

ELITE PHARMACEUTICALS INC /NV/  
Form S-1  
March 01, 2012

**AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON March 1, 2012**

**REGISTRATION NO. 333-\_\_\_\_\_**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**ELITE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Nevada	2834	22-3542636
(State or jurisdiction of incorporation or organization) Code Number)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

165 Ludlow Avenue

Northvale, NJ 07647

201-750-2646

(Address and telephone number of principal executive offices)

Jerry Treppel

165 Ludlow Avenue

Northvale, NJ 07647

201-750-2646

(Name, address and telephone number of agent for service)

Copies to:

Richard Feiner, Esq

381 Park Avenue South, 16<sup>th</sup> Floor

New York, NY 10016

212-779-8600

212-720-0863 (fax)

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

**(COVER CONTINUES ON FOLLOWING PAGE)**

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Amount to be Registered(5)	Proposed Maximum Offering Price Per Security (1)	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee
Common Stock, \$0.001 par value per share (2)	17,500,000	\$ 0.095	\$ 1,662,500	\$ 190.52
Common Stock, \$0.001 par value per share (3)	50,000,000	\$ 0.095	\$ 4,750,000	\$ 554.35
Common Stock, \$0.001 par value per share (4)	3,571,429	\$ 0.095	\$ 339,286	\$ 38.88
Total	71,071,429		\$ 6,751,786	\$ 773.75

Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of (1) 1933, as amended, using the average of the high and low prices reported on the Over-the-Counter Bulletin Board on February 28 2012, which was \$0.095 per share.

(2) Represents shares of common stock of Elite Pharmaceuticals, Inc., issuable upon the exercise of warrants, offered by the selling stockholder.

- (3) Represents shares of common stock of Elite Pharmaceuticals, Inc., issuable upon the exercise of additional investment rights, offered by the selling stockholder.
- (4) Represents shares of common stock of Elite Pharmaceuticals, Inc., issuable upon payment of a Commitment Fee to the selling stockholder, offered by the selling stockholder.
- (5) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, the shares of common stock offered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED March 1, 2012**

**ELITE PHARMACEUTICALS, INC.**

**71,071,429 Shares of Common Stock**

This prospectus relates to the public offering of up to 71,071,429 shares of common stock, par value \$.001 per share, of Elite Pharmaceuticals Inc. (“Common Stock”), by the selling stockholder. These shares of Common Stock include 17,500,000 shares issuable upon exercise of warrants, 50,000,000 shares issuable upon exercise of additional investment rights and 3,571,429 shares issuable upon payment of the Commitment Fee.

The selling stockholder may sell Common Stock from time to time in the principal market on which the stock is traded at the prevailing market price or in negotiated transactions.

We will not receive cash proceeds from the exercise of warrants and additional investment rights because they are being paid for with promissory notes and we will not receive any of the proceeds from the sale of Common Stock by the selling stockholder. We will pay the expenses of registering these shares.

**Investment in the Common Stock involves a high degree of risk. You should consider carefully the risk factors beginning on page 8 of this prospectus before purchasing any of the shares offered by this prospectus.**

Socius CG II, Ltd., the selling stockholder, is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended (the “Securities Act”), and any profits on the sales of shares of our Common Stock by Socius and any discounts, commissions or concessions received by Socius may be deemed to be underwriting discounts and commissions under the Securities Act.

Our Common Stock is quoted on the Over-the-Counter Bulletin Board and trades under the symbol "ELTP". The last reported sale price of our Common Stock on the Over-the-Counter Bulletin Board on February 28, 2012, was approximately \$0.09 per share.

**We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**The date of this prospectus is \_\_\_\_ 2012.**

**ELITE PHARMACEUTICALS, INC.****TABLE OF CONTENTS**

	Page
Prospectus Summary	1
Risk Factors	4
Forward-Looking Statements	15
Use of Proceeds	15
Selling Stockholder	16
Plan of Distribution	18
Description of Transaction and Securities to be Registered	20
Description of Business	23
Description of Property	36
Legal Proceedings	37
Market Price of and Dividends on Registrant's Common Equity and Related Stockholder Matters	37
Management's Discussion and Analysis of Financial Condition and Results of Operations	38
Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	43
Directors, Executive Officers, Promoters and Control Persons	44
Executive Compensation	47
Security Ownership of Certain Beneficial Owners and Management	55
Certain Relationships and Related Transactions, and Corporate Governance	58
Additional Information	59
Legal Matters	59
Experts	59
Unaudited Financial Statements	F-1
Audited Financial Statements	F-16

You may only rely on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the Common Stock offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any Common Stock in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or that the information contained by reference to this prospectus is correct as of any time after its date.

