Extended Release Products, should such approvals be granted by the FDA.

Royalties on in-market sales of the Lodrane® Extended Release Products earned during the nine months ended December 31, 2011 and 2010 were \$225k and \$351k, respectively. While Elite's manufacturing of the Lodrane® Extended Release Products has ceased, the sale of such products in the US market was still permitted by the FDA until August 30, 2011. The Company earned royalties on any in-market sales that occurred up to that date.

Revenues from contract laboratory and formulation development services for the nine months ended December 31, 2011 and 2010 were \$496k and \$234k, respectively. Contract laboratory services for the Lodrane® Extended Products will continue, on a residual basis, through the fiscal year ended March 31, 2012, as such services consist of stability studies that must be performed over certain defined time periods. These revenues are expected to be significantly less than laboratory service revenues earned in prior periods.

### **Contract Manufacturing of Isradipine and Phendimetrazine**

On June 1, 2011, Elite executed a Manufacturing and Supply Agreement (the "Isradipine/ Phendimetrazine Agreement") with Mikah Pharma, LLC ("Mikah") to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg ("Isradipine") and Phendimetrazine Tartrate Tablets USP, 35 mg ("Phendimetrazine"), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Elite's facility and the appropriate regulatory filing for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the United States, its territories, possessions, and commonwealths in accordance with the requirements of the Isradipine/ Phendimetrazine Agreement; Elite is required to perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing Isradipine and Phendimetrazine for commercial sale by Mikah or its designees in accordance with the terms of the Isradipine/ Phendimetrazine Agreement. During the term of the Isradipine/ Phendimetrazine Agreement and subject to the provisions therein, Mikah is required to purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Isradipine and Phendimetrazine as Mikah may order from time to time pursuant to the Isradipine/ Phendimetrazine Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of Isradipine and Phendimetrazine. For the Isradipine product, Elite will also receive a 10% royalty on net profits of the finished Product. The payment is to be calculated and paid quarterly. Elite will also receive a onetime milestone payment for each Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch. The Isradipine/ Phendimetrazine Agreement has a term of five years and automatically renews for additional periods of one year unless Mikah provides written notice of termination to Elite at least six months prior to the expiration of the Term or any Renewal Term. Transfer of the manufacturing site to the Northvale Facility, a prerequisite of commercial launch of Isradipine and Phendimetrazine, is currently in progress.

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

Revenues earned by the Company in relation to the Isradipine/Phendimetrazine Agreement during the nine months ended December 31, 2011 were \$25,000.

### **Contract Manufacturing of Methadone**

On June 23, 2011, Elite entered into a commercial manufacturing and supply agreement with ThePharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories LLC (together "TPN"). Under the terms of the agreement, Elite will perform manufacturing and packaging for TPN's Methadone Hydrochloride, 10mg tablets ("Methadone 10mg"). The FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and commercial launch of this product is expected during this fiscal year.

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

The initial shipment to TPN of Methadone 10mg was made on January 17, 2012. A Current Report on Form 8-K was filed on January 17, 2012 with regards to this initial shipment, with such filing being herein incorporated by reference.

No revenues were earned by the Company in relation to this contract manufacturing agreement with TPN during the nine months ended December 31, 2011. As the initial shipment of this product occurred subsequent to December 31, 2011, any revenues earned in relation to this contract manufacturing agreement will be recorded in periods beginning subsequent to December 31, 2011.

### **Products Under Development**

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

#### **ELI-154 and ELI-216**

ELI-154, a once-daily oxycodone formulation, was developed by Elite, 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, 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. 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. An interested party was identified that would fund half of the clinical costs for Europe, however Elite is not able to find a way to fund the remaining costs at this time.

