

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

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2011

or

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

For the transition period ended _____ to _____

Commission File Number: 001-15697

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

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

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

(201) 750-2646

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(Registrant's telephone number, including area code)

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

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

Yes S No £

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

Yes S No £

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

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

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

Yes £ No S

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

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

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

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

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

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

INCOME (LOSS) BEFORE PROVISION FOR
INCOME TAXES

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

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

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

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

through the
issuance of stock
options

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

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

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

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

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

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

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

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

THREE AND NINE MONTHS ENDED DECEMBER 31, 2011 AND 2010

(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION AND LIQUIDITY

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

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

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

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

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

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

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

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

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$225k and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$225k was not made.

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

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

Please refer to Note 5 to our financial statements for a more detailed discussion of the NJEDA Bonds and Notice of Default. Please also note that the working capital deficit of \$3.2 million as of December 31, 2011, includes the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million was first classified as a current liability as of March 31, 2010, due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds.

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

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

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

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

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

NOTE
2 - CASH AND CASH EQUIVALENTS

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

NOTE
3 - INVENTORIES

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

NOTE
4 - INTANGIBLE ASSETS

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

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

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

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

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

Intangible assets at
December 31, 2011
(unaudited)

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

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

NOTE
5 - NJEDA BONDS

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

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

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

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

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

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

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling \$225k and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$225k was not made.

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

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

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

The Company has received Notice of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the debt service reserve, and has requested a postponement of principal payments due on September 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.

NOTE
6 - PREFERRED STOCK DERIVATIVE LIABILITIES

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

Preferred Stock Derivative Liability as of December 31, 2011

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

Preferred stock derivative liability at March
31, 2011

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CHANGE IN VALUE OF PREFERRED STOCK DERIVATIVE LIABILITY

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

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

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

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

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

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

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

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

Warrant Derivative Liabilities

The portion of derivative liabilities related to outstanding warrants was valued using the Black-Scholes option valuation model and the following assumptions on the following dates:

FAIR VALUE OF WARRANT DERIVATIVE LIABILITY

| | March 31 2011 | June 30 2011 | Sept 30 2011 | Dec 31 2011 |
|--------------------------|------------------|-----------------|-----------------|----------------|
| Risk-Free interest rate | 0.09% - 2.9% | 0.3% - 2.5% | 0.02% - 1.3% | 0.02% - 1.09% |
| Expected volatility | 138% - 194% | 153% - 217% | 133% - 196% | 100% - 175% |
| Expected life (in years) | 0.3 - 7.0 | 0.0 - 6.8 | 0.2 - 6.5 | 0.3 - 6.3 |
| Expected dividend yield | — | — | — | — |
| Number of warrants | 155,325,048 | 154,334,659 | | |