

ELITE PHARMACEUTICALS INC /NV/  
Form 10-Q  
February 14, 2013

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  
<sup>x</sup> 1934

For the quarterly period ended December 31, 2012

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  
(State or other jurisdiction of incorporation or organization)

22-3542636  
(I.R.S. Employer Identification No.)

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

(201) 750-2646

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

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

Yes  No

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

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

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

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of February 6, 2013 the issuer had outstanding 356,720,969 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>2012<br>(Unaudited) | March 31,<br>2012<br>(Audited) |
|---|-------------------------------------|--------------------------------|
| <b>ASSETS</b>   |                                     |                                |
| <b>CURRENT ASSETS</b>   |                                     |                                |
| Cash and cash equivalents   | \$ 65,655                           | \$ 668,407                     |
| Accounts receivable (net of allowance for doubtful accounts of -0- and -0-, respectively)                           | 526,386                             | 396,847                        |
| Inventories (net of reserve of \$93,338 and \$93,338, respectively)   | 984,431                             | 304,882                        |
| Prepaid expenses and other current assets   | 65,878                              | 127,704                        |
| <b>Total Current Assets</b>   | <b>1,642,350</b>                    | <b>1,497,840</b>               |
| <b><u>PROPERTY AND EQUIPMENT</u></b> , net of accumulated depreciation of \$4,979,270 and \$4,659,670, respectively | 4,108,774                           | 4,284,786                      |
| <b><u>INTANGIBLE ASSETS</u></b> – net of accumulated amortization of \$-0- and \$-0-, respectively                  | 682,849                             | 642,848                        |
| <b>OTHER ASSETS</b>   |                                     |                                |
| Investment in Novel Laboratories, Inc.  | 3,329,322                           | 3,329,322                      |
| Security deposits   | 14,314                              | 14,913                         |
| Restricted cash – debt service for EDA bonds  | 343,051                             | 280,585                        |
| EDA bond offering costs, net of accumulated amortization of \$100,429 and \$93,339, respectively                    | 250,478                             | 261,423                        |
| <b>Total Other Assets</b>   | <b>3,937,165</b>                    | <b>3,886,243</b>               |
| <b>TOTAL ASSETS</b>   | <b>\$ 10,371,138</b>                | <b>\$ 10,311,717</b>           |

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

|  | December 31,<br>2012<br>(Unaudited) | March 31,<br>2012<br>(Audited) |
|--|-------------------------------------|--------------------------------|
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                                     |                                |
| <b>CURRENT LIABILITIES</b>   |                                     |                                |
| EDA bonds payable  | \$3,385,000                         | \$3,385,000                    |
| Short term loans and current portion of long-term debt   | 506,760                             | 13,316                         |
| Accounts payable and accrued expenses  | 1,400,690                           | 1,066,494                      |
| Deferred revenues – current  | 13,333                              | 13,333                         |
| Preferred share derivative interest payable  | 27,500                              | 70,966                         |
| Customer Deposits  | 50,132                              | —                              |
| <b>Total Current Liabilities</b>   | <b>5,383,415</b>                    | <b>4,549,109</b>               |
| <b>LONG TERM LIABILITIES</b>   |                                     |                                |
| Deferred revenues  | 155,556                             | 165,558                        |
| Other long term liabilities  | 90,505                              | 87,404                         |
| Derivative liability – preferred shares  | 7,916,397                           | 8,506,106                      |
| Derivative liability – warrants  | 9,181,427                           | 11,987,222                     |
| <b>Total Long Term Liabilities</b>   | <b>17,343,885</b>                   | <b>20,746,290</b>              |
| <b>TOTAL LIABILITIES</b>   | <b>22,727,300</b>                   | <b>25,295,399</b>              |
| <b>STOCKHOLDERS' DEFICIT</b>   |                                     |                                |
| Common stock – par value \$0.001, Authorized 690,000,000 shares Issued and outstanding – 350,340,298 shares and 331,649,728 shares, respectively | 350,342                             | 331,650                        |
| Additional paid-in-capital   | 117,628,663                         | 114,910,812                    |
| Accumulated deficit  | (130,028,326)                       | (129,919,303)                  |
| Treasury stock at cost (100,000 common shares)   | (306,841 )                          | (306,841 )                     |
| <b>TOTAL STOCKHOLDERS' DEFICIT</b>   | <b>(12,356,162 )</b>                | <b>(14,983,682 )</b>           |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   | <b>\$10,371,138</b>                 | <b>\$10,311,717</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 |            | NINE MONTHS ENDED |              |
|--|--------------------|------------|-------------------|--------------|
|  | December 31,       |            | December 31,      |              |
|  | 2012               | 2011       | 2012              | 2011         |
| REVENUES   |                    |            |                   |              |
| Manufacturing Fees   | \$400,494          | \$170,099  | \$1,246,210       | \$847,832    |
| Royalties & Profit Splits  | 156,454            | 20,127     | 439,117           | 430,228      |
| Lab Fee Revenues   | 110,734            | 319,712    | 195,427           | 495,987      |
| Total Revenues   | 667,682            | 509,938    | 1,880,754         | 1,774,047    |
| COSTS OF REVENUES  | 266,792            | 156,590    | 1,200,787         | 658,289      |
| Gross Profit   | 400,890            | 353,348    | 679,967           | 1,115,758    |
| OPERATING EXPENSES   |                    |            |                   |              |
| Research and Development   | 238,268            | 386,430    | 663,625           | 1,030,141    |
| General and Administrative   | 380,976            | 288,416    | 1,147,112         | 1,089,909    |
| Non-cash compensation through issuance of stock options                      | 15,133             | 6,113      | 36,379            | 18,340       |
| Depreciation and Amortization  | 40,723             | 103,339    | 108,094           | 336,454      |
| Total Operating Expenses   | 675,100            | 784,298    | 1,955,210         | 2,474,844    |
| (LOSS) FROM OPERATIONS   | (274,210 )         | (430,950 ) | (1,275,243 )      | (1,359,086 ) |
| OTHER INCOME / (EXPENSES)  |                    |            |                   |              |
| Interest expense, net  | (63,924 )          | (57,138 )  | (183,709 )        | (172,438 )   |
| Change in fair value of warrant derivatives                                  | 5,765,992          | 4,586,076  | 2,770,912         | 1,499,682    |
| Change in fair value of preferred share derivatives                          | 3,963,126          | 4,749,332  | (867,741 )        | (7,665,268 ) |
| Interest expense attributable to preferred share derivatives                 | (27,818 )          | (86,325 )  | (111,719 )        | (353,500 )   |
| Discount in Series E issuance attributable to beneficial conversion features | —                  | —          | (437,500 )        | —            |
| Total Other Income / (Expense)   | 9,637,376          | 9,191,945  | 1,170,243         | (6,691,524 ) |
| INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES                              | 9,363,166          | 8,760,995  | (105,000 )        | (8,050,610 ) |



|  |             |             |             |               |
|--|-------------|-------------|-------------|---------------|
| PROVISION FOR INCOME TAXES                               | —           | —           | 4,023       | 2,500         |
| NET INCOME (LOSS) ATTRIBUTABLE TO<br>COMMON SHAREHOLDERS | \$9,363,166 | \$8,760,995 | \$(109,023) | \$(8,053,110) |
| NET (LOSS) PER SHARE                                     |             |             |             |               |
| Basic  | \$0.03      | \$0.03      | \$(0.00)    | \$(0.03)      |
| Diluted  | \$0.02      | \$0.02      | \$(0.00)    | \$(0.03)      |
| WEIGHTED AVERAGE NUMBER OF COMMON<br>SHARES OUTSTANDING  |             |             |             |               |
| Basic  | 350,220,224 | 262,067,347 | 345,384,514 | 247,443,617   |
| Diluted  | 486,207,413 | 427,037,498 | 345,384,514 | 247,443,617   |