## Prospectus Summary

This summary highlights information contained elsewhere in this prospectus. You should read the entire prospectus carefully, including, the section entitled “Risk Factors” before deciding to invest in our Common Stock.

## About Us

Elite Pharmaceuticals, Inc., a Nevada corporation (the “Company”, “Elite”, “we”, “us” or “our”), through its wholly-owned subsidiaries, is a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology and the development and manufacture of generic pharmaceuticals. We were incorporated on October 1, 1997 under the laws of the State of Delaware and reincorporated in Nevada on January 5, 2012. Our wholly-owned subsidiaries, Elite Laboratories, Inc. (“Elite Labs”) and Elite Research, Inc. (“Elite Research”), were incorporated on August 23, 1990 and December 20, 2002, respectively, under the laws of the State of Delaware.

We have three products currently being sold commercially, as follows:

- Phentermine 37.5 mg tablets
- Lodrane D® immediate release Brompheniramine/Pseudoephedrine capsules
- Methadone 10 mg tablets

We have purchased the following approved generic products and are in the process of transferring the commercial manufacturing processes from the facility of the previous ANDA holders to our facilities in Northvale, NJ:

- Generic Hydromorphone (approved for commercial production on January 23, 2012)
- Generic Naltrexone

We also have an undisclosed generic product filed with US-FDA that we are awaiting review and a pipeline of additional generic drug candidates under active development.

Our principal executive offices are located at 165 Ludlow Avenue, Northvale, New Jersey 07647, and our telephone number is (201) 750-2646. We maintain a website at “<http://www.elitepharma.com>.” Information contained on our website is not considered to be a part of, nor incorporated by reference in, this Prospectus.



Elite's facility in Northvale, New Jersey (the "Facility") operates under Good Manufacturing Practice ("GMP") and is a United States Drug Enforcement Agency ("DEA") registered facility for research, development and manufacturing.

## **About This Offering**

### **The Socius Transaction**

An aggregate of 71,071,429 shares of Common Stock are being registered herein pursuant to

#### Pursuant to the Securities Purchase Agreement:

The Company has agreed to sell, and Socius has agreed to purchase, in one or more tranches from time to time (each such purchase, a "Tranche") in the Company's sole discretion (subject to the conditions set forth in the Securities Purchase Agreement), up to 500 shares of Series F Preferred Stock (the "Series F Preferred Shares") at a purchase price of \$10,000 per share, for an aggregate purchase price of up to \$5,000,000. On the Effective Date, the Company issued to Socius a two-year warrant (the "Socius Warrant") obligating Socius to purchase shares of the Company's Common Stock with an aggregate exercise price equal to 35% of the purchase price paid by Socius for the Series F Preferred Shares sold in each Tranche, at an exercise price per share of \$0.10 subject to adjustment as described therein. On each date that the Company delivers a notice (the "Tranche Notice") to Socius, Socius shall also become obligated, pursuant to a right automatically vesting and automatically exercised on such Tranche Notice date (the "Additional Investment Right"), to purchase that number of shares of Common Stock ("Additional Investment Shares") equal in dollar amount to 100% of the Tranche amount set forth in the Tranche Notice at a price per share of \$0.10. Socius shall pay the exercise price for the Socius Warrant and/or the Additional Investment Shares through the issuance of a recourse note (each, a "Note"). Any such Note will bear interest at 2.0% per annum calculated on a simple interest basis and be secured by securities owned by Socius with a fair market value equal to the principal amount of the Note. The entire principal balance and interest on each Note is due and payable on the fourth anniversary of the date of such Note or earlier in the case of an acceleration event under such Note; provided, however, that the Notes will not become due and payable so long as (a) the Company is in default of any of its material obligations under the Securities Purchase Agreement, or the Socius Warrant or other security of the Company issued pursuant to the Securities Purchase Agreement or the Socius Warrant, or any loan agreement or other material agreement between Socius and the Company, or (b) there are any Series F Preferred Shares issued or outstanding. In connection with a redemption of the Series F Preferred Shares by the Company, all outstanding Notes will be offset, exchanged and cancelled for all outstanding Series F Preferred Shares held by Socius such that following such offset, exchange and cancellation, no further amounts shall be due or payable with respect to such Series F Preferred Shares or such Notes and all of such Series F Preferred Shares and Notes shall no longer be outstanding.