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

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

### **Product Development Agreements**

Elite is currently performing services pursuant to product development agreements with the following:

- Mikah Pharma LLC (the "Mikah Development Agreement")
- Hi-Tech Pharmacal Co. (the "Hi-Tech Development Agreement")

For further details on the Mikah Development Agreement, please refer to the current report on Form 8-K filed with the SEC on September 1, 2010 and exhibit 10.63 of the Annual Report on Form 10-K filed with the SEC on June 29, 2011, such filings being herein incorporated by reference.



Revenues earned by the Company in relation to the Mikah Development Agreement during the nine months ended December 31, 2011 totaled \$25,000.

For further details on the Hi-Tech Development Agreement, please refer to the current report on Form 8-K filed with the SEC on January 4, 2011 and exhibit 10.68 of the Annual Report on Form 10-K filed with the SEC on June 29, 2011, such filings being herein incorporated by reference.

Revenues totaling \$305k were earned by the Company in relation to the Hi-Tech Development Agreement during the nine months ended December 31, 2011.

### **Novel Labs Investment**

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

## **Critical Accounting Policies and Estimates**

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

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

## **Results of Consolidated Operations**

### **Three Months Ended December 31, 2011 Compared to Three Months Ended December 31, 2010**

Our revenues for the three months ended December 31, 2011 were \$510k a decrease of \$716k or approximately 58% over revenues for the comparable period of the prior year, and consisted of \$170k in manufacturing fees, \$319k in lab and product development fees and \$20k in royalties and license fees. Revenues for the three months ended December 31, 2010, consisted of \$902k in manufacturing fees, \$93k in lab and product development fees, and \$232k in royalties and license fees. Manufacturing fees decreased by approximately 81% due to the removal from the market of the Lodrane® Extended Release Products, pursuant to a directive from the FDA issued in March 2011. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 for further details, with such filing being herein incorporated by reference. Lab and product development fees increased by approximately 244% due to product development fees earned from the Hi-Tech Development Agreement and the Mikah Development Agreement, offset by decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees decreased by 91% due to the removal from the market of the Lodrane® Extended Release Products as of August 30, 2011, pursuant to the directive of the FDA issued in March 2011.

Research and development costs for the three months ended December 31, 2011 were \$386k, an increase of \$206k or approximately 115% from \$180k of such costs for the comparable period of the prior year. The increase was primarily due to the shifting of personnel and operational resources from commercial manufacturing to product development as a result of the discontinuance of the Lodrane® Extended Release Products.

General and administrative expenses for the three months ended December 31, 2011, were \$288k, a decrease of \$27k, or approximately 9% from \$316k of general and administrative expenses for the comparable period of the prior year. The decrease was primarily due to continuing overhead cost reductions being implemented by management.

Depreciation and amortization for the three months ended December 31, 2011 was \$103k, an increase of \$94k, or approximately 1023%, from \$9k for the comparable period of the prior year. The increase was primarily due to depreciation expense related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products.

Non-cash compensation through the issuance of stock options and warrants for the three months ended December 31, 2011 was \$6k, a decrease of \$2k, or approximately 25% from \$8k for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for the three months ended December 31, 2011 was \$431k, compared to a profit from operations of \$73k for the three months ended December 31 2010.

Other income for the three months ended December 31, 2011 was \$9,192k, an increase in other income of \$3,336k from the net other income of \$5,856k for the comparable period of the prior year. The increase in other income was due to derivative income relating to changes in the fair value of our preferred shares and outstanding warrants during the quarter ended December 31, 2011 totaling \$9,335k, as compared to a net derivative income of \$6,221k for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company's convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company's Common Stock as of December 31, 2011 was \$0.07, as compared to a closing price of \$0.10 as of September 30, 2011. Closing prices on the various dates on which shares of convertible preferred stock were converted to common stock ranged from \$0.07 to \$0.10 during the quarter ended December 31, 2011. These variances in the closing price of the Company's Common Stock as compared with the closing price at the end of the immediately preceding quarter were significant factors in the derivative income recorded during the quarter ended December 31, 2011.

As a result of the foregoing, our net income for the three months ended December 31, 2011 was \$8,761k, compared to a net income of \$5,928k for the three months ended December 31, 2010.

### **Nine Months Ended December 31, 2011 Compared to Nine Months Ended December 31, 2010**

Our revenues for the nine months ended December 31, 2011 were \$1,774k a decrease of \$1,279k or approximately 42% over revenues for the comparable period of the prior year, and consisted of \$848k in manufacturing fees, \$496k in lab and product development fees and \$430k in royalties and license fees. Revenues for the nine months ended December 31, 2010, consisted of \$2,236k in manufacturing fees, \$234k in lab and product development fees, and \$583k in royalties and license fees. Manufacturing fees decreased by approximately 62% due to the removal from the market of the Lodrane® Extended Release Products, pursuant to a directive from the FDA issued in March 2011. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 for further details, with such filing being herein incorporated by reference. Lab and product development fees increased by approximately 112% due to product development fees earned from the Hi-Tech Development Agreement and the Mikah Development Agreement, offset by decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees decreased by 26% due to the removal from the market of the Lodrane® Extended Release Products as of August 30, 2011, offset by milestone payments received pursuant to the Precision

Dose Agreement and related to the April 2011 launch of Phentermine 37.5mg tablets. In-market sales of the Lodrane® Extended Release Products were only permitted for five of the nine months in the nine month period ended December 31, 2011, as compared with a full nine months of sales occurring during the comparable period of the prior year.

Research and development costs for the nine months ended December 31, 2011 were \$1,030k, an increase of \$535k or approximately 108% from \$495k of such costs for the comparable period of the prior year. The increase was primarily due to the shifting of personnel and operational resources from commercial manufacturing to product development as a result of the discontinuance of the Lodrane® Extended Release Products.

General and administrative expenses for the nine months ended December 31, 2011, were \$1,090k, an increase of \$142k, or approximately 15% from \$948k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to overhead costs related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products, increased real estate taxes at the Northvale Facility and increased legal fees related to the conversion of Series B,C,D and E Preferred Shares to Common Shares and preparation of the preliminary and final proxy statements which were filed during the nine month period ended December 31, 2011.

Depreciation and amortization for the nine months ended December 31, 2011 was \$336k, an increase of \$223k, or approximately 197%, from \$113k for the comparable period of the prior year. The increase was primarily due to depreciation expense related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products.

Non-cash compensation through the issuance of stock options and warrants for the nine months ended December 31, 2011 was \$18k, a decrease of \$15k, or approximately 45% from \$33k for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for the nine months ended December 31, 2011 was \$1,359k, compared to a loss from operations of \$155k for the nine months ended December 31, 2010.

Other expenses for the nine months ended December 31, 2011 were a net expense of \$6,692k, an increase in other net expenses of \$9,878k from the net other income of \$3,186k for the comparable period of the prior year. The increase in other expenses was due to derivative expenses relating to changes in the fair value of our preferred shares and outstanding warrants during the nine months ended December 31, 2011 totaling \$6,166k, as compared to a net derivative income of \$4,376k for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company's convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company's Common Stock as of December 31, 2011 was \$0.07, as compared to a closing price of \$0.08 as of March 31, 2011. Closing prices on the various dates on which shares of convertible preferred stock were converted to common stock ranged from \$0.07 to \$0.22 during the nine months ended December 31, 2011. These variances in the closing price of the Company's Common Stock as compared with the closing price at the end of the immediately preceding fiscal year end were significant factors in the derivative income recorded during the nine months ended December 31, 2011.

As a result of the foregoing, our net loss for the nine months ended December 31, 2011 was \$8,051k, compared to a net income of \$3,023k for the nine months ended December 31, 2010.