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 Deficit | Stockholders' Deficit |
|--|--------------|-----------|----------------------------|----------------|-------------|---------------------|-----------------------|
|  | Shares       | Amount    | Additional Paid-In Capital | Shares         | Amount      |                     |                       |
| Balance at Mar 31, 2012  | 331,649,738  | \$331,650 | \$114,910,812              | 100,000        | \$(306,841) | \$(129,919,303)     | \$(14,983,682)        |
| Net Loss   |              |           |                            |                |             | (109,023 )          | (109,023 )            |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expense | 1,512,272    | 1,512     | 153,672                    |                |             |                     | 155,184               |
| Conversion of Series B, Series C and Series E Preferred Shares into Common Shares              | 13,917,061   | 13,918    | 1,881,033                  |                |             |                     | 1,894,951             |
| Non-cash compensation through the issuance of stock options                                    |              |           | 36,379                     |                |             |                     | 36,379                |
| Costs associated with raising capital  |              |           | (9,856 )                   |                |             |                     | (9,856 )              |
| Issuance of Common Shares pursuant to the exercise of Warrants                                 | 3,261,227    | 3,262     | 219,123                    |                |             |                     | 222,385               |

|  |             |           |               |         |             |                 |  |                |
|--|-------------|-----------|---------------|---------|-------------|-----------------|--|----------------|
| Proceeds received<br>in exchange for<br>beneficial<br>conversion<br>provisions<br>embedded in Series<br>E Preferred Shares |             |           |               | 437,500 |             |                 |  | 437,500        |
| Balance at<br>December 31, 2012  | 350,340,298 | \$350,342 | \$117,628,663 | 100,000 | \$(306,841) | \$(130,028,326) |  | \$(12,356,162) |

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 DECEMBER |                     |
|--|----------------------------|---------------------|
|  | 31                         |                     |
|  | 2012                       | 2011                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |                            |                     |
| Net (Loss)   | \$ (109,023                | ) \$ (8,053,110 )   |
| Adjustments to reconcile net loss to cash used in operating activities:              |                            |                     |
| Depreciation and amortization  | 330,543                    | 363,542             |
| Change in fair value of warrant derivative liability                                 | (2,770,912                 | ) (1,499,682 )      |
| Change in fair value of preferred share derivative liability                         | 867,741                    | 7,665,268           |
| Discount in Series E issuance attributable to embedded beneficial conversion feature | 437,500                    | —                   |
| Preferred share derivative interest satisfied by the issuance of common stock        | 155,184                    | 549,854             |
| Non-cash compensation satisfied by the issuance of common stock and options          | 36,379                     | 18,339              |
| Non-cash rent expense  | 7,215                      | 8,686               |
| Non-cash lease accretion   | 1,008                      | 949                 |
| Changes in Assets and Liabilities  |                            |                     |
| Accounts receivable  | (129,539                   | ) 88,356            |
| Inventories  | (679,549                   | ) 184,963           |
| Prepaid and other current assets   | 62,425                     | 88,135              |
| Accounts payable, accrued expenses and other current liabilities                     | 327,640                    | 41,355,             |
| Deferred revenues and Customer deposits  | 40,130                     | (49,399 )           |
| Derivative interest payable  | (43,466                    | ) (196,354 )        |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>   | <b>(1,466,724</b>          | <b>) (789,098 )</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |                            |                     |
| Purchases of property and equipment  | (110,787                   | ) (78,427 )         |
| Cost of leasehold improvements   | (32,801                    | ) (390,845 )        |
| Costs incurred for intellectual property assets                                      | (40,001                    | ) (32,406 )         |
| Deposits to restricted cash, net   | (62,466                    | ) (41,826 )         |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>   | <b>(246,055</b>            | <b>) (543,504 )</b> |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |                            |                     |
| Proceeds from issuance of Series E Convertible Preferred Stock                       | 437,500                    | 125,000             |
| Proceeds from Executions of Cash Warrants  | 187,500                    |                     |
| Proceeds from draws against Treppel Credit Line                                      | 500,000                    | —                   |
| Other loan payments  | (5,117                     | ) (9,565 )          |
| Costs associated with raising capital  | (9,856                     | ) (40,000 )         |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                                     | <b>1,110,027</b>           | <b>75,435</b>       |

|   |           |   |            |   |
|---|-----------|---|------------|---|
| NET CHANGE IN CASH AND CASH EQUIVALENTS           | (602,752  | ) | (1,257,167 | ) |
| CASH AND CASH EQUIVALENTS – beginning of period   | 668,407   |   | 1,825,858  |   |
| CASH AND CASH EQUIVALENTS – end of period         | \$ 65,655 |   | \$ 568,691 |   |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION |           |   |            |   |
| Cash paid for interest                            | 115,623   |   | 172,439    |   |
| Cash paid for taxes                               | 4,023     |   | 2,500      |   |

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, 2012 AND 2011**

**(UNAUDITED)**

**NOTE 1 - DEFINITIONS**

**“2012 Bond Principal Payment”** equals \$260,000

**“Cash Reserves”** are equal to the amount listed in Note 2

**“Current Balance Sheet Date”** means December 31, 2012

**“Current Bond Liability”** is equal to the amount listed in Note 2

**“Current Fiscal Year”** means the twelve months ended March 31, 2013

**“Current Quarter”** means the three months ended December 31, 2012

**“Current YTD”** means the nine months ended December 31, 2012

**“Derivative Interest Liability Common Shares”** means the following Common Shares issued in lieu of cash in payment of Derivative Interest due and owing as of the Current Balance Sheet Date:

**Common Shares Issued**

348,671

**“Epic Quarterly Payment Amount”** is equal to \$62,500

“**FDA**” means the U.S. Food and Drug Administration

“**Outstanding Bond Principal Payments**” means principal payments which were due and owing on the NJEDA Bonds on or before the Current Balance Sheet Date and not made, consisting of the following:

| Payment Date      | Amount  |
|-------------------|---------|
| September 1, 2010 | 225,000 |
| September 1, 2011 | 470,000 |
| September 1, 2012 | 730,000 |

“**Prior Year Balance Sheet Date**” means December 31, 2011

“**Prior Fiscal Year**” means the twelve months ended March 31, 2012

“**Prior Year Quarter**” means the three months ended December 31, 2011

“**Restricted Cash Interest Payments**” means the following withdrawal of funds from the debt service reserve, with such funds being used to make interest payments due to holders of the NJEDA Bonds:

| Payment Date      | Amount    |
|-------------------|-----------|
| March 1, 2009     | \$120,775 |
| September 1, 2009 | 120,775   |
| March 1, 2010     | 113,075   |
| September 1, 2010 | 113,075   |
| March 1, 2011     | 113,075   |
| September 1, 2011 | 113,075   |
| March 1, 2012     | 113,075   |
| September 1, 2012 | 113,075   |

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

**“Restricted Cash Principal Payments”** means the following withdrawal of funds from the debt service reserve, with such funds being used to make principal payments due to holders of the NJEDA Bonds:

| Payment Date      | Amount  |
|-------------------|---------|
| September 1, 2009 | 210,000 |

**“SEC”** means the Securities and Exchange Commission

**“Treppel Credit Line Balance”** equals \$500,000

**“Treppel Credit Line Interest Due”** equals \$6,932

**“Treppel Credit Line Limit”** equals \$1,000,000

**“Working Capital Deficit”** is equal to the amount listed in Note 2

#### **NOTE 2 - 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 Current Quarter and Prior Year Quarter. 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, 2012 and filed with the SEC on June 29, 2012. There have been no changes in significant accounting policies since March 31, 2012.