The Company has agreed to pay to Socius a commitment fee of \$250,000 (the “Commitment Fee”), at the earlier of the closing of the first Tranche or the six month anniversary of the Effective Date, payable at the Company’s election in cash or Common Stock valued at 85% of the volume weighted average price of the Company’s Common Stock on the five trading days preceding the payment date.

The Company agreed to use its commercially reasonable best efforts to file within 30 days of the Effective Date, and cause to become effective as soon as possible thereafter, a registration statement with the Securities and Exchange Commission for the resale of all shares of Common Stock issuable pursuant to the Securities Purchase Agreement, including the shares of Common Stock underlying the Socius Warrant, shares of Common Stock issuable as Additional Investment Shares, and shares of Common Stock issuable in payment of the Commitment Fee.

On January 5, 2012, in accordance with the Securities Purchase Agreement, the Company included in the Articles of Incorporation filed in Nevada, a designation for the Series F Preferred Stock. Pursuant to this designation, the Series F Preferred Shares shall, with respect to dividend, rights upon liquidation, winding-up or dissolution, rank: (i) senior to the Company’s Common Stock (the “Junior Securities”); and (ii) junior to all existing and future indebtedness of the Company and any class or series of Preferred Stock of the Company (collectively, together with any warrants, rights, calls or options exercisable for or convertible into such Preferred Stock, the “Senior Securities”). In addition, the Series F Preferred Shares (a) subject to the rights of the Senior Securities, shall be entitled to receive cumulative dividends on each outstanding Series F Preferred Share at a rate of 10.0% per annum from the issuance date, payable in Series F Preferred Shares, (ii) shall not have voting rights except as set forth therein, and (iii) subject to the rights of the Senior Securities, may be redeemed at the Company’s option, at any time after the date of the initial issue of Series F Preferred Shares.

With respect to the shares of our Common Stock offered by Socius, this prospectus includes (i) 17,500,000 shares of the Company’s Common Stock issuable upon exercise of the Socius Warrant, (ii) 50,000,000 shares of the Company’s Common Stock issuable as Additional Investment Shares, and (iii) 3,571,429 shares of the Company’s Common Stock issuable upon payment of the Commitment Fee.

For more detailed information on the transaction with Socius, please see “*Description of Transaction and Securities to be Registered*” below.

The number of shares of Common Stock issuable upon exercise of the Socius Warrant and the Additional Investment Right was based on \$0.10 per share. The number of shares of Common Stock issuable as a Commitment Fee was estimated based on \$0.07 per share.

#### **Estimated use of proceeds**

This prospectus relates to shares of our Common Stock that may be offered and sold from time to time by the selling stockholder. The shares of Common Stock issued to Socius upon exercise of the Socius Warrant and Additional Investment Right will be paid for by Socius using promissory notes, rather than cash. Accordingly, we will not receive any cash proceeds from the sale of the Common Stock to Socius. We will not receive any of the proceeds resulting from the sale of Common Stock by the selling stockholder.

**Summary of the Shares offered by the Selling Stockholder**

The following is a summary of the shares being offered by the selling stockholder:

Common Stock offered by the selling stockholder Up to an aggregate of 71,071,429 shares of Common Stock (including 17,500,000 shares of Common Stock issuable upon exercise of warrants, 50,000,000 shares of Common Stock issuable upon exercise of the Additional Investment Right and up to 3,571,429 shares of Common Stock issuable in payment of the Commitment Fee.

Common Stock outstanding prior to the offering 321,827,276 (1)

Common Stock to be outstanding after the offering 392,898,705 assuming the full exercise of the Socius Warrant, full exercise of the Additional Investment Right and the issuance of 3,571,429 shares of Common Stock issuable in payment of the Commitment Fee.

Use of proceeds The shares of Common Stock issued to Socius upon exercise of the Socius Warrant and Additional Investment Right will be paid for by Socius using promissory notes, rather than cash. Accordingly, we will not receive any cash proceeds from the sale of the Common Stock to Socius. We will not receive any proceeds from the resale of the Common Stock by Socius hereunder. Socius will pay any underwriting discounts and commissions and expenses incurred by Socius for brokerage, accounting, tax or legal services or any other expenses incurred by Socius in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, exchange listing fees and fees and expenses of our counsel and our accountants.

Risk Factors See "Risk Factors" beginning on page 4 of the accompanying prospectus for a discussion of factors you should carefully consider before investing in shares of our Common Stock.

OTC Bulletin Board Our Common Stock is quoted on the OTC Bulletin Board under the symbol "ELTP".

(1) Based upon the total number of issued and outstanding shares as of February 21, 2012.

## **RISK FACTORS**

An investment in the Company's Common Stock involves a high degree of risk. You should carefully consider the risks described below as well as other information provided to you in this prospectus, including information in the section of this document entitled "Forward Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our Common Stock could decline, and you may lose all or part of your investment.

### **RISKS RELATED TO OUR BUSINESS**

*We have a relatively limited operating history, which makes it difficult to evaluate our future prospects.*

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and our presence in the generic pharmaceutical market. As a result, our potential for future profitability must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

- develop new products;
- obtain regulatory approval of our products;
- manage our growth, control expenditures and align costs with revenues;
- attract, retain and motivate qualified personnel; and respond to competitive developments.

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products.

*We have not been profitable and expect future losses.*

To date, we have not been profitable and we may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. For the past two fiscal years, we incurred net losses of \$13,582,159 and \$8,056,874, respectively and losses from operations of \$1,936,321 and \$445,758, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to

support our operations and offset operating costs.

***Without obtaining additional financing, there is doubt as to our ability to meet our business objectives and to continue as a going concern.***

As of September 30, 2011, we had cash reserves of approximately \$1.3 million. In addition, as discussed below in “*Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight as evidenced by the FDA’s removal from the market of our Lodrane® extended release product line*”, the U.S. Food and Drug Administration’s (“FDA”) removed our Lodrane® extended release product line from the market in March 2011. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA’s directive. The FDA has also reclassified our Changes Being Effected in 30 Days supplements (“CBE-30”) filed in relation to the transfer of manufacturing of two approved generic products to the Facility to a “prior approval supplemental application”. Such reclassifications have resulted in significant delays in the commercialization of these two approved generic products, with accordingly significant delays in our being able to generate revenues, if any, from the manufacture and sale of such approved generic products.

We believe that the completion of all transactions contemplated by the Epic Strategic Alliance Agreement will provide additional funds to permit us to continue development of our product pipeline. We are anticipating that, with the growth of the generic phentermine product, the contract manufacturing of methadone, Lodrane D® immediate release, Phendimetrazine and Isradipine, the eventual launch of the generic hydromorphone and naltrexone products and other opportunities in our pipeline, Elite could be profitable. In addition, the commercialization of the Epic products developed under the Epic Strategic Alliance Agreement should add a new revenue source for Elite. However, there can be no assurances as to the approval by the FDA of generic Naltrexone, the success of the development of such Epic products or the commercialization of such Epic products or the success or commercialization of other pipeline products of Elite. For more detailed information about the Epic Strategic Alliance Agreement please see “*Description of Business; Epic Strategic Alliance Agreement.*”

Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate quarterly payment closings pursuant to the terms and conditions of the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.6875 million. We also anticipate obtaining funds pursuant to the Securities Purchase Agreement. Even if we are able to successfully complete the quarterly payment closings of the Epic Strategic Alliance Agreement and obtain funds from the Securities Purchase Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all.

To sustain operations and meet our business objectives we must be able to commercialize the above products and other products or pipeline opportunities. If we are unable to timely obtain additional financing from the Epic Strategic Alliance Agreement, the Securities Purchase Agreement or other sources and we are unable to timely generate greater revenues from our operations, we will be required to cease operations and liquidate our assets. No assurance can be given that we will be able to commercialize the new opportunities, consummate the quarterly payment closings under the Epic Strategic Alliance Agreement or receive funding from the Securities Purchase Agreement on a timely basis, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets.

***We are in default on our obligations under the NJEDA Bonds. If we are unable to work out an arrangement to delay payment, repay or otherwise cure or settle this default, our ability to operate in the future will be materially and adversely affected.***

We are in default of our obligations on a loan through tax-exempt bonds from the New Jersey Economic Development Authority (“NJEDA”). Our liability under this obligation as of September 30, 2011 was approximately \$3.4 million. Our real property and the improvements thereon are encumbered by a mortgage in favor of as security for a loan through the NJEDA Bonds. We have received a Notice of Default from the Trustee in relation to the NJEDA Bonds and we have 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 our 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. For more information on the NJEDA Bonds, see “*Management’s Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; NJEDA Bonds*”.

***Substantially all of our product candidates are at an early stage of development and only a portion of these are in clinical development.***

ELI-154 and ELI-216 are pre-Phase III and some of our generic products are still at an early stage of development. Other than generic phentermine, which is a commercial drug product, and two additional generic drug products which Elite purchased in 2010, but are not yet commercialized, and a generic product that has been filed but not yet

approved by the FDA, we will need to perform additional development work for the additional product candidates in our pipeline before we can seek the regulatory approvals necessary to begin commercial sales.

*If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.*

We need FDA approval prior to marketing our product candidates in the United States of America. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States of America and we will not generate any revenue from the sale of such products.

This regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of our product candidates, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our product candidates are both safe and effective for each indication where approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might submit for regulatory approval any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use.



The FDA has substantial discretion in the approval process and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed by several years, or we may be required to expend more resources than we have available. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not an FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to manufacturing or marketing the product in those countries. The approval process varies from country to country and the time needed to secure approval may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval of our product in one country will result in approval in any other country.

***Before we can obtain regulatory approval, we need to successfully complete clinical trials, outcomes of which are uncertain.***

In order to obtain FDA approval to market a new drug product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct extensive preclinical testing and “adequate and well-controlled” clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. Completion of necessary clinical trials may take several years or more. Delays associated with products for which we are directly conducting preclinical or clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;
- delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards;
- slower than expected rate of patient recruitment and enrollment; inability to adequately follow and monitor patients after treatment; difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- government or regulatory delays; and
- clinical trial costs that are greater than we currently anticipate.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial or require us to conduct additional trials. We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Our clinical trials may be suspended at any time for a variety of reasons, including if the FDA or we believe the patients participating in our trials are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

Because of these risks, our research and development efforts may not result in any commercially viable products. Any delay in, or termination of, our preclinical or clinical trials will delay the filing of our drug applications with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained, or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

***If our collaboration or licensing arrangements are unsuccessful, our revenues and product development may be limited.***

We have entered into several collaborations and licensing arrangements for the development of products. However, there can be no assurance that any of these agreements will result in FDA approvals, or that we will be able to market any such finished products at a profit. Collaboration and licensing arrangements pose the following risks:

- collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;
- collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial or abandon a product candidate;
- expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;
- collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;
- the terms of our contracts with current or future collaborators and licensees may not be favorable to us in the future;
- a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration;
- one or more third-party developers could obtain approval for a similar product prior to the collaborator or licensee resulting in unforeseen price competition in connection with the development product; and

Epic may decide that the further or continuing development of one or more of the eight designated drug products being developed by Epic at our facility is no longer commercially feasible, delaying a potential source of revenue to us pursuant to the Epic Strategic Alliance Agreement. In addition, there can be no assurance that any drug product designated by the parties as a replacement would be as strong a candidate for commercial viability as the drug product that it replaced.

***We have been dependence on one or a few major customers. If we are unable to develop more customers our business most likely will be adversely affected***

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with ECR and Precision Dose for the sales and distribution of products that we manufacture. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

In April 2011, we ceased production of the Lodrane Extended Release Products, which are the subject of the agreements with ECR, pursuant to the FDA's announcement of its intention to remove approximately 500 cough/cold and allergy related products from the US market, including the Lodrane Extended Release Products. After this announcement by the FDA, the Company's customer for the Lodrane Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane Extended Release Products has ceased. The Lodrane Extended Release Products for which production has ceased were responsible for 97% of the Company's revenues during the fiscal year ended March 31, 2011.

***If we are unable to protect our intellectual property rights or avoid claims that we infringed on the intellectual property rights of others, our ability to conduct business may be impaired.***

Our success depends on our ability to protect our current and future products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to ours.

We currently hold five patents and we have four patents pending. We intend to file further patent applications in the future. We cannot be certain that our pending patent applications will result in the issuance of patents. If patents are issued, third parties may sue us to challenge our patent protection, and although we know of no reason why they should prevail, it is possible that they could. It is likewise possible that our patent rights may not prevent or limit our present and future competitors from developing, using or commercializing products that are similar or functionally equivalent to our products.

In addition, we may be required to obtain licenses to patents, or other proprietary rights of third parties, in connection with the development and use of our products and technologies as they relate to other persons' technologies. At such time as we discover a need to obtain any such license, we will need to establish whether we will be able to obtain such a license on favorable terms, if at all. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

We rely particularly on trade secrets, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by entering into confidentiality agreements with licensees, suppliers, employees and consultants. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that there will be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not otherwise become known or be independently developed by our competitors or, if patents are not issued with respect to products arising from research, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights can be costly, time-consuming and/or ultimately unsuccessful.

***Litigation is common in our industry, particularly the generic pharmaceutical industry, and can be protracted and expensive and could delay and/or prevent entry of our products into the market, which, in turn, could have a material adverse effect on our business.***

Litigation concerning patents and proprietary rights can be protracted and expensive. Companies that produce brand pharmaceutical products routinely bring litigation against applicants that seek FDA approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant. Because the eight drug products being developed by Epic at the Facility are generics, such drug products may be subject to such litigation brought by companies that produce brand pharmaceutical products. If Epic were to become subject to litigation in connection with any drug products it is developing at the Facility under the Epic Strategic Alliance Agreement, Epic may choose to, or be required to, decrease or cease its development and commercialization of such product for an indefinite period of time, which may prevent or delay the first commercial sale of such product and cause us to receive reduced or no product fees payable to us by Epic based on the commercial sales of such product in accordance with the Epic Strategic Alliance Agreement.

Likewise, other patent holders may bring patent infringement suits against us alleging that our products, product candidates and technologies infringe upon intellectual property rights. Litigation often involves significant expense and can delay or prevent introduction or sale of our products.

There may also be situations where we use our business judgment and decide to market and sell products, notwithstanding the fact that allegations of patent infringement(s) have not been finally resolved by the courts. The

risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be trebled. Moreover, because of the discount pricing typically involved with bioequivalent products, patented brand products generally realize a substantially higher profit margin than bioequivalent products. An adverse decision in a case such as this or in other similar litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our Common Stock to decline.

***The pharmaceutical industry is highly competitive and subject to rapid and significant technological change, which could impair our ability to implement our business model.***

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, the pharmaceutical industry is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

As we expand our presence in the generic pharmaceuticals market our product candidates may face intense competition from brand-name companies that have taken aggressive steps to thwart competition from generic companies. In particular, brand-name companies continue to sell or license their products directly or through licensing arrangements or strategic alliances with generic pharmaceutical companies (so-called “authorized generics”). No significant regulatory approvals are required for a brand-name company to sell directly or through a third party to the generic market, and brand-name companies do not face any other significant barriers to entry into such market. In addition, such companies continually seek to delay generic introductions and to decrease the impact of generic competition, using tactics which include:

- obtaining new patents on drugs whose original patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay approval from the FDA;
- filing citizens’ petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues; developing controlled-release or other “next-generation” products, which often reduce demand for the generic version of the existing product for which we may be seeking approval;
- changing product claims and product labeling;
- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

These strategies may increase the costs and risks associated with our efforts to introduce our generic products under development and may delay or prevent such introduction altogether.

***If our product candidates do not achieve market acceptance among physicians, patients, health care payors and the medical community, they will not be commercially successful and our business will be adversely affected.***

The degree of market acceptance of any of our approved product candidates among physicians, patients, health care payors and the medical community will depend on a number of factors, including:

- acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability of alternative treatments;
- pricing and cost effectiveness;
- effectiveness of sales and marketing strategies; and
- ability to obtain sufficient third-party coverage or reimbursement.

If we are unable to achieve market acceptance for our product candidates, then such product candidates will not be commercially successful and our business will be adversely affected.

*We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products.*

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved. In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers.

Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;



interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and

- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

In addition, patent laws in certain foreign jurisdictions (primarily in Europe) may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable United States or foreign patents. Any delay or inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, can materially adversely affect our ability to produce products. This can materially adversely affect our business and operations.

***Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight as evidenced by the FDA's removal from the market of our Lodrane® extended release product line. In addition, although Lodrane D® is marketed under the Over-the-Counter Monograph) and, accordingly, can be lawfully marketed in the US without prior regulatory approval, the FDA has revised its enforcement policies during the past few years, significantly limiting the circumstances under which unapproved products may be marketed.***

Even if regulatory approval is obtained for a particular product candidate, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to or obtain re-approvals of our contract manufacturers' facilities or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

On March 4, 2011, the FDA issued a directive removing from the market approximately 500 cough/cold and allergy products, including our Lodrane® extended release product line. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA's directive.

Lodrane D® is marketed under the Over-the-Counter Monograph (the "OTC Monograph") and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval. Under the Federal Food Drug and Cosmetic Act ("FDCA"), FDA regulations and statements of FDA policy, certain drug products are permitted to be

marketed in the U.S. without prior approval. Within the past few years, the FDA has revised its enforcement policies, significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

***If key personnel were to leave us or if we are unsuccessful in attracting qualified personnel, our ability to develop products could be materially harmed.***

Our success depends in large part on our ability to attract and retain highly qualified scientific, technical and business personnel experienced in the development, manufacture and marketing of oral, controlled-release drug delivery systems and generic products. Our business and financial results could be materially harmed by the inability to attract or retain qualified personnel.

***If we were sued on a product liability claim, an award could exceed our insurance coverage and cost us significantly.***

The design, development and manufacture of our products involves an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. The amount of our insurance coverage, which has been limited due to our limited financial resources, may be materially below the coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of the date hereof.

*If Novel Laboratories issues additional equity in the future our equity interest in Novel may be diluted, resulting in a decrease in our share of any dividends or other distributions which Novel may issue in the future.*

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

As a result of our determination not to fund our remaining contributions to Novel at the valuation set forth in the Novel Alliance Agreement and the resulting purchase from us of a portion of our shares of Class A Voting Common Stock of Novel by VGS Pharma, LLC, our remaining ownership interest in equity of Novel was reduced to approximately 10% of the outstanding shares of Novel. Novel may seek to raise additional operating capital in the future and may do so by the issuance of equity. If Novel issues additional equity, our future equity interest in Novel will decrease and we will be entitled to a decreased portion of any dividends or other distributions which Novel may issue in the future. Novel also has a company sponsored stock option plan and any equity issued from this stock plan will also reduce Elite's equity interest in Novel.

## **RISKS RELATED TO OUR COMMON STOCK**

*Our stock price has been volatile and may fluctuate in the future.*

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended December 31, 2011, the closing sale price on the OTC Bulletin Board (“OTC-BB”) of our Common Stock fluctuated from a high of \$0.10 per share to a low of \$0.04 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including:

- Results of our clinical trials;
- Approval or disapproval of our ANDAs or NDAs;
- Announcements of innovations, new products or new patents by us or by our competitors;
- Governmental regulation;
- Patent or proprietary rights developments;
- Proxy contests or litigation;

- News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- Economic and market conditions, generally and related to the pharmaceutical industry;
  - Healthcare legislation;
  - Changes in third-party reimbursement policies for drugs;
  - Fluctuations in our operating results; and
- Commercial success of the eight drug products of Epic identified under the Epic Strategic Alliance Agreement

***Future sales of our Common Stock could lower the market price of our Common Stock.***

Sales of substantial amounts of our shares in the public market could harm the market price of our Common Stock, even if our business is doing well. A significant number of shares of our Common Stock are eligible for sale in the public market under Rule 144, promulgated under the Securities Act of 1933, as amended (the “Securities Act”) and additional shares are eligible for public sale by the Selling Stockholder pursuant to this prospectus.

In this regard, as of February 21, 2012, there were outstanding 321,827,276 shares of Common Stock, shares of preferred stock convertible into approximately 152 million shares of Common Stock and warrants to purchase an aggregate of approximately 155 million shares of Common Stock at exercise prices that range from \$0.0625 per share to \$3.25 per share. Additional shares of Common Stock may be issuable as a result of: (i) the exercise of the Socius Warrant and Additional Investment Rights issuable under the Securities Purchase Agreement; (ii) anti-dilution provisions in the outstanding preferred stock and warrants; and, dividends on outstanding preferred stock and any Series F Preferred Shares issued pursuant to the Securities Purchase Agreement. Sales of these shares, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

***The issuance of additional shares and securities convertible into or exercisable for shares of Commons Stock pursuant to existing agreements or otherwise will cause existing holders of our Common Stock to experience substantial dilution.***

We are obligated to issue a significant number of additional shares of Common Stock pursuant to existing agreements, including the Epic Strategic Alliance Agreement and outstanding warrants and preferred stock, and we anticipate issuing Socius Warrants and Additional Investment Rights under the Securities Purchase Agreement that are exercisable for shares of our Common Stock. Existing holders of our Common Stock will experience substantial dilution from the issuance of shares of Common Stock pursuant to these obligations. By way of example, if we and Epic consummate the quarterly payment closings under the Epic Strategic Alliance Agreement, we will issue to Epic an aggregate of 562.5 shares of Series E Preferred Stock, convertible into an aggregate of approximately 23 million shares of Common Stock, based on a conversion price as of February 21, 2012. In addition, with respect to the products developed by Epic under the Epic Strategic Alliance Agreement, we may issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of our Common Stock upon the receipt by us from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at the Facility and (b) up to an aggregate of 40,000,000 additional shares of our Common Stock following the receipt by us from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and immediate-release products developed by Epic at the Facility.

***Raising of additional funding through sales of our securities could cause existing holders of our Common Stock to experience substantial dilution.***

Any financing that involves the further sale of our securities could cause existing holders of our Common Stock to experience substantial dilution. On the other hand, if we incurred debt, we would be subject to risks associated with indebtedness, including the risk that interest rates might fluctuate and cash flow would be insufficient to pay principal and interest on such indebtedness.

***The issuance of additional shares of our Common Stock or our preferred stock could make a change of control more difficult to achieve.***

The issuance of additional shares of our Common Stock or the issuance of shares of an additional series of preferred stock could be used to make a change of control of us more difficult and expensive. Under certain circumstances, such shares could be used to create impediments to, or frustrate persons seeking to cause, a takeover or to gain control of us. Such shares could be sold to purchasers who might side with our Board of Directors in opposing a takeover bid that the Board of Directors determines not to be in the best interests of our stockholders. It might also have the effect of discouraging an attempt by another person or entity through the acquisition of a substantial number of shares of our Common Stock to acquire control of us with a view to consummating a merger, sale of all or part of our assets, or a

similar transaction, since the issuance of new shares could be used to dilute the stock ownership of such person or entity.

*Epic has the ability to exert substantial influence over us.*

Under the Epic Strategic Alliance Agreement, we agreed that we and our Board of Directors will take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the “Epic Directors”) will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the initial closing of the Epic Strategic Alliance Agreement and ending on the later of (a) the date immediately following the first anniversary of the Initial Closing Date and (b) the Third Closing Date, Epic owns less than (1) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by Epic or (2) following the conversion by Epic of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither we nor our Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be removed from office for cause unless such removal is directed or approved by (A) a majority of the independent members of the Board of Directors and (B) all of the non-affected Epic Director(s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the request of Epic, with or without cause. Epic, by virtue of having the right to designate the three Epic Directors, will have the ability to exert substantial influence over the election of the other members of our Board of Directors, the outcome of issues submitted to our stockholders for approval and the management and affairs of Elite. In accordance with these rights, three of our current directors are nominees of Epic.

In addition, the Series E Designation provides that on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), Epic, as a holder of Series E Preferred Stock, will be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Series E Preferred Stