

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

ELITE PHARMACEUTICALS INC /DE/
Form 10-Q
February 14, 2006

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

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

For the quarterly period ended _____ December 31, 2005

or

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

For the transition period ended _____ to _____

Commission File Number: 333-45241

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

22-3542636

(I.R.S. Employer
Identification No.)

165 Ludlow Avenue, Northvale, New Jersey

(Address of principal executive offices)

07647

(Zip Code)

(201) 750-2646

(Registrant's telephone number, including area code)

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

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

Yes No

APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY
PROCEEDINGS DURING THE PRECEDING FIVE YEARS:

Indicate by check mark whether the registrant has filed all documents and
reports required to be filed by Sections 12, 13 or 15 (d) of the Securities
Exchange Act of 1934 subsequent to the distribution of securities under a plan

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

confirmed by a court.

Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of the common stock, \$.01 par value, as of February 10, 2006: 19,258,141 (exclusive of 100,000 shares held in treasury).

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Consolidated Balance Sheets as of December 31, 2005 (unaudited) and March 31, 2005

Consolidated Statements of Operations for the three and nine months ended December 31, 2005 and December 31, 2004 (unaudited)

Consolidated Statement of Changes in Stockholders' Equity for the nine months ended December 31, 2005 (unaudited)

Consolidated Statements of Cash Flows for the nine months ended December 31, 2005 and December 31, 2004 (unaudited)

Notes to Consolidated Financial Statements

Item 2. Management's Discussion And Analysis of Financial Condition And Results Of Operations

Item 3. Quantitative And Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

PART II OTHER INFORMATION

Item 1A. Risk Factors

Item 2. Unregistered Sales of Equity Securities.

Item 6. Exhibits

SIGNATURES

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

ASSETS

CURRENT ASSETS:

Cash and cash equivalents
Accounts receivable, net of allowance for doubtful accounts of
\$153,250 and \$153,250, respectively
Current portion of restricted cash - capital project fund
Prepaid expenses and other current assets

Total current assets

PROPERTY AND EQUIPMENT, net of accumulated
depreciation and amortization

INTANGIBLE ASSETS - net of accumulated amortization

OTHER ASSETS:

Deferred charges
Security deposit
Restricted cash - debt service
EDA bond offering costs, net of accumulated amortization
of \$4,000 and \$73,648, respectively

Total other assets

Total assets

The accompanying notes are an integral part of the

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

consolidated financial statements.

1

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Current portion - note payable
Current portion of EDA bonds
Accounts payable and accrued expenses

Total current liabilities

LONG TERM LIABILITIES:

Note payable - net of current portion
EDA bonds - net of current portion

Total long-term liabilities

Total liabilities

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY:

Preferred Stock -- \$.01 par value;
Authorized 4,483,442 shares
None issued and outstanding
Common Stock - \$.01 par value;
Authorized - 65,000,000 shares
Issued and outstanding - 19,258,141 shares and 18,022,183
shares respectively
Additional paid-in capital

Accumulated deficit

Treasury stock, at cost (100,000 shares)

Total stockholders' equity

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

Total liabilities and stockholders' equity

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

2

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	THREE MONTHS ENDED DECEMBER 31,	
	2005	2004
	----- (Unaudited)	----- (Unaudited)
REVENUES	\$ 15,635	\$ --
	-----	-----
COST OF OPERATIONS:		
Research and development	1,124,581	726,175
General and administrative	379,893	625,323
Depreciation and amortization	96,450	45,360
	-----	-----
	1,600,924	1,396,858
	-----	-----
LOSS FROM OPERATIONS	(1,585,289)	(1,396,858)
	-----	-----
OTHER INCOME (EXPENSES):		
Interest income	22,562	13,131
Sale of New Jersey tax losses	219,121	205,792
Interest expense	(70,612)	(62,499)
Non-cash compensation through issuance of stock options and stock warrants	(287,303)	(44,982)
	-----	-----
	(116,232)	111,442
	-----	-----
LOSS BEFORE PROVISION FOR INCOME TAXES	(1,701,521)	(1,285,416)
	-----	-----
PROVISION FOR INCOME TAXES	--	--
	-----	-----
NET LOSS	(1,701,521)	(1,285,416)
	=====	=====

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

Preferred stock dividends	--	(75,076)
	=====	=====
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	\$ (1,701,521)	\$ (1,360,492)
	=====	=====
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (.09)	\$ (.11)
	=====	=====
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	18,426,960	12,258,569
	=====	=====

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

3

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

	COMMON STOCK SHARES	COMMON STOCK AMOUNT	ADDITIONAL PAID-IN CAPITAL	TREASURY STOCK
	-----	-----	-----	-----
BALANCE AT MARCH 31, 2005 (Audited)	18,022,183	\$ 180,222	\$ 47,006,379	\$ (306,84)
Nine Months ended December 31, 2005: (unaudited)				
Exercise of stock options	20,000	200	39,800	-
Exercise of stock warrants	1,215,958	12,159	1,240,836	-
Non-cash compensation through the issuance of stock options and warrants	--	--	618,580	-
Net loss for nine months ended December 31, 2005	--	--	--	-
	-----	-----	-----	-----
BALANCE AT DECEMBER 31, 2005 (Unaudited)	19,258,141	\$ 192,581	\$ 48,905,595	\$ (306,84)

=====

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

4

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

CASH FLOWS FROM OPERATING ACTIVITIES:

Net loss
Adjustments to reconcile net loss to cash used in operating activities:
 Depreciation and amortization
 Charges related to issuance of common stock
 Non-cash compensation
Changes in assets and liabilities:
 Accounts receivable
 Prepaid expenses and other current assets
 Security deposit
 Accounts payable, accrued expenses and other current liabilities