The Company does not anticipate being profitable for the Current Fiscal Year; therefore a current provision for income tax was not established for the Current Quarter. 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 the Current Balance Sheet Date, the Company had the following:

|   |                |
|---|----------------|
| Cash reserves ("Cash Reserves")                     | \$ 0.1 million |
| Working capital deficit ("Working Capital Deficit") | \$ 3.7 million |
| Losses from operations for the Current Quarter      | \$ 0.3 million |
| Other income for the Current Quarter                | \$ 9.6 million |
| Net income for the Current Quarter                  | \$ 9.4 million |
| NJEDA Bonds Payable ("Current Bond Liability")      | \$ 3.4 million |

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 FDA's removal of the Lodrane® extended release product line from the market. The Lodrane® extended release products, which constituted substantially all 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 NJEDA 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 then, with the Restricted Cash Interest Payments constituting such payments.

The Company has replenished all amounts withdrawn from the debt service reserve for the payment of semi-annual interest payments, as required, and in accordance with the applicable terms and conditions of such replenishments.

The Company did not have sufficient funds available to make the Restricted Cash Principal Payments and the Outstanding Principal Payments.

The debt service reserve was utilized to make the Restricted Cash Principal Payments, with the Company replenishing such amounts withdrawn from the debt service reserve, as required and in accordance with the applicable terms and conditions of such replenishments.

The Company requested that the Trustee utilize the debt service reserve to pay the principal payment due on September 1, 2010. This request was denied and accordingly the principal payment due on September 1, 2010 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011 and 2012, with such amount due including principal payments due in the prior year but not paid. There were not sufficient funds available in the debt service reserve and the payment was not made.

Please refer to the definition of Outstanding Bond Principal Payments for details on the amounts of the principal payments which were due and 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 6 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 includes the Current Bond Liability. This amount 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. Please refer to the balance sheet and note 5 to our financial statements for details on the Current Bond Liability.

As of the Current Balance Sheet Date, we had Cash Reserves.

We have successfully completed the initial, second and third closings of the Epic Strategic Alliance Agreement and the twelve quarterly payments, with each such quarterly payment being equal to the Epic Quarterly Payment Amount and have accordingly received the full investment from Epic, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement. 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.

Despite having received the full investment from Epic Investments LLC, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement, we still most likely will 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.

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. On June 20, 2012, the Company filed a letter with the SEC requesting withdrawal of the Registration Statement on Form S-1 (the “Registration Statement”) that it had filed with the SEC on March 1, 2012. The Company had filed the Registration Statement in accordance with the terms of a Socius Agreement. The withdrawal request was deemed granted as the Company did not receive timely notice from the SEC that this request would not be granted.

The Company withdrew the Registration Statement because, after discussion with the SEC’s staff, it determined that the transactions as structured in the Socius Agreement could not be implemented. Accordingly the Company will not be proceeding with the financing under the Socius Agreement. A Current Report on Form 8-K was filed with the SEC on June 21, 2012, such filing being herein incorporated by reference.

On June 12, 2012, Elite entered into a bridge loan agreement, as amended on December 5, 2012, (the “Treppel Credit Line Agreement”) with Jerry Treppel, the Company’s Chairman and CEO. Under the terms of the Treppel Credit Line Agreement, Elite has the right, in its sole discretion to a line of credit (the “Treppel Credit Line”) in the maximum principal amount of up to the Treppel Credit Line Limit, at any one time. Mr. Treppel provided the Treppel Credit Line for the purpose of supporting the acceleration of Elite’s product development activities. The outstanding amount is evidenced by a promissory note which shall mature on the earlier of (i) such date as Elite raises at least two million dollars in gross proceeds from the sale of any of its equity securities or (ii) July 31, 2013, at which time the entire unpaid principal balance, plus accrued interest thereon shall be due and payable in full. Elite may prepay any amounts

owed without penalty. Any such prepayments shall first be due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Treppel Credit Line Agreement, the Company may borrow, repay and reborrow under the Treppel Credit Line through maturity. Amounts borrowed under the Treppel Credit Line bear interest at the rate of ten percent (10%) per annum. For more detailed information, please refer to the Current Reports on Form 8-K filed with the SEC on June 13, 2012 and December 10, 2012, with such filings being herein incorporated by reference.

As of the Current Balance Sheet, the principal balance of the Treppel Credit Line was equal to the Treppel Credit Line Balance and the interest due was equal to the Treppel Credit Line Interest Due.

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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 Effectuated in 30 Days Supplement ("CBE-30") related to a change in the manufacturing and packaging site of this product.

Management has evaluated subsequent events or transactions occurring through the date the financial statements were issued (please see note 13).

### **Segment Reporting**

FASB ASC 280-10-50, "Disclosure about Segments of an Enterprise and Related Information" requires use of the "management approach" model for segment reporting. The management approach is based on the way a company's management organizes segments within the company for making operating decisions and assessing performance. Reportable segments are based on products and services, geography, legal structure, management structure, or any other manner in which management disaggregates a company. The Company operates in one segment for the nine months ended December 31, 2012.

### **NOTE 3 - 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 4 - INVENTORIES**

Inventories consist of raw materials, work in process and finished goods and are stated at the lower of cost (first-in, first-out basis) or market (net realizable value), and summarized as follows:

|                 | December 31, 2012 | March 31, 2012 |
|-----------------|-------------------|----------------|
| Raw Materials   | 547,455           | 304,882        |
| Work-in-Process | 436,976           | —              |
| Finished Goods  | —                 | —              |
| Total Inventory | 984,431           | 304,482        |

**NOTE 5 - INTANGIBLE ASSETS**

Costs to acquire intangible assets, such as asset purchases of Abbreviated New Drug Applications (“ANDAs”) 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.

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As of the Current Balance Sheet Date, the following costs were recorded as intangible assets on the Company's balance sheet:

|  | Patent<br>Application<br>Costs | ANDA<br>Acquisitions | Total<br>Intangible<br>Assets |
|--|--------------------------------|----------------------|-------------------------------|
| Intangible Assets as of March 31, 2012                       | 192,848                        | 450,000              | 642,848                       |
| Costs Capitalized During Current Fiscal Year                 |                                |                      |                               |
| Three months ended June 30, 2012                             | 15,947                         | —                    | 15,947                        |
| Three months ended September 30, 2012                        | 7,368                          | —                    | 7,368                         |
| Three months ended December 31, 2012                         | 16,686                         | —                    | 16,686                        |
| Total Costs Capitalized-nine months ended Dec 31, 2012       | 40,001                         | —                    | 40,001                        |
| Amortization of Intangible Assets During Current Fiscal Year |                                |                      |                               |
| Three months ended June 30, 2012                             | —                              | —                    | —                             |
| Three months ended September 30, 2012                        | —                              | —                    | —                             |
| Three months ended December 31, 2012                         | —                              | —                    | —                             |
| Total Amortization – nine months ended Dec 31, 2012          | —                              | —                    | —                             |
| Intangible Assets as of December 31, 2012                    | 232,849                        | 450,000              | 682,849                       |

The costs incurred in patent applications for the Current YTD and Current Quarter, were related to our abuse resistant opioid product lines. 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 6 - 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") via the issuance of the following:

| Description   | Principal<br>Amount<br>On<br>Issue Date | Interest<br>Rate |  | Maturity          |
|---------------|---|------------------|--|-------------------|
| Series A Note | 3,660,000                               | 6.50 %           |  | September 1, 2030 |
| Series B Note | 495,000                                 | 9.0 %            |  | 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 the Current Balance Sheet Date, 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 Debt Service Reserve Fund as follows:

| Description            | Amount  |
|------------------------|---------|
| Series A Note Proceeds | 366,000 |
| Series B Note Proceeds | 49,500  |
| Total                  | 415,500 |

The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets.

Bond issue costs were paid from the bond proceeds and are being amortized over the life of the bonds. These costs and amortization activity are summarized as follows:

| Description              | Balances<br>As of<br>March 31, 2012 | Amortization<br>Expense<br>Current YTD | Balances<br>As of<br>Current<br>Balance Sheet<br>Date |
|--------------------------|-------------------------------------|--|---|
| Bond Issue Costs         | 354,453                             |  | 354,453   |
| Accumulated Amortization | (93,339                             | ) (10,634                              | ) (103,974 )  |
| Unamortized Balance      | 261,113                             |  | 250,478   |

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 Restricted Cash Interest Payments were made as a result of the Company not having sufficient funds to make such payments when due.

The Restricted Cash Principal Payment was made as a result of the Company not having sufficient funds to make such payments when due.

The Company did not have sufficient funds available to make the Outstanding Principal Payments, as follows:

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, 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, was not made. Please refer to Note 1 of these notes to financial statements for a listing of the principal payment due on September 1, 2010 which is part of the Outstanding Principal Payments.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, with such amounts due inclusive of amounts due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve. The Principal payment due on September 1, 2011 was not paid. Please refer to Note 1 of these notes to financial statements for a listing of the principal payment due on September 1, 2011 which is part of the Outstanding Principal Payments.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2012, with such amounts due inclusive of amounts due on September 1, 2011 and not paid. There were not sufficient funds available in the debt service reserve. The Principal payment due on September 1, 2012 was not paid. Please refer to Note 1 of these notes to financial statements for a listing of the principal payment due on September 1, 2011 which is part of the Outstanding Principal Payments.

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 in relation to the Restricted Cash Interest Payments and the Restricted Cash Principal Payment.

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 Current Bond Liability, as a current liability.

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**NOTE 7 - 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, 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 Current Balance Sheet Date**

|  | Series B  | Series C    | Series E    | Total       |
|--|-----------|-------------|-------------|-------------|
| Preferred shares Outstanding                                       | —         | 1,375       | 2,187.5     | 3,562.5     |
| Underlying common shares into which Preferred may convert          | —         | 9,166,669   | 89,788,298  | 98,954,967  |
| Closing price on valuation date                                    | \$0.08    | \$0.08      | \$0.08      | \$0.08      |
| Preferred stock derivative liability at Current Balance Sheet Date | \$—       | \$1733,334  | \$7,183,064 | \$7,916,397 |
| Preferred stock derivative liability at March 31, 2012             | \$477,935 | \$1,599,600 | \$6,428,571 | \$8,506,106 |

**CHANGE IN VALUE OF PREFERRED STOCK DERIVATIVE LIABILITY**

|  | Three months ended Dec 31, |              | Nine months ended Dec 31, |                 |
|--|----------------------------|--------------|---------------------------|-----------------|
|  | 2012                       | 2011         | 2012                      | 2011            |
| Change in Preferred Stock Derivative Liability | \$ 3,963,126               | \$ 4,749,332 | \$ (867,741 )             | \$ (7,665,268 ) |

**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>2012 | June 30<br>2012 | Sept 30<br>2012 | Dec 31<br>2012 |
|--------------------------|------------------|-----------------|-----------------|----------------|
| Risk-Free interest rate  | 0.05% - 1.3 %    | 0.04% - 0.92 %  | 0.06% - 0.83 %  | 0.02% - 0.72 % |
| Expected volatility      | 57% - 181 %      | 67% - 182 %     | 102% - 180 %    | 100% - 168 %   |
| Expected life (in years) | 0.1 – 6.1        | 0.0 – 5.8       | 1.0 – 5.6       | 0.7 – 5.3      |
| Expected dividend yield  | —                | —               | —               | —              |

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|  |              |              |              |              |
|--|--------------|--------------|--------------|--------------|
| Number of warrants                         | 161,478,979  | 152,168,403  | 145,376,939  | 145,376,939  |
| Fair Value of Warrant Derivative Liability | \$11,987,222 | \$17,041,072 | \$14,947,419 | \$11,987,222 |

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**CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY**

|  | Three months ended Dec 31, |              | Nine months ended Dec 31, |              |
|--|----------------------------|--------------|---------------------------|--------------|
|  | 2012                       | 2011         | 2012                      | 2011         |
| Change in Warrant Derivative Liability | \$ 5,765,992               | \$ 4,586,076 | \$ 2,770,912              | \$ 1,499,682 |

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 8 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE**

Preferred share derivative interest payable as of the Current Balance Sheet Date consisted of the amount reported on the liability section of the balance sheet and titled "Preferred Share Derivative Interest Payable". This amount was paid via the issuance of the Derivative Interest Liability Common Shares in January 2013.

**NOTE 9 - 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 required significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use and in January 2013, the Company began using the facility at 135 Ludlow Avenue for commercial production and commenced shipping packaged products from the facility.

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

|                                  |          |
|----------------------------------|----------|
| 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   |

|                                     |           |
|-------------------------------------|-----------|
| Fiscal year ended March 31, 2017    | 89,112    |
| Total Minimum 5 year lease payments | \$426,306 |

\* 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.

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

**RENT EXPENSE**

|                                   | Three months ended Dec 31, |           | Nine months ended Dec 31, |           |
|-----------------------------------|----------------------------|-----------|---------------------------|-----------|
|                                   | 2012                       | 2011      | 2012                      | 2011      |
| Rent Expense                      | \$ 22,584                  | \$ 22,584 | \$ 67,753                 | \$ 45,169 |
| Change in deferred rent liability | \$ 2,403                   | \$ 2,895  | \$ 7,210                  | \$ 45,169 |

**DEFERRED RENT LIABILITY (LONG-TERM LIABILITY)**

|                                    | March 31  | June 30   | Sept 30   | Dec 31    |
|------------------------------------|-----------|-----------|-----------|-----------|
|                                    | 2012      | 2012      | 2012      | 2012      |
| Balance of Deferred Rent Liability | \$ 59,154 | \$ 61,557 | \$ 63,960 | \$ 66,364 |

**NOTE 10 - DEFERRED REVENUES**

Deferred revenues are summarized as follows:

|   |           |
|---|-----------|
| Advance payment received  | \$200,000 |
| Total revenue recognized as of March 31, 2012                             | (21,109 ) |
| Revenue recognized nine months ended December 31, 2012                    | (10,000 ) |
| Total Deferred Revenues as of Current Balance Sheet Date                  | 168,891   |
| Current Portion of Deferred Revenues as of Current Balance Sheet Date     | 13,333    |
| Non-Current Portion of Deferred Revenues as of Current Balance Sheet Date | 155,556   |

Deferred revenues represents the unamortized amount of an 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, represents the revenue that will be recognized over the 12 months immediately subsequent to Current Balance Sheet Date. The long term portion of deferred revenues, represents the revenue that will be recognized during the period that begins more than twelve months subsequent to the Current Balance Sheet Date. 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 11 - STOCKHOLDERS' EQUITY**



**Common Stock**

During the Current YTD, the Company issued shares of Common Stock, as follows:

| Description  | Shares<br>Of<br>Common Stock |
|--|------------------------------|
| Common Shares issued in lieu of cash in payment of Preferred Share Derivative Interest                         | 1,512,272                    |
| Common Shares issued pursuant to the conversion of Series B, Series C and Series E Preferred Share derivatives | 13,917,061                   |
| Common Shares issued pursuant to the exercise of warrants  | 3,261,227                    |
| Total Common Shares issued during the Current YTD  | 18,690,541                   |

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**Options**

**Options issued and outstanding as of the Current Balance Sheet Date are summarized as follows:**

|                    | Number of Options | Range of Exercise Prices |
|--------------------|-------------------|--------------------------|
| Vested Options     | 2,210,333         | \$ 0.06 to \$2.80        |
| Non-Vested Options | 1,728,667         | \$ 0.10 to \$2.25        |

Each option represents the right to purchase one share of common stock. The non-vested options are scheduled to vest in various increments during dates that are within the period beginning on January 18, 2013 and through June 19, 2015, 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 12 - 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.

The calculation of Basic EPS and Diluted EPS is summarized as follows:

|   | For the Three Months<br>Ended Dec 31, |             | For the Nine Months<br>Ended Dec 31, |                |
|---|---------------------------------------|-------------|--------------------------------------|----------------|
|   | 2012                                  | 2011        | 2012                                 | 2011           |
| Numerator   |                                       |             |                                      |                |
| Net Income (loss) attributable to common shareholders - Basic | 9,363,166                             | 8,720,994   | \$(109,023 )                         | \$(8,093,110 ) |
| Net Income attributable to common shareholders - Diluted      | 9,390,983                             | 8,807,320   | n/a                                  | n/a            |
| Denominator   |                                       |             |                                      |                |
| Weighted-average shares of common stock outstanding           | 350,220,224                           | 262,067,348 | 345,284,514                          | 247,443,617    |
|   | 135,987,189                           | 164,970,150 | n/a                                  | n/a            |

Dilutive effect of stock options, warrants and convertible securities

Net (loss) income per share

|         |        |        |        |         |   |
|---------|--------|--------|--------|---------|---|
| Basic   | \$0.03 | \$0.03 | \$0.00 | \$(0.03 | ) |
| Diluted | \$0.02 | \$0.02 |        |         |   |

**NOTE 13 - RELATED PARTY TRANSACTION - BORROWING AGAINST TREPPEL CREDIT LINE**

As of the Current Balance Sheet Date, Elite owed the Treppel Credit Line Balance and the Treppel Credit Line Interest Due in relation to the Treppel Credit Line. Both amounts were recorded as current liabilities on Elite's balance and included in the line item titled "Short term loans and current portion of long-term debt".

For further details on the Treppel Credit Line, please refer to Note 2 of these financial statements and the Current Reports on Form 8-K filed with the SEC on June 13, 2012 and December 10, 2012, with such filings being herein incorporated by reference.

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**NOTE 14 - SUBSEQUENT EVENTS**

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

The Derivative Interest Liability Common Shares were issued during January 2013 in payment of those amounts listed as a current liability as of December 31, 2012 under the line item "Preferred Share Derivative Interest Payable".

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

In January 2013, the Company received final approval from the New Jersey Economical Development Authority for the sale of New Jersey net operating losses with net tax benefits equal to \$391,105 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 for every benefit dollar. The proceeds of such sale, totaling \$359,817, were received by the Company during January 2013

**Exercise of Warrants by Epic Investments LLC**

On January 14, 2013, Epic Investments LLC exercised cash warrants to purchase 6,032,000 shares of Common Stock at a price of \$0.0625 per share, with the proceeds of such warrant exercise totaling \$377,000.

**FDA Approval of Supplemental Application for Naltrexone Hydrochloride 50mg tablets**

On January 31, 2013, the FDA approved the Company's supplemental application for the manufacturing and packaging of naltrexone hydrochloride 50mg tablets. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, 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 February 6, 2013, with such filing being herein incorporated by reference.

**Commencement of Commercial operations at the expanded facility at 135 Ludlow**

In January 2013, the Company commenced commercial operations at the expanded facility located at 135 Ludlow Avenue, and began shipping packaged product from this facility. The 15,000 square foot facility expansion includes cGMP manufacturing suites and packaging line. Packaging onsite provides a cost reduction for the Company and the use of the new manufacturing suites allows additional capacity and larger scale production resulting in greater manufacturing efficiencies.

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**ITEM 2.**

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

**THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2012**

**COMPARED TO THE**

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

**(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, 2012. 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 own, license or contract manufacture five products currently being sold commercially, as follows:

- Phentermine 37.5mg tablets (“Phentermine 37.5mg”)
- Lodrane D® Immediate Release capsules (“Lodrane D”)
- Methadone 10mg tablets (“Methadone 10mg”)
- Hydromorphone Hydrochloride 8mg tablets (“Hydromorphone 8mg”)
- Phendimetrazine tartrate 35mg tablets (“Phendimetrazine 35mg”)

We own the following products which have been approved for manufacture by the United States Food and Drug Administration (“US-FDA”), but for which commercial production has not yet begun:

- Phentermine 15mg capsules (“Phentermine 15mg”)
- Phentermine 30mg capsules (“Phentermine 30mg”)
- Naltrexone HCl (“Naltrexone Generic”)

Elite has executed a license agreement with Precision Dose, Inc. (the “Precision Dose Agreement”) and a manufacturing agreement with The PharmaNetwork LLC (the “TPN Agreement”). The PharmaNetwork LLC was recently purchased by Alkem Laboratories Ltd (“Alkem”). The PharmaNetwork now goes by the name Ascend Laboratories LLC (“Ascend”) and is a wholly owned subsidiary of Alkem.

The Precision Dose Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg, Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA. Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine Capsules were approved by the US-FDA on September 28, 2012, but not yet launched. Naltrexone Generic has not yet been approved by the US-FDA for manufacture by Elite.

The TPN Agreement, executed on June 23, 2011, and amended on September 24, 2012, provides for the manufacture and packaging by the Company of Ascend’s methadone hydrochloride, 10mg tablets (“Methadone 10mg”), with the Methadone 10mg to be marketed by Ascend. The FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and the initial shipment of Methadone 10mg occurred during January 2012.

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 abuse resistant opioid products, and once-daily opioid products.

On May 22, 2012, the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 8,182,836, entitled “Abuse-Resistant Oral Dosage Forms and Method of Use Thereof with such patent providing further protection for the Elite’s Abuse Resistant Technology.



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; (ii) manufacturing of a line of generic pharmaceutical products with approved ANDAs; (iii) development of additional generic pharmaceutical products; (iv) development of the other products in our pipeline including the products with our partners; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations; and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

Elite believes that its business strategy enables it to reduce its 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**

### Phentermine 37.5mg tablets

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.

### Lodrane D® Immediate Release capsules

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.

#### Methadone 10mg tablets

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend Laboratories, LLC. (“Ascend”) pursuant to a commercial manufacturing and supply agreement dated June 23, 2011 between Elite and Ascend (the “Methadone Manufacturing and Supply Agreement”). Under the terms of the Methadone Manufacturing and Supply Agreement, Elite performs manufacturing and packaging of Methadone 10mg for Ascend. Please refer to the Current Report on Form 8-K filed with the SEC on January 17, 2012 for more details, with such filing being herein incorporated by reference. For details on the commercial manufacturing and supply agreement dated June 23, 2011 between Elite and Ascend, please refer to Exhibit 10.71 of the Annual Report on Form 10-K filed with the SEC on June 29, 2011.

Hydromorphone 8mg tablets

On March 13, 2012, Elite commenced shipping Hydromorphone 8mg to TAGI Pharma. This triggered a milestone payment under the License, Manufacturing and Supply Agreement with Precision Dose. Hydromorphone 8mg is now a commercial product being distributed by our partner, TAGI Pharma. Please refer to the Current Report on Form 8-K filed with the SEC on March 13, 2012 for more details, with 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.

Phendimetrazine Tartrate 35 mg tablets

On November 13, 2012, the Company made the initial shipment of Phendimetrazine tartrate 35mg tablets, the generic equivalent of Bontril PDM® 35mg tablets under a previously announced manufacturing and supply agreement with Mikah Pharma (“Mikah”). Actavis Inc. (“Actavis”), recently acquired by Watson Pharmaceuticals, Inc. will distribute the product as part of a distribution agreement between Mikah and Actavis.

Bontril PDM® and its generic equivalents had total U.S. sales of approximately \$3.5 million for the twelve months ended September 2012, based on IMS Health Data. The Company will be compensated at an agreed upon price for the manufacturing and packaging of this product.

For further details, please refer to the Current Reports on Form 8-K filed with the SEC on November 13, 2012 for the initial shipment and June 7, 2011, for the manufacturing and supply agreement between the Company and Mikah, with both such filings being herein incorporated by reference.

Please also refer to Exhibit 10.70 the Annual Reports on Form 10-K filed with the SEC on June 29, 2012 and June 29, 2011 for further details on the manufacturing and supply agreement between the Company and Mikah, with both such filings being herein incorporated by reference.

**Approved Products**

Elite is the owner of the following approved Abbreviated New Drug Applications:

- Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)
- Hydromorphone HCl 8mg tablets (“Hydromorphone 8mg”)
- Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)
- Phentermine HCl 15mg capsules (“Phentermine 15mg”)
- Phentermine HCl 30mg capsules (“Phentermine 30mg”)

Phentermine HCl 37.5mg tablets

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.

Hydromorphone HCl 8mg tablets

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.

#### Naltrexone HCl 50mg tablets

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. 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. However, on January 31, 2013, the FDA approved the Company's supplemental application for the manufacturing and packaging of naltrexone hydrochloride 50mg tablets. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, 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 February 6, 2013 in relation to this approval, such filing being incorporated herein by this reference. As a result of the prior 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.

#### Phentermine 15mg and Phentermine 30mg

Elite received approval as of September 28, 2012 from the US-FDA for Phentermine 15mg and Phentermine 30mg. These products were developed by Elite. The commercial launch of Phentermine 15mg and Phentermine 30mg has been delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. Please refer to the Current Report on Form 8-K filed with the SEC on October 15, 2012, with such filing being herein incorporated by reference. We have resolved this issue for the next year. The purchase orders now in place will allow us to obtain adequate amounts of API, although at a substantially higher price than previously paid, to supply both the Phentermine tablet product and the soon to be launched Phentermine capsule products. Elite

anticipates that some of the increase in API pricing could be offset with increase manufacturing efficiencies.

### **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.

On November 13, 2012, the Company made the initial shipment of Phendimetrazine tartrate 35mg tablets, the generic equivalent of Bontril PDM® 35mg tablets under a previously announced manufacturing and supply agreement with Mikah Pharma (“Mikah”). Actavis Inc. (“Actavis”), recently acquired by Watson Pharmaceuticals, Inc. will distribute the product as part of a distribution agreement between Mikah and Actavis.

Bontril PDM® and its generic equivalents had total U.S. sales of approximately \$3.5 million for the twelve months ended September 2012, based on IMS Health Data. The Company will be compensated at an agreed upon price for the manufacturing and packaging of this product.

For further details, please refer to the Current Reports on Form 8-K filed with the SEC on November 13, 2012 for the initial shipment and June 7, 2011, for the manufacturing and supply agreement between the Company and Mikah, with both such filings being herein incorporated by reference.

Please also refer to Exhibit 10.70 the Annual Reports on Form 10-K filed with the SEC on June 29, 2012 and June 29, 2011 for further details on the manufacturing and supply agreement between the Company and Mikah, with both such filings being herein incorporated by reference



Development activities related to Isradipine have been discontinued. For further details, please refer to the section below titled “Discontinued Development – Israpidine”

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

On March 3, 2011, the 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 Company has received no further information from ECR with regards to the status of the Petition filed.

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 three months ended June 30, 2012 and 2011 were zero and \$252k, 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 unless and 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 three months ended June 30, 2012 and 2011 were zero and \$150k, 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.

Contract laboratory services for the Lodrane® Extended Products will continue, on a residual basis, 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 periods prior to the removal of the Extended Release Lodrane products from the market.

#### **Discontinued Development – Isradipine**

Isradipine was one of two products in an agreement with Mikah Pharma that was intended to be transferred to Elite for manufacture. (Phendimetrazine was the second product and its launch is described above.) Preliminary production batches of Isradipine at Elite, using the equipment provided in the agreement, was not cost effective. Mikah and Elite therefore mutually agreed in an amendment to the agreement to discontinue transfer of the Isradipine.

### **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.

### **Abuse Resistant and Sustained Release Opioids**

A once-daily oxycodone formulation was developed by Elite, using its proprietary technology. An investigational new drug application, or IND, has been filed. Elite has completed two pharmacokinetic studies in healthy subjects and has scaled up the product. We are looking for a partner for this product.

The abuse resistant opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist, in a sustained-release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, 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. 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.

Elite has developed, and retains the rights to these abuse resistant and sustained release opioid products. Elite may 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 development underlying the sustained release products was initiated 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 the sustained release opioid products. Upon licensing or commercialization of a once daily oxycodone product, 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). Although the initial term of this agreement has expired, cooperation under the Epic Strategic Alliance Agreement is ongoing. 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 1 of Part I of our Annual Report on Form 10-K for the fiscal year ended March 31, 2012, 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. See also, Note 2 to the financial statements included herein.

### **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”)
- A Private Hong Kong based company (the “Hong Kong D&L 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2011, such filings being herein incorporated by reference.

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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2011, such filings being herein incorporated by reference.

For further details on the Hong Kong D&L Agreement, please refer to the current report on Form 8-K filed with the SEC on March 22, 2012, our amended Annual Report on Form 10-K/A for the fiscal year ended March 31, 2012 (filed with the SEC on September 14, 2012), and exhibit 10.77 of our Annual Report on Form 10-K for the fiscal year ended March 31, 2012, such filings being herein incorporated by reference.

### **Novel Labs Investment**

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

### **Critical Accounting Policies and Estimates**

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

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development

contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe 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, 2012 Compared to Three Months Ended December 31, 2011

Our revenues for the three months ended December 31, 2012 were \$668k an increase of \$158k or approximately 31% over revenues for the comparable period of the prior year, and consisted of \$401k in manufacturing fees, \$111k in lab and product development fees and \$156k in royalties and license fees. Revenues for the three months ended December 31, 2011, consisted of \$171k in manufacturing fees, \$319k in lab and product development fees, and \$20k in royalties and license fees. Manufacturing fees increased by approximately 135% as a result of the current year's operations including Hydromorphone 8mg and Phendimetrazine 35mg, which were launched in March 2012 and November 2012, respectively, and also as a result of strong growth in the Phentermine and Methadone product lines. Lab and product development fees decreased by approximately 65% due to the decreased lab stability study revenues relating to the discontinuance of the Lodrane® Extended Release Products and also development fees being earned in the prior year in relation to the Hi-Tech Development Agreement and the Mikah Development Agreement. Royalties and license fees increased by approximately 677% due to the strong growth in sales from the Phentermine and Hydromorphone product lines. Please see the discussion above in "Overview; Approved Products concerning certain delays related to Phentermine due to issues with the sole supplier that have been resolved.

Research and development costs for the three months ended December 31, 2012 were \$238k, a decrease of \$148k or approximately 38% from \$386k of such costs for the comparable period of the prior year. The decrease was primarily due to the prior year including enhanced product development activities which were related to products that were subsequently approved and commercialized.

General and administrative expenses for the three months ended December 31, 2012, were \$381k, an increase of \$93k, or approximately 32% from \$288k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to increased regulatory costs, including, without limitation, increased fees paid to the US-FDA and the hiring of additional staff to support regulatory compliance activities, and increases in legal fees, insurance, employee benefits and various other overhead costs.

Depreciation and amortization for the three months ended December 31 2012 was \$40k, a decrease of \$63k, or approximately 61%, from \$103k for the comparable period of the prior year. The decrease was primarily due to manufacturing fixed assets being utilized at higher levels during the current year as a result of the current year's operations being comprised of a broader line of commercial products, as compared to operations of comparable period of the prior year which consisted of a limited commercial production due to 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, 2012 was \$15k, an increase of \$9k, or approximately 148% from \$6k for the comparable period of the prior year. The



increase is due to the issuance of employee stock options in June of 2012. For further details on such employee stock options, please see Note 11 of the financial statements filed with this Current Report on Form 10-Q.

As a result of the foregoing, our loss from operations for the three months ended December 31, 2012 was \$274k, compared to a loss from operations of \$431k for the three months ended December 31, 2011.

Other income for the three months ended December 31, 2012 were a net of \$9,637k, an increase in other income of \$445k from the net other income of \$9,192k for the comparable period of the prior year. The decrease 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, 2012 totaling \$9,729k, as compared to a net derivative income of \$9,335k for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the number of preferred shares outstanding and the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period. As of December 31, 2012, there were an aggregate of 3,562.5 shares of Preferred Series C and Preferred Series E outstanding, as compared to an aggregate of 7,025 shares of Preferred Series B, Preferred Series C and Preferred Series E outstanding as of December 31, 2011.

As a result of the foregoing, our net income for the three months ended December 31, 2012 was \$9,363k, compared to a net income of \$8,761k for the three months ended December 31, 2011.

### **Nine Months Ended December 31, 2012 Compared to the Nine Months Ended December 31, 2011**

Our revenues for the nine months ended December 31, 2012 were \$1,880k, an increase of \$107k or approximately 6% from for the comparable period of the prior year, and consisted of \$1,246k in manufacturing fees, \$195k in lab and product development fees and \$439k in royalties and license fees. Revenues for the nine months ended December 31, 2011, consisted of \$848k in manufacturing fees, \$496k in lab and product development fees, and \$430k in royalties and license fees. Manufacturing fees increased by approximately 47% as a result of the current year's operations including Hydromorphone 8mg and Phendimetrazine 35mg, which were launched in March 2012 and November 2012, respectively, and also as a result of strong growth in the Phentermine and Methadone product lines. Lab and product development fees decreased by approximately 61% due to the decreased lab stability study revenues relating to the discontinuance of the Lodrane® Extended Release Products and also development fees being earned in the prior year in relation to the Hi-Tech Development Agreement and the Mikah Development Agreement. Royalties and license fees increased by approximately 2% due to the strong growth in sales from the Phentermine and Hydromorphone product lines, offset by the prior year's results included product launch milestone revenues and the remaining royalties earned from the sale of Lodrane® Extended Release Products. Please see the discussion above in "Overview; Commercial Products and Part II; Item 1A: "Risk Factors" concerning certain delays related to Phentermine due to issues with the sole supplier.

Research and development costs for the nine months ended December 31, 2012 were \$664k, a decrease of \$367k or approximately 36% from \$1,030k of such costs for the comparable period of the prior year. The decrease was primarily due to the prior year including enhanced product development activities which were related to products that were subsequently approved and commercialized.

General and administrative expenses for the nine months ended December 31, 2012, were \$1,147k, an increase of \$57k, or approximately 5% from \$1,090k of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to increased regulatory costs, including, without limitation, increased fees paid to the US-FDA and the hiring of additional staff to support regulatory compliance activities, and increases in legal fees, insurance, employee benefits and various other overhead costs.

Depreciation and amortization for the nine months ended December 31, 2012 was \$108k, a decrease of \$228k, or approximately 68%, from \$336k for the comparable period of the prior year. The decrease was primarily due to manufacturing fixed assets being utilized at higher levels during the current year as a result of the current year's operations being comprised of a broader line of commercial products, as compared to operations of comparable period of the prior year which consisted of a limited commercial product that was undergoing an almost complete shutdown due to 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, 2012 was \$36k, an increase of \$18k, or approximately 98% from \$18k for the comparable period of the prior year. The increase is due to the issuance of employee stock options in June of 2012. For further details on such employee stock options, please see Note 11 of the financial statements filed with this Current Report on Form 10-Q.

As a result of the foregoing, our loss from operations for the nine months ended December 31, 2012 was \$1,275k, compared to a loss from operations of \$1,359k for the nine months ended December 31, 2011.

Other income for the nine months ended December 30, 2012 were a net of \$1,170k, an increase in net other expenses of \$7,862k from the net other expense of \$6,692k 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 nine months ended December 31, 2012 totaling \$1,903k, as compared to a net derivative expense of \$6,166k for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the number of preferred shares outstanding and the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period. As of December 31, 2012, there were an aggregate of 3,562.5 shares of Preferred Series C and Preferred Series E outstanding, as compared to an aggregate of 7,025 shares of Preferred Series B, Preferred Series C and Preferred Series E outstanding as of December 31, 2011.

As a result of the foregoing, our net loss for the nine months ended December 31, 2012 was \$109k, compared to a net loss of \$8,053k for the nine months ended December 31, 2011.

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

Our working capital (total current assets less total current liabilities), decreased to a deficit of \$3.7 million as of December 31, 2012 from a working capital deficit of \$3.1 million as of March 31, 2012, 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 6 to our financial statements and Item 3 of this quarterly report on Form 10-Q for further details.

Net cash used by operations was \$1.5 million for the nine months ended December 31, 2012, primarily due to our net income from continuing operations of \$1.2 million, offset by non-cash charges totaling \$0.9 million, which included, without limitation, depreciation and amortization of \$0.3 million, net income from the change in fair value of derivative liabilities of \$1.9 million, derivative interest payments satisfied through the issuance of common shares in lieu of cash of \$0.2 million, and the discount in Series E issuance attributed to an embedded beneficial conversion feature in the amount of \$0.4 million. In addition, net cash used by operations was effected by changes in the balances of assets and liabilities, including, without limitation, increases in accounts receivable and inventories of \$0.1 million and \$0.7 million, respectively (resulting in a net outflow of cash).

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Going concern considerations**

As of December 31, 2012, the Company had a working capital deficit of \$3.7 million, losses from operations totaling \$1.2 million for the nine months ended December 31, 2012, net other income totaling \$1.25 million for the nine months then ended and a net loss of \$0.1 million for the nine months ended December 31, 2012. 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, 2013.

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.

### **Treppel \$1,000,000 Bridge Revolving Credit Line.**

On June 12, 2012 (the “Effective Date”), we entered into a bridge loan agreement (the “Loan Agreement”) with Jerry Treppel, our Chairman and CEO. Under the terms of the Loan Agreement, we have the right, in our sole discretion, to a line of credit (the “Credit Line”) in the maximum principal amount of up to \$500,000 at any one time. By amendment, the maximum principal amount was increased to \$1,000,000 in December 2012. Mr. Treppel provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount will be evidenced by a promissory note which shall mature on the earlier of (i) such date as we raise at least \$2,000,000 in gross proceeds from the sale of any of our equity securities or (ii) July 31, 2013, at which time the entire unpaid principal balance plus accrued interest thereon shall be due and payable in full. We may prepay any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Loan Agreement, we may borrow, repay, and reborrow under the Credit Line through maturity. Amounts borrowed under the Credit Line will bear interest at the rate of ten percent (10%) per annum. As of December 31, 2012, the principal balance owed under the Credit Line was \$500,000 with an additional \$6,932 in accrued interest being also owed, in accordance with the terms and conditions of the Credit Line. For more detailed information, please see the Loan Agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on June 13, 2012, and the amendment thereto filed as an exhibit to our Current Report on Form 8-K filed with the SEC on December 10, 2012 which forms 8-K and exhibits are incorporated by reference herein.

As of December 31, 2012, we had cash reserves of \$0.1 million. Please note that the cash reserves as of December 31, 2012 were unusually low as a result of the timing of the collection of a large amount of receivables which were due as of the balance sheet date. These receivables were collected in early January 2013 and cash reserves as at the end of January 2013 were \$0.5 million.

We have successfully completed the initial, second and third closings of the Epic Strategic Alliance Agreement and the twelve quarterly payments, with each such quarterly payment being equal to the Epic Quarterly Payment Amount and have accordingly received the full investment from Epic, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement. 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.

Despite having received the full investment from Epic Investments LLC, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement, we still will most likely 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.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50mg were experienced as a result of the a 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. The Supplemental Application for Naltrexone 50mg was approved by the FDA on January 31, 2013.

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, 2012, we sustained a negative cash flow from operations of approximately \$1.5 million, compared with a negative cash flow from operations of approximately \$0.8 million being achieved during the comparable period in the prior year. Our working capital deficit at December 31, 2012 was approximately \$3.7 million compared with working capital deficit of approximately \$3.1 million at December 31, 2011. 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, 2012, were approximately \$0.1 million, a decrease of approximately \$0.5 million from the approximately \$0.6 million balance of cash and cash equivalents at December 31, 2011.

As of December 31, 2012, our principal source of liquidity was approximately \$0.1 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 December 31, 2012, 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 \$354,453 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$14,178 for the fiscal year March 31, 2012.

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 1st and September 1st of 2009, 2010 and 2011, as well as the interest payments due on March 1st 2012 and September 1<sup>st</sup> 2012, totaling \$920,000 for all eight payments, 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 they were 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 \$225,000 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 \$225,000 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470,000, 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 \$470,000 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2012, with such amounts due inclusive of amounts due on September 1, 2011 and not paid. There were not sufficient funds



available in the debt service reserve and accordingly, the principal payment totaling \$730,000 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, September 1, 2011 and March 1, 2012.

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 three and nine months ended December 31, 2012 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, 2012, as supplemented by the disclosure on our Quarterly Report on Form 10-Q for the Quarter ended September 30, 2012.

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

During the nine months ended December 31, 2012, we issued 15,429,333 shares of Common Stock to the holders of our Series B, Series C and Series E Preferred Stock. Of this amount, 1,512,272 shares were issued in satisfaction of our obligation to pay \$155,184 in dividends earned and/or owing during the nine months ended December 31, 2012, and 13,917,061 shares were issued pursuant to the conversion of Series B, Series C and Series E Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$1,894,951 at the time of their conversion. In addition, the Company issued a total of 261,227 shares of Common Stock during the nine months ended December 31, 2012 pursuant to the exercise of cashless warrant derivatives, valued at \$34,884 at the time of their execution and 3,000,000 shares of Common Stock during the nine months ended December 31, 2012 pursuant to the exercise of cash warrants that carried an exercise price of \$0.0625. In June 2012, the Company issued options to employees for the purchase of an aggregate of 985,000 shares of common stock at an exercise price of \$0.12 per share, including options to purchase 150,000 shares of Common Stock each issued to Chris Dick and Carter J. Ward. The options are not vested on their date of grant and vest in equal annual increments on the first, second and third anniversaries of the grant date. The options expire on the earlier of the date that is ten years after the grant date or three months after the date of termination of the employee to whom such option was issued. We relied on the exemption provided by Section 4(a)(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**

On December 31, 2012, Mr. Ram Potti resigned from our Board of Directors, citing personal reasons. A Current Report on Form 8-K was filed with the SEC on January 3, 2013, with such being herein incorporated by reference.

In January 2013, we commenced commercial operations at our expanded facility located at 135 Ludlow Avenue, and began shipping packaged product from this facility. The 15,000 square foot facility expansion includes cGMP manufacturing suites and packaging line. Packaging onsite provides us with a cost reduction and the use of the new manufacturing suites allows additional capacity and larger scale production resulting in greater manufacturing efficiencies.

**Item 6. Exhibits**

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

| <b>Exhibit Number</b> | <b>Description</b>   |
|-----------------------|--|
| 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.\*
- 4.12 Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*
- 4.13 Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*



4.14 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*

4.15 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*

4.16 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*

4.17 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.\*

4.18 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference to Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*

4.19 Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference to Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*

4.20 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*

4.21 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*

4.22 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*

4.23 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*

4.24 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*

4.25 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.

10.4 Treppel Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 13, 2012.

10.5 December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2012.

10.6 Development And License Agreement between the Company and a Hong Kong-based client dated March 16, 2012 incorporated by reference to Exhibit 10.77 to the Annual Report on Form 10-K filed with the SEC on June 29, 2012. 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.

10.7 Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012. 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.

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 June 30, 2012, 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, 2013 /s/ Jerry Treppel  
Jerry Treppel  
Chief Executive Officer  
(Principal Executive Officer)

Date: February 14, 2013 /s/ Carter J. Ward  
Carter J. Ward  
Chief Financial Officer  
(Principal Financial and Accounting Officer)