### **Material Changes in Financial Condition**

Our working capital (total current assets less total current liabilities), decreased to a deficit of 3.2 million as of December 31, 2011 from a working capital deficit of \$1.5 million as of March 31, 2011, primarily due to our net loss from operations, exclusive of non-cash charges. In addition, it should be noted that current liabilities includes the entire principal amount due on the Company's NJEDA Bonds Payable. This amount, totaling \$3.4 million has been classified as a current liability as a result of the Company receiving a notice of default from the Trustee of the

NJ-EDA Bonds. Please refer to Note 5 to our financial statements and Item 3 of this quarterly report on Form 10-Q for further details.

Net cash used by operations was \$789k for the nine months ended December 31, 2011, primarily due to our net loss from continuing operations of \$8,053k, offset by non-cash charges totaling \$7,264k, which included, without limitation, depreciation and amortization of \$363k, net expense from the change in fair value of derivative liabilities of \$6,166k, derivative interest payments satisfied through the issuance of common shares in lieu of cash of \$550k, non-cash compensation satisfied by the issuance of common stock and options of \$18k, decreases in inventories of \$185k, decreases in accounts receivable of \$88k and increases in accounts payable and other current liabilities of \$41k.

## LIQUIDITY AND CAPITAL RESOURCES

### **Going concern considerations**

As of December 31, 2011, the Company had a working capital deficit of \$3.2 million, losses from operations totaling \$1.4 million for the nine months ended December 31, 2011, other expenses totaling \$6.7 million for the nine months ended and a net loss of \$8.1 million for the nine months ended December 31, 2011. Please note that the Company's other income/(expenses) are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that such fair values strongly correlate to and vary inversely with the market share price of the Company's Common Stock.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2012.

Revenues and operating profits for the foreseeable future are expected to be significantly and adversely effected by the FDA removal of the Lodrane® Extended Release Products from the market. The Lodrane® Extended Release Products, which constituted approximately 97% of the Company's revenues in the periods immediately preceding the nine month period ended December 31, 2011, were included on a list of approximately 500 cough/cold and allergy products which are being removed from the U.S. market pursuant to a directive from the FDA. Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011 and the Annual Report on Form 10-K filed with the SEC on June 29, 2011 for further details, such filings being herein incorporated by reference.

In addition, the Company has received Notice of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments. See "NJEDA Bonds" below.

As of December 31, 2011, we had cash reserves of \$0.6 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that we will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. We also anticipate obtaining funds pursuant to the Securities Purchase Agreement with Socius (see the next paragraph). Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement and obtain funds pursuant to the Socius Securities Purchase Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under "Epic Strategic Alliance Agreement" in Item 7 of Part II of our Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009, June 5, 2009, July 1, 2010 and June 29, 2011, which disclosures are incorporated herein by reference.

On December 30, 2011, Elite entered into a securities purchase agreement (the "Socius Agreement") with Socius CG II, Ltd. ("Socius"), under which, subject to the terms of the Socius Agreement, Elite may sell up to \$5 million on non-convertible Series F preferred stock (the "Series F Preferred Stock") to Socius. Such terms include, without limitation, the filing and effectiveness of a registration, as a prerequisite of any sales of Series F Preferred Stock to Socius. There can be no assurance that we will be able to meet the terms and conditions representing such prerequisites of any sales of Series F Preferred Stock to Socius. Even if we were to sell to Socius up to \$5 million of Series F Preferred Stock, 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 on the Socius Agreement, please refer to the Current Report on Form 8-K filed with the SEC on January 5, 2012, with such filing being herein incorporated by reference.



Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50mg are expected as a result of the a recent notification received from the FDA reclassifying to a Prior Approval Supplement, the Company's Changes Being Effectuated in 30 Days Supplement ("CBE-30") related to a change the manufacturing and packaging site of Naltrexone 50mg.

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

For the nine months ended December 31, 2011, we sustained a negative cash flow from operations of approximately \$0.8 million, compared with a positive cash flow from operations of approximately \$0.3 million being achieved during the comparable period in the prior year. Our working capital deficit at December 31, 2011 was approximately \$3.2 million compared with working capital deficit of approximately \$2.7 million at December 31, 2010. Please note that the working capital deficits include the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million is classified as a current liability due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please see “NJEDA Bonds” below.

Cash and cash equivalents at December 31, 2011, were approximately \$0.6 million, an increase of approximately \$0.2 million from the approximately \$0.4 million at December 31, 2010.

As of December 31, 2011, our principal source of liquidity was approximately \$0.6 million of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. There can be no assurance that the exercise of outstanding warrants or options will generate or provide sufficient cash.

### **NJEDA Bonds**

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the “Bonds”). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of September 30, 2011, all of the proceeds were utilized by the Company for such stated purposes.

Interest is payable semiannually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company’s facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a \$415,500 Debt Service Reserve Fund consisting of \$366,000 from the Series A Notes proceeds and \$49,500 from the Series B Notes proceeds. The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets. \$1,274,311 of the proceeds had been deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company’s facility.

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$3,533 and \$7,068 for the three and six months ended September 30, 2011.

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

The interest payments due on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011 and September 1, 2011 totaling \$120,775, \$120,775, \$113,075, \$113,075, \$113,075, and \$113,075, respectively were paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make such payments when due.

The principal payment due on September 1, 2009, totaling \$210,000 was paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make the payment when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$225k 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 \$225k was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470k, with such amount including the principal payments due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$470k was not made.

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

The Company does not expect to have sufficient available funds as of September 1, 2012, to make principal payments, totaling \$730,000, and consisting of \$260,000 due on September 1, 2012, \$245,000 which was due on September 1, 2011 and not paid and \$225,000 which was due on September 1, 2010 and not paid.

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

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

### **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.

##### **Changes in Internal Controls**

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15 (f) under the Exchange Act) during the quarter ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In the ordinary course of business we may be subject to litigation from time to time. There is no past, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects, financial condition or operations.

### **ITEM 1A. RISK FACTORS**

There have been no material changes from the Risk Factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2011.

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

During the quarter ended December 31, 2011, we issued 10,051,661 shares of Common Stock to the holders of our Series B and Series C Preferred Stock. Of this amount, 1,531,658 shares were issued in satisfaction of our obligation to pay \$124,370 in dividends earned and/or owing during the quarter ended December 31, 2011, and 8,520,003 shares were issued pursuant to the conversion of Series C Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$776,134 at the time of their conversion. We did not receive any proceeds in exchange for the issuance of these securities. We relied on the exemption provided by Section 4(2) of the Securities Act of 1933 to issue the common stock. The securities were offered and sold without any form of general solicitation or general advertising and the offerees made representations that they were accredited investors.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

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

### **ITEM 4. Mine Safety Disclosures.**

Not applicable.

## **ITEM 5. Other Information**

### **Reincorporation in Nevada**

As disclosed in more detail in a Current Report on Form 8-K filed with the SEC on January 9, 2012, on January 5, 2012 the Company consummated a merger with Elite Pharmaceuticals, Inc., its newly formed wholly-owned Nevada subsidiary, pursuant to the terms and conditions of an Agreement and Plan of Merger (the "Reincorporation"). As a result of the Reincorporation, the legal domicile of Company is now Nevada. Please see the foregoing Current Report for more information about the Reincorporation.

### **Methadone shipment**

As disclosed in more detail in a Current Report on Form 8-K filed with the SEC on January 17, 2012, on January 12, 2012, Elite made the initial shipment of methadone hydrochloride 10mg tablets to ThePharmaNetwork LLC, and its wholly owned subsidiary, Ascend Laboratories, LLC under the commercial manufacturing and supply agreement dated June 23, 2011.

The methadone hydrochloride tablets are the generic equivalent of the Dolophine® hydrochloride 10 mg tablets. The product and its equivalents had annual sales of approximately \$44 million based on September 2011 data.

Elite will be compensated at an agreed upon price for the manufacturing and packaging of the products.

### **Approval of Hydromorphone 8mg**

As disclosed in more detail in a Current Report on Form 8-K filed with the SEC on January 27, 2012, on January 23, 2012, the Company received notice from the FDA that the FDA approved the Company's supplemental application for the manufacturing and packaging of Hydromorphone Hydrochloride USP 8mg. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, Precision Dose Inc. and its wholly owned subsidiary, TAGI Pharmaceuticals Inc., which will distribute the product as part of a multi-product distribution agreement.

### **Sale of New Jersey State Net Operating Losses**

In January 2012, the Company received final approval from the NJEDA for the sale of New Jersey net operating losses with net tax benefits equal to \$529,132 under the Technology Business Tax Certificate Transfer Program. The Company sold the net operating loss approved for sale at a transfer price equal to ninety two cents equal to every benefit dollar. The proceeds of such sale, totaling \$486,801, were received by the Company during January 2012.

### **Item 6. Exhibits.**

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

#### **Exhibit**

Description

#### **Number**

- |        |  |
|--------|--|
| 2.1    | Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation ("Elite-Delaware") and Elite Pharmaceuticals, Inc., a Nevada corporation ("Elite-Nevada"), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.  |
| 3.1(a) | Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.   |
| 3.1(b) | Certificate of Incorporation of Elite-Delaware, 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(c) 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(d) 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(e) 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(f) 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(g) 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(h) 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(i) 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(j) 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(k) 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(l) 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(m) 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(n) 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.\*
- 3.1 (o) Amended Certificate of Designations of the Series B Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on August 12, 2011, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated August 12, 2011 and filed with the SEC on August 18, 2011.\*
- 3.1 (p) Amended Certificate of Designations of the Series C Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on August 12, 2011, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated August 12, 2011 and filed with the SEC on August 18, 2011.\*
- 3.1 (q)

Certificate of Correction Relating to the Amended Certificate of Designations of the Series B Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on August 12, 2011, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated August 31, 2011 and filed with the SEC on August 31, 2011.\*

- 3.1 (r) Certificate of Correction Relating to the Amended Certificate of Designations of the Series C Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on August 12, 2011, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated August 31, 2011 and filed with the SEC on August 31, 2011.\*
- 3.2(a) By-Laws of Elite-Nevada, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
- 3.2(b) By-Laws of Elite-Delaware, 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 Socius Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 4.2 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.3 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.\*
- 4.4 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.\*
- 4.5 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.\*
- 4.6 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.\*
- 4.7 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.\*
- 4.8 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.\*
- 4.9 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.\*
- 4.10 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.\*

4.11 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.\*

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Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of  
4.12 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.\*

Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant  
4.13 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.\*

Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed  
4.14 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.\*

Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing,  
4.15 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.\*

Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the  
4.16 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.\*

Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by  
4.17 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.\*

Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC,  
4.18 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.\*

Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan  
4.19 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.\*

Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed  
4.20 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.\*

Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing,  
4.21 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.\*

Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by  
4.22 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.\*

Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed  
4.23 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.\*

Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, 4.24 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.\*

4.25 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.\*

4.26 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 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount 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.

10.2 Securities Purchase Agreement with Socius dated December 30, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.

10.3 Form of Lock-Up Agreement (included as Exhibit D to the Securities Purchase Agreement with Socius mentioned in 10.2 above), incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.

31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101 The following materials from Elite Pharmaceuticals' Quarterly Report on Form 10-Q for the period ended December 31, 2011, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

\* On January 5, 2011, the Company changed its domicile from Delaware to Nevada. All corporate documents from Delaware have been superseded by Nevada corporate documents filed or incorporated by reference herein. All outstanding Delaware securities certificates are now outstanding Nevada securities certificates.



SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELITE  
PHARMACEUTICALS,  
INC.

Date: February 14, 2012 /s/ Jerry Treppel  
Jerry Treppel  
Chief Executive Officer  
(Principal Executive  
Officer)

Date: February 14, 2012 /s/ Carter J. Ward  
Carter J. Ward  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)