NET CASH USED IN OPERATING ACTIVITIES

CASH FLOWS FROM INVESTING ACTIVITIES:

Purchases of property and equipment
Deposits to restricted cash
Release of restricted cash

NET CASH (USED IN) PROVIDED BY INVESTING ACTIVITIES

CASH FLOWS FROM FINANCING ACTIVITIES:

Net proceeds from issuance of Series A 8% Convertible Preferred Stock and Warrants
Principal equipment note payments
Principal bank note payments
Proceeds from equipment loan
Principal repayments of NJEDA Bonds
Proceeds - NJEDA Tax Exempt Bonds
Payment - NJEDA Bond Offering Costs
Deferred lease payments
Proceeds from exercise of stock options
Proceeds from exercise of stock warrants

NET CASH PROVIDED BY FINANCING ACTIVITIES

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

NET CHANGE IN CASH AND CASH EQUIVALENTS

CASH AND CASH EQUIVALENTS - beginning of period

CASH AND CASH EQUIVALENTS - end of period

SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for interest

Cash paid for income taxes

SCHEDULE OF NON-CASH FINANCING ACTIVITIES:

Preferred Stock dividends of \$75,076 paid by issuance of 26,961
shares of Common Stock

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

5

12

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION

The information in this Form 10-Q Report includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the "Company") including its wholly-owned subsidiaries, Elite Laboratories, Inc. ("Elite Labs") and Elite Research, Inc. ("ERI"), for the three and nine months ended December 31, 2005 and December 31, 2004. As of December 31, 2005, the financial statements of all entities are consolidated and all significant intercompany accounts are eliminated upon consolidation. The accompanying unaudited consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation of the 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.

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

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted for interim financial statement presentation and 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, 2005. There have been no changes in significant accounting policies since March 31, 2005.

The Company does not anticipate being profitable for fiscal year 2006; therefore a current provision for income tax was not established for the three or nine months ended December 31, 2005. Only the minimum corporation tax liability required for state purposes is reflected.

NOTE 2 - NJEDA REFINANCING

On August 31, 2005, the Company successfully completed a refinancing through the issuance of the tax-exempt bonds (the "Bonds") by the New Jersey Economic Development Authority (the "Authority"). The refinancing involved the borrowing of \$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 or will be used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other former equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products.

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 3 - STOCKHOLDERS' EQUITY

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

WARRANTS AND OPTIONS

On November 8, 2005 the Company granted pursuant to a six month service agreement, to an investor relations firm non-qualified options to purchase 75,000 shares of the Company's Common Stock with an exercise price equal to \$2.26 per share, the fair market value of a share of Common Stock at the date of the grant, vesting pro-rata daily over a six month period. If the agreement should be extended beyond six months, the Company is to grant another 75,000 non-qualified options with an exercise price equal to the then fair market value of a share of Common Stock, which would vest over the service period.

The per share weighted-average fair value of the above mentioned options was \$1.70 using the Black-Scholes options pricing model.

Pursuant to the terms of an Exchange Offer, the Company sold on or before the expiration date of December 31, 2005, an aggregate of 735,674 shares of common stock upon the exercise for cash of Short Term Warrants for aggregate gross proceeds of \$1,172,912 and issued five year Replacement Warrants to purchase at a price of \$3.00 per share an aggregate 220,705 shares of the Company's Common Stock. The Placement Agent received cash commissions aggregating \$76,418 and five-year placement warrants to purchase an aggregate of 25,473 shares of common stock at a price of \$3.00 per share. The remaining unexercised Short Term Warrants, issued as part of the Private Placement in October 2004, expired on December 31, 2005.

The per share weighted average of the above mentioned warrants was \$1.48 using the Black-Scholes options pricing model with the following weighted average assumptions: no dividend yield; expected volatility of 97.84%; risk free interest rate of 4.18% and expected lives of 5 years.

The value of \$364,343 on above warrants has no effect on Retained Earnings or Additional Paid in Capital because it is reflected as a cost associated with raising capital.

The Company's Series B and Series C Stock Purchase Warrants to purchase 2,402,181 shares of Common Stock expired November 30, 2005.

The following grants were made under the Company's 2004 Stock Option Plan:

On July 14, 2005 ten (10) year options to purchase at an exercise price of \$2.80 per share (i) to employees an aggregate of 152,200 shares of Common Stock with vesting ranging from immediate to a period of five years from date of grant; and (ii) to the Chief Financial Officer 20,000 shares of Common Stock vesting over a three-year period.

On August 24, 2005 to employees ten (10) year options to purchase in the aggregate 2,000 shares at an exercise price of \$2.81 vesting over a three year period.

The stock options to purchase an aggregate of 174,200 shares of Common Stock at prices ranging from \$2.80 to \$2.81 vest over periods from immediate to five years. The per share weighted-average value of the options ranged

from \$2.52 to \$2.53 using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 97.84%, risk free interest of 4.18% and expected lives of ten years.

7

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 3 - STOCKHOLDERS' EQUITY (Continued)

WARRANTS AND OPTIONS (continued)

On August 30, 2005 to the Directors, options to purchase an aggregate of 120,000 shares at an exercise price of \$2.75 per share vesting over a three-year period. The per share weighted-average fair value of the 120,000 options amounted to \$2.48 using the Black-Scholes options pricing model with the following weighted average assumptions: no dividend yield; expected volatility of 97.84%; risk free interest rate of 4.18%; and expected lives of ten years.

On September 2, 2005, the Company granted to the Chief Executive Officer ten (10) year options to purchase 600,000 shares of Common Stock at a price of \$2.69 per share with 100,000 options to vest on September 2, 2006, 100,000 options to vest on September 2, 2007 and the remaining 400,000 options to vest subject tot the following contingencies:

- (a) 50,000 options upon the closing of each product license or product sales transaction in which the Company receives an aggregate of at least \$5,000,000 in net cash;
- (b) 10,000 options upon filing with FDA of either an abbreviated new drug application (an "ANDA") or new drug application (an "NDA"); and
- (c) 40,000 options upon approval by the FDA of any ANDA or NDA for a product not previously approved by the FDA.

On September 2, 2005, the Chief Executive Officer waived his rights to 75,000 of 300,000 options granted to him on July 23, 2003. The Company determined that the remaining 225,000 options are fully vested.

The Company, in May 2005, revoked 180,000 of outstanding unexercised options granted prior to the adoption of the 2004 Stock Option Plan originally earmarked to members of the abandoned Scientific Advisory Board.

The Company took a charge of \$618,580 for the nine months ended

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

December 31, 2005 (\$287,303 for the three months ended December 31, 2005), which represents the fair value of the vested options, utilizing the Black-Scholes options pricing model on the grant date.

8

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
 THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
 (UNAUDITED)

NOTE 3 - STOCKHOLDERS' EQUITY (Continued)

WARRANTS AND OPTIONS (continued)

The following table illustrates the effect on net loss and loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all outstanding and unvested awards in each period presented:

	THREE MONTHS ENDED DECEMBER 31,		NINE M D
	2005	2004	2005
Net loss as reported	\$ (1,701,521)	\$ (1,285,416)	\$ (4,648,618)
Add: Stock-based compensation expense included in reported net loss, net of related tax effects	287,303	44,982	618,618
Deduct: Total stock-based compensation expense determined under fair value method for all awards net of related tax effects	(296,639)	(58,739)	(646,618)
Pro-forma net loss	\$ (1,710,857)	\$ (1,299,173)	\$ (4,676,618)
Loss per share as reported	(.09)	(.10)	(.10)
Pro-forma loss per share	(.09)	(.10)	(.10)

At December 31, 2005, Elite had outstanding 2,896,250 options with exercise prices ranging from \$1.50 to \$2.81 and 3,424,797 warrants with exercise prices ranging from \$1.50 to \$4.20; each option and warrant representing the right to purchase one share of Common Stock.

9

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 4 - COMMITMENTS AND CONTINGENCIES

COLLABORATIVE AGREEMENTS

On June 21, 2005, the Company and IntelliPharmaCeutics Corp. ("IPC"), entered into an agreement for the development and commercialization of a controlled released generic drug for certain gastric diseases by the parties. The Company is to share in the profits, if any, from the sales of the drug. This agreement was amended on December 12, 2005, whereby IPC and a Canadian company with marketing and distribution capabilities in Canada, have agreed to develop and commercialize the product for Canada. Elite and IPC will share their proceeds of commercialization in Canada on same terms as in the June 21, 2005 Agreement.

On June 22, 2005, the Company and Pliva, Inc. ("Pliva") entered into a Product Development and License Agreement, providing for the development and license of a controlled released generic anti-infective drug formulated by the Company. The Company is to manufacture and Pliva is to market and sell the product. The development costs are to be paid by Pliva and the Company and the profits are to be shared equally. Pliva is to make milestone payments to the Company.

On March 30, 2005, the Company entered into a product, development, manufacturing and distribution agreement with Harris Pharmaceutical, Inc. ("Harris") and Tish Technologies LLC ("Tish") with respect to a controlled release generic anti-infective drug. The product is a generic equivalent to a branded drug. The agreement provides for (i) the drug development by Elite with costs of development to be shared by Elite and Harris, (ii) the manufacture of the product by Elite and its sale to Harris for distribution, and (iii) Tish to be responsible for any requisite submissions to the FDA relating to the product. Elite is to share in the profits, if any, generated from the sale of the product.

The aforementioned agreements are in their infancy stages.

CONSULTING AGREEMENTS

The Company entered into one year consulting agreements with each of Saggi Capital Corp. and Bridge Ventures Inc. on November 4, 2003 which were extended through November 4, 2005. Each of the consultant's services included advice with respect to overall strategic planning, financing opportunities, acquisition policy, commercial and investment banking relationships and stockholder matters. The Company paid each consultant a fee of \$75,000 per annum in monthly installments of \$6,250 and issued to each consultant a five (5) year warrant to purchase 100,000 shares of the Company's Common Stock at a price of \$2.00 per

share.

On November 8, 2005, the Company entered into an agreement with an investor relations firm to provide investor relation services including, but not limited to, overall management of the Company's corporate communications program, securing group appointments, assistance with mass targeted mailings, compiling promotional materials, editing news releases and other corporate functions. The consultant is to receive \$10,000 a month beginning November 1, 2005 and was granted non-qualified options to purchase 75,000 shares of the Company's Common Stock, vesting pro-rata over a six month period at a price of \$2.26 per share, the fair market value of a share of Common Stock on the date of the grant. The per share weighted average fair value of the above mentioned options was \$1.70 using the Black-Scholes option pricing model

10

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 4 - COMMITMENTS AND CONTINGENCIES (Continued)

CONSULTING AGREEMENTS (Continued)

For the three and nine months ended December 31, 2005, consulting expenses under these agreements amounted to an aggregate of \$25,000 and \$85,000, respectively. For the three and nine months ended December 31, 2004, consulting expenses under these agreements amounted to an aggregate of \$30,000 and \$120,000, respectively.

EMPLOYMENT AGREEMENT

On September 2, 2005, the Company entered into an amended and restated Employment Agreement with Bernard J. Berk, providing for Mr. Berk to continue to serve as the Company's Chief Executive Officer through August 31, 2009. The Employment Agreement also provides for an annual bonus as determined by the Compensation Committee of the Company's Board of Directors.

Pursuant to the agreement:

- Mr. Berk waived his rights to 75,000 of 300,000 options granted to him on July 23, 2003. The Company determined that the remaining 225,000 options are fully vested.
- Mr. Berk's salary was increased to \$330,140. Such increase became effective May 1, 2005 and will accrue but not be payable until November 1, 2005.
- Mr. Berk was granted under the Company's 2004 Stock Option Plan, ten-year options to purchase 600,000 shares of Common

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

Stock at \$2.69, the fair market value of Common Stock as of the time of grant. See Note 3 as to the vesting of these options.

- Mr. Berk will be entitled to receive severance in accordance with the employment agreement if he is terminated without cause or because of his death or permanent disability or if he terminates his employment for good reason or as a result of a "change of control" (as defined in the employment agreement). The severance will be payable in accordance with the terms of his employment agreement.

LEASE

On July 15, 2005, the Company entered into a lease for two years commencing on July 1, 2005 for part of a one-story warehouse for the storage of finished and raw material of pharmaceutical products and equipment. The lease has a renewal option for a five-year period.

Future minimum lease payments for the periods ending December 31, are:

2006	\$27,923
2007	\$20,942

11

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
THREE AND NINE MONTHS ENDED DECEMBER 31, 2005 AND 2004
(UNAUDITED)

NOTE 5 - SUBSEQUENT EVENTS

On January 4, 2006, the Company received a letter from the American Stock Exchange ("AMEX") notifying the Company that based on the Company's unaudited financial statements as of September 30, 2005, the Company was not in compliance with the continued listing standards set forth in the AMEX Company Guide in that under one standard its shareholders' equity was less than \$4,000,000, it had losses from continuing operations and/or net losses in three of its four most recent fiscal years, and under another standard its shareholders' equity was less than \$6,000,000 and it had losses from continuing operations and/or net losses in its five most recent fiscal years.

The Company submitted at AMEX's request, a plan advising of action it plans to take to bring the Company in compliance with the above continued listing standards within a maximum of 18 months from January 4, 2006. If the plan is not accepted, the Company may be subject to delisting proceedings. Additionally, if the plan is accepted but the Company is not in compliance with the continued listing standards or does not make progress consistent with such plan during the plan period, AMEX may initiate delisting proceedings.

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

On January 10, 2006, the Company entered into a Product Development and Commercialization Agreement with Orit Laboratories LLC ("ORIT") providing that the Company and Orit will co-develop and commercialize an extended release drug product for treatment of anxiety, and upon completion of development, the possibility of licensing the product for manufacture and sale. The parties intend to develop all dose strengths of the product. The Company is to share in the profits, if any from the sales of the drug. The term of the agreement is for the longer of (i) 15 years from the date the product is first commercially sold to a third party, or (ii) the life of the applicable patent(s), if any. The agreement is automatically renewable for 3-year periods unless terminated by either party by providing the other party with twelve (12) months written notice prior to any renewal period.

In January 2006, the Food and Drug Administration accepted the Company's investigational - new drug application for OxyQD(TM), its once-a-day oxycodone painkiller. Under the new drug application, the Company will begin its development program with an early stage study to evaluate OxyQD(TM)'s sustained release formation. Currently there is no once-daily oxycodone available, however the U.S. market for sustained release, twice-daily was about \$2 billion as of September, 2005.

12

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements, the related Notes to Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2005 (the "10-K") and the Unaudited Consolidated Financial Statements and related Notes to Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q.

The Company has included in this Quarterly Report certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 concerning the Company's business, operations and financial condition. "Forward-looking statements" consist of all non-historical information, and the analysis of historical information, including the references in this Quarterly Report to future revenue growth, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Company's plans for future periods. In addition, the words "could", "expects", "anticipates", "objective", "plan", "may affect", "may depend", "believes", "estimates", "projects" and similar words and phrases are also intended to identify such forward-looking statements.

Actual results could differ materially from those projected in the Company's forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, unanticipated technological

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

difficulties, the volatile and competitive environment for drug delivery products, changes in domestic and foreign economic, market and regulatory conditions, the results of development agreements with pharmaceutical companies, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors" in other filings by the Company with the SEC including its Annual Report on Form 10-K. Such factors may also cause substantial volatility in the market price of the Company's Common Stock. All such forward-looking statements are current only as of the date on which such statements were made. The Company does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

OVERVIEW

The Company is a specialty pharmaceutical company principally engaged in the development and manufacture of oral controlled-release products. The Company develops controlled release products using proprietary technology and licenses these products. The Company's strategy includes developing generic versions of controlled release drug products with high barriers to entry and assisting partner companies in the life cycle management of products to improve off-patent drug products. The Company's technology is applicable to develop delayed, sustained or targeted release pellets, capsules, tablets, granules and powders. The Company has one product currently being sold commercially and a pipeline of eight drug products under development in the therapeutic areas that include cardiovascular, pain management, allergy and infection. The addressable market for the Company's pipeline of products exceeds \$4.25 billion. The Company's current facility in Northvale, New Jersey also is a GMP and DEA registered facility for research, development, and manufacturing.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion addresses the Company's 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 long-lived assets, intangible assets, income taxes, equity-based 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.

13

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

CRITICAL ACCOUNTING POLICIES AND ESTIMATES (Continued)

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the

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

preparation of its consolidated financial statements.

The Company's most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. Revenues from these contracts are recognized when management determines the Company has completed its obligation under each phase. The Company also assesses a need for an allowance to reduce its deferred tax assets to the amount that it believes are more likely than not to be realized. Management estimates its net operating losses will probably not be utilized in the near future, and has not recognized a tax benefit from this deferred tax asset. If management anticipated being profitable, a deferred tax benefit would be recognized and such estimate would reduce net loss and net loss per share accordingly. The Company assesses the recoverability of long-lived assets and intangible assets whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Management estimates the Company's patents and property and equipment are not impaired. If these assets were considered impaired, the Company would recognize an impairment loss which would increase the Company's net loss and net loss per share accordingly. It should be noted that actual results may differ from these estimates under different assumptions or conditions.

During the fiscal year ended March 31, 2003, the Company elected to prospectively recognize the fair value of stock options granted to employees and members of the Board of Directors, effective as of the beginning of the fiscal year. The prospective method allowed by the Financial Accounting Standards Board affects the Company's results of operations for the three and nine month periods ended December 31, 2005 and 2004 as options were granted or repriced during these periods which either vested immediately or vest over three to five years. The Company does not know the future effect of options and warrants which may be granted to employees and members of the Board of Directors. The Financial Accounting Standards Board provided three transition alternatives for recognizing stock-based compensation cost using the fair value method. If management did not elect the prospective method during the three and nine-month periods ended December 31, 2005 and 2004, net loss and net loss per share would have been reduced. However, the two other methods would have required either greater compensation cost to be recognized as an expense or retroactive restatement of previously reported net loss.

RESULTS OF CONSOLIDATED OPERATIONS

THREE MONTHS ENDED DECEMBER 31, 2005 COMPARED TO THREE MONTHS ENDED DECEMBER 31, 2004

Revenues consisted of royalties of \$15,635, for the three months ended December 31, 2005. There were no reported revenues for the three months ended December 31, 2004.

General and administrative expenses for the three months ended December 31, 2005 were \$379,893, a decrease of \$245,430, or approximately 39.2%, from \$625,323 for the comparable period of the prior year. The decrease was substantially due to reductions in bad debt expense of \$153,250 and consulting and legal fees approximating \$90,000, partially offset by an increase of allocated salaries of \$10,000.

Research and development costs for the three months ended December 31, 2005 were \$1,124,581, an increase of \$398,406, or approximately 54.9%, from \$726,175 for the comparable period of the prior year, primarily the result of increases in wages, raw materials, laboratory and manufacturing supplies. The costs associated with the manufacturing of batches of Lodrane 24(R) and the work completed on newly signed development agreements have contributed to this increase.

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO
THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

RESULTS OF CONSOLIDATED OPERATIONS (Continued)

THREE MONTHS ENDED DECEMBER 31, 2005 COMPARED TO THREE MONTHS
ENDED DECEMBER 31, 2004 (Continued)

We are unable to provide a break-down of the specific costs associated with the research and development of each product on which we devoted resources because a significant portion of the costs are generally associated with salaries, laboratory supplies, laboratory and manufacturing expenses, utilities and similar expenses. We have not historically allocated these expenses to any particular product. In addition, we cannot estimate the additional costs and expenses that may be incurred in order to potentially complete the development of any product, nor can we estimate the amount of time that might be involved in such development because of the uncertainties associated with the development of controlled release drug delivery products as described in this report.

Depreciation and amortization for the three months ended December 31, 2005 increased by \$51,090 to \$96,450 from \$45,360 for the year earlier comparable period due to the full write-off of financing costs of \$124,212 associated with the redemption of the tax exempt Bonds (the "Bonds") originally issued by the Authority on September 2, 1999, offset by the reduction in amortization and depreciation of certain assets which had been fully depreciated and amortized.

Other expenses, net for the three months ended December 31, 2005 were \$116,232, an increase of \$227,674, or approximately 20.5%, from the comparable period of the prior year. The increase was primarily due to an increase of \$242,321 in charges related to issuance of stock options. Additional interest income, due to higher compensating balances as a result of the private placement and EDA refinancing, was somewhat offset by increased interest expense resulting from the equipment financing.

As a result of the foregoing, the Company's net loss for the three months ended December 31, 2005 increased 32.4% to \$1,701,521 from the net loss of \$1,285,416 for the comparable period of the prior year.

NINE MONTHS ENDED DECEMBER 31, 2005 COMPARED TO NINE MONTHS ENDED
DECEMBER 31, 2004

The Company's revenues for the nine months ended December 31, 2005 were \$402,578, consisting of manufacturing fees of \$369,173 and royalties of \$33,405. Revenues for the nine months ended December 31, 2004 were \$151,450, of which \$150,000 was a non-refundable payment received from Purdue Pharma L.P. granting it the right to evaluate certain abuse resistance drug formulation technology of the Company.

General and administrative expenses for the nine months ended December 31, 2005 were \$1,241,108, a decrease of \$433,933 or 25.9% as compared with

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

\$1,675,041 for the same period of the prior year, substantially due to reductions in amounts paid and accrued in settlements of litigation, bad debt write-offs and legal fees partially offset by modest increases in salaries and accounting fees.

Research and development costs for the nine months ended December 31, 2005 were \$2,862,908, an increase of \$925,114, or 47.7% as compared to \$1,937,794 for the same period of the prior year, primarily the result of increased wages, laboratory and manufacturing supplies and raw materials, largely due to the manufacture of commercial batches of Lodrane 24(R).

Other expenses, net for the nine months ended December 31, 2005 were \$540,549, a decrease of \$375,813, or 41.0% as compared to \$916,362 for the same period of the prior year, due primarily to a reduction during the current year of \$344,720 in non-cash compensation through issuance of stock options and warrants, and a charge of \$397,732 during the nine months ended December 31, 2004 related to repricing of stock options. Additional interest income was due to higher compensating balances as a result of a private placement and EDA refinancing, somewhat offset by an increase in interest expense resulting from the equipment financing.

15

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

RESULTS OF CONSOLIDATED OPERATIONS (Continued)

NINE MONTHS ENDED DECEMBER 31, 2005 COMPARED TO NINE MONTHS ENDED DECEMBER 31, 2004 (Continued)

The Company's net loss for the nine months ended December 31, 2005 was \$4,648,549 compared to \$4,649,827 for the comparable period of the prior year. Increases in revenues and decreases in general, administrative and other expenses net for the nine months ended December 31, 2005 were offset by increases in research and development.

MATERIAL CHANGES IN FINANCIAL CONDITION

The Company's working capital (total current assets less total current liabilities), decreased to \$1,968,499 December 31, 2005 from \$3,328,583 as of March 31, 2005, primarily due to the use of cash in funding net loss of \$4,107,000 from operations.

The Company experienced negative cash flow from operations of \$3,246,283 for the nine months ended December 31, 2005, primarily due to the Company's net loss from operations due to an increase in research and development activities as to the drug products in its pipeline

On November 15, 2004, Elite's partner, ECR, launched Lodrane 24(R), once a day allergy product, utilizing Elite's extended release technology to provide for once daily dosing. Under its agreement with ECR, Elite is currently manufacturing commercial batches of Lodrane 24(R) in exchange for manufacturing margin and royalties on product revenues. Royalty income earned for the nine months ended December 31, 2005 was \$33,405. The Company expects future cash flows from royalties to provide additional cash to help fund its operations.

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

On March 30, 2005, the Company entered into a product, development, manufacturing and distribution agreement with Harris Pharmaceutical, Inc. ("Harris") and Tish Technologies LLC ("Tish") with respect to a controlled release generic anti-infective drug. The product is a generic equivalent to a branded drug which the Company estimates has addressable market revenues of approximately \$80 million per year. The agreement provides for (1) the development of the drug by Elite with costs of development to be shared by Elite and Harris, (2) the manufacture by Elite and its sale to Harris for distribution and (3) Tish to be responsible for any requisite submissions to the FDA relating to the product. Elite is to share in the profits generated from the sale of the product.

On June 21, 2005, the Company and IntelliPharmaCeutics Corp. ("IPC"), entered into an agreement for the development and commercialization of a controlled released generic drug for certain anti-infective diseases by the parties. The Company estimates that the product had an addressable market in the U.S. of approximately \$4 billion in 2004. The Company is to share in the profits, if any, from the sales of the drug. On December 12, 2005, the agreement was amended with respect to the development and commercialization of the controlled release drug product in Canada. Since IPC intended to enter into an agreement with a Canadian company with respect to the development, distribution and sale of the drug product in Canada, the parties agreed to suspend their obligations under the agreement with respect to the development and commercialization of the controlled release drug product in Canada. IPC agreed to pay the Company a certain percentage of any payments received by IPC with respect to the commercialization of the controlled release drug product by such Canadian company.

On June 22, 2005, the Company and Pliva, Inc. ("Pliva") entered into a Product Development and License Agreement providing for the development and license of a controlled released generic anti-infective drug formulated by the Company. The Company is to manufacture and Pliva will market and sell the product. Under the agreement, the partner is to make milestone payments to the Company. The development costs are to be paid both by Pliva and the Company, they have agreed to share the profits equally.

No assurance can be given that any of the above products will be successfully developed or that individually or in the aggregate they will generate any material revenues for the Company.

16

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

LIQUIDITY AND CAPITAL RESOURCES

For the nine months ended December 31, 2005, the Company experienced negative cash flow and financed its operations primarily through utilization of its existing cash. As of December 31, 2005, the Company had approximately \$1.6 million of cash and cash equivalents, a decrease of approximately \$3.0 million from the \$4.6 million at December 31, 2004 and had working capital of approximately \$2.0 million. At December 31, 2004, the Company had recently consummated its private placement of Series A Preferred Stock, raising net cash of \$5,866,000.

Net cash used in operating activities was \$3,246,283 during the nine

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

months ended December 31, 2005, compared to \$3,610,066 for the nine months ended December 31, 2004. Net cash used in operating activities during the nine months ended December 31, 2005 included the Company's net loss of \$4,648,549 and increases in prepaid expenses and other current assets, offset in part by non-cash charges of \$618,580 in stock option charges and \$405,562 in depreciation and amortization expense. Net cash used in operating activities during the nine months ended December 31, 2004 included the Company's net loss of \$4,649,827 offset in part by non-cash charges of \$964,300 in stock option and warrant charges and \$271,080 in depreciation and amortization expense.

Investing activities used net cash of \$1,482,011 during the nine months ended December 31, 2005, which resulted primarily from an increase in restricted cash requirements as a result of the EDA refinancing.

During the nine months ended December 31, 2005, financing activities provided net cash of \$2,474,482 derived from net proceeds of \$1,292,995 from the exercise of stock options and warrants and \$1,455,548 from the refinancing of Bonds, offset by \$274,061 used to repay indebtedness. During the nine months ended December 31, 2004, financing activities provided net cash of \$5,866,000 derived from private placement of Series A Preferred Stock. For the nine months ended December 31, 2004, \$439,989 was used to repay indebtedness.

The Company's capital expenditures were \$205,625 in the nine months ended December 31, 2005 as compared to \$427,499 in the nine months ended December 31, 2004, the latter financed through an equipment loan.

As of December 31, 2005 the Company had cash and cash equivalents of approximately \$1.6 million. The Company anticipates that such position is adequate to finance its operations through June 30, 2006 but thereafter additional financing may be required, particularly in view of the Company's expenditures required for the further development and commercialization of its products. The Company has no current arrangements with respect to additional financings. The Company intends to seek additional funds through the sale of additional debt or equity, however no assurance can be given that the Company will be able to obtain the required additional financing or if obtained it will be on favorable terms. The Company's inability to obtain additional financing when needed would impair its ability to meet its business objectives. Other possible sources for such additional financings are the cash exercises of the Long Term Warrants issued in the October 2004 private placement, the Replacement Warrants issued in the December 2005 private placement and other warrants and options that are currently outstanding.

The Company had outstanding, as of December 31, 2005, bonds in the aggregate amount of \$4,155,000, consisting of \$3,660,000 of 6.5% tax exempt Bonds with an outside maturing of September 1, 2030 and \$495,000 of 9% Bonds with an outside maturity of September 1, 2012. The bonds are secured by a first lien on the Company's facility in Northvale, New Jersey. Pursuant to the terms of the bonds, several restricted cash accounts have been established for the payment of bond principal and interest. Bond proceeds were utilized for the redemption of previously issued tax exempt bonds issued by the Authority in September 1999 and to refinance equipment financing, as well as provide approximately \$1,000,000 of capital for the purchase of additional equipment for the manufacture and development at the Company's facility of pharmaceutical products and the maintenance of a \$415,500 debt service reserve. All of the restricted cash, other than the debt service reserve, is expected to be expended within twelve months ended December 31, 2006 and is therefore categorized as a current asset on the Company's consolidated balance sheet as of December 31, 2005. Pursuant to the terms of the related bond indenture agreement, the Company is required to observe certain covenants, including covenants relating to the incurrence of additional indebtedness, the granting of liens

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

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

THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2005 COMPARED TO THE THREE AND NINE MONTH PERIODS ENDED DECEMBER 31, 2004 (UNAUDITED)

LIQUIDITY AND CAPITAL RESOURCES (Continued)

and the maintenance of certain financial covenants. As of December 31, 2005, the Company was in compliance with the bond covenants.

On July 8, 2004, Elite Labs entered into a loan and financing agreement to finance the purchase of certain machinery and equipment. Elite Labs borrowed \$400,000 payable in 36 monthly installments of \$13,671 each, including principal and interest at 14% per annum. The first four and the last three months of scheduled payments are held by the lender to be applied to the principal balance when due. The loan is secured by two pieces of equipment and the guaranty of the Company. In addition, the Company issued to designees of the lender 50,000 warrants, which vested immediately, to purchase 50,000 shares of the Company's Common Stock at \$4.20 per share. The cost of \$41,252 for these warrants was charged in the nine months ended December 31, 2004. Proceeds from the refinancing of the Company's EDA Bonds were used to pay-off this loan.

The Company from time to time will consider potential strategic transactions including acquisitions, strategic alliances, joint ventures and licensing arrangements with other pharmaceutical companies. The Company retained an investment banking firm to assist with its efforts. There can be no assurance that any such transaction will be available or consummated.

As of December 31, 2005, the Company's principal source of liquidity was approximately \$1,648,191 of cash and cash equivalents. The Company also may receive funds through the exercise of outstanding stock options and warrants in addition to funds that may be generated from the potential sale of New Jersey tax losses. There can be no assurance that proceeds from the sale of tax losses and from the exercise, if any, of outstanding warrants or options will be material.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company had no investments in marketable securities as of December 31, 2005 or assets and liabilities which are denominated in a currency other than U.S. dollars or involve commodity price risks.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this report, based on an evaluation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934), the Chief Executive and Chief Financial Officer of the Company concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in its Exchange Act reports is recorded, processed, summarized and reported within the applicable time periods specified by the SEC's rules and forms.

There was no change in the Company's internal controls over financial reporting that occurred during the fiscal quarter ended December 31, 2005 that materially affected or is reasonably likely to materially affect the Company's internal controls over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the Risk Factors set forth in the Company's Annual Report on Form 10-K for the year ended March 31, 2005, stockholder and potential investors should consider the following in evaluating an investment in the Company and in analyzing the Company's forward looking statements:

THE FAILURE TO MAINTAIN THE AMERICAN STOCK EXCHANGE LISTING OF THE COMMON STOCK WOULD HAVE A MATERIAL ADVERSE EFFECT ON THE MARKET FOR THE COMMON STOCK AND ITS MARKET PRICE.

On January 4, 2006, the Company received a letter from the American Stock Exchange ("AMEX") notifying it that based on the Company's unaudited financial statements as of September 30, 2005, the Company is not in compliance with the continued listing standards set forth in the AMEX Company Guide in that under one listing standard its shareholders' equity is less than \$4,000,000 and it had losses from continuing operations and/or net losses in three of its four most recent fiscal years and under another listing standard its shareholders' equity is less than \$6,000,000 and it had losses from continuing operations and/or net losses in its five most recent fiscal years. The Company, at the request of AMEX, submitted a plan on February 3, 2006 advising AMEX of action it has taken, and will take, to bring it in compliance with the continued listing standards within a maximum of 18 months from January 4, 2006. However, if AMEX does not accept the plan, the Company may be subject to delisting proceedings. Additionally, if a plan is accepted but the Company is not in compliance with the continued listing standards or does not make progress consistent with such plan during the plan period, AMEX may then initiate delisting proceedings. The failure to maintain listing of the Common Stock on AMEX will have an adverse effect on the market and the market price for the Common Stock.

IF THE COMPANY IS UNABLE TO OBTAIN ADDITIONAL FINANCING NEEDED FOR THE EXPENDITURES FOR THE DEVELOPMENT AND COMMERCIALIZATION OF THE COMPANY'S DRUG PRODUCTS, IT WOULD IMPAIR THE COMPANY'S ABILITY TO MEET ITS BUSINESS OBJECTIVES.

As of December 31, 2005, the Company had cash and cash equivalents aggregate approximately \$1.6 million. The Company anticipates that such position as of December 31, 2005 is adequate to finance its operations through June 30, 2006 but thereafter, the Company will require additional financing to insure that the Company will be able to meet the expenditures to develop and commercialize its products for which the Company has no current arrangements. The Company intends to seek additional funds through the sale of additional debt or equity. No representation can be made that the Company will be able to obtain additional financing or if obtained it will be on favorable terms, or at all. No assurance can be given that any offering if undertaken will be successfully concluded or that if concluded the proceeds will be material. The Company's inability to obtain additional financing when needed would impair its ability to meet its business objectives. Other possible sources of the additional financing are the cash exercises of the Long Term Warrants issued in the October 2004 private placement, the Replacement Warrants issued in the December 2005 private placement and other warrants and options that are currently outstanding.

If any future financing involves the further sale of the Company's securities, the Company's then-existing stockholders' equity could be substantially diluted. On the other hand, if the Company incurred debt, the Company would be subject to risks associated with indebtedness, including the

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

risk that interest rates might fluctuate and cash flow would be insufficient to pay principal and interest on such indebtedness.

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

On November 8, 2005, the Company entered into a six month agreement with an investor relations firm to provide investor relation services including, but not limited to, overall management of the Company's corporate communications program, securing group appointments, assistance with mass targeted mailings, compiling promotional materials, editing news releases and other corporate functions. As part of the compensation, the Company granted the consultant non-qualified options to purchase 75,000 shares of the Company's Common Stock, vesting pro-rata over a six month period at an exercise price of \$2.26 per share, equal to the fair market value of a share of Common Stock on the date of the grant. If the agreement should be extended beyond six months, the Company is to grant another 75,000 non-qualified options with an exercise price equal to the then fair market value of a share of Common Stock, which would vest over the service period.

19

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

- (a) Exhibits:
 - 4.1 Form of Replacement Warrant to purchase shares of Common Stock, incorporated by reference to exhibit 4.1 to the Form 8-K filed December 20, 2005.
 - 4.2 Form of Placement Agent Warrant to purchase shares of Common Stock, incorporated by reference to exhibit 4.2 to the Form 8-K filed December 20, 2005.
 - 10.1 Product Development, Manufacturing and Distribution Agreement, dated as of March 30, 2005, by and among Harris Pharmaceutical, Inc., Tish Technologies, LLC and Elite Labs, incorporated by reference to exhibit 10.1 to the Form 8-K filed April 5, 2005 as amended by Form 8-K/A filed July 20, 2005, as amended by Form 8-K/A filed August 23, 2005, as amended by Form 8-K/A filed September 27, 2005, as amended by the Form 8-K/A filed December 7, 2005.
 - 10.2 Product Development and Commercialization Agreement, dated as of June 21, 2005, by and among Intellepharmaceutics Corp., Elite Labs and the Company, incorporate by reference to exhibit 10.1 to the Form 8-K filed June 27, 2005, as amended by Form 8-K/A filed September 7, 2005, as amended by the Form 8-K/A filed December 7, 2005.
 - 10.3 Product Development and License Agreement, dated as of June 22, 2005, between Pliva, Inc. and Elite Labs, incorporated by reference to exhibit 10.1 to the Form 8-K filed June 28, 2005, as amended by Form 8-K/A filed September 6, 2005, as amended by the Form 8-K/A filed December 7, 2005.

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

- 10.4 Agreement, dated December 12, 2005, by and among the Registrant, Elite Laboratories, Inc., and IntelliPharmaCeutics Corp., incorporated by reference to exhibit 10.1 to the Form 8-K filed December 16, 2005.*
- 10.5 Form of Warrant Exercise Agreement between the Registrant and holders of Existing Warrants, incorporated by reference to exhibit 10.1 to the Form 8-K filed December 20, 2005.
- 10.6 Form of Registration Rights Agreement between the Registrant and holders of Replacement Warrants, incorporated by reference to exhibit 10.2 to the Form 8-K filed December 20, 2005.
- 10.7 Placement Agent Agreement between Indigo Securities LLC and the Registrant, incorporated by reference to exhibit 10.3 to the Form 8-K filed December 20, 2005.
- 10.8 Product Development and Commercialization Agreement, as of January 10, 2006, by and among Orit Laboratories LLC, Elite Laboratories, Inc. and Elite Pharmaceuticals, Inc. incorporated by reference to the Form 8-K filed January 17, 2006.*
- 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 by Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002..
- 99.1 Letter from Listing Qualifications, AMEX, dated January 4, 2006, incorporated by reference to exhibit 99.1 to the Form 8-K filed January 10, 2006.

* The Registrant has requested confidential treatment with respect to the referenced exhibit. In the event that the Securities and Exchange Commission should deny such request in whole or in part, such exhibit thereof shall be filed by amendment to this Current Report on Form 8-K.

20

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, 2006

By: /s/ Bernard Berk

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

Bernard Berk
Chief Executive Officer
(Principal Executive Officer)

Date: February 14, 2006

By: /s/ Mark I. Gittelman

Mark I. Gittelman
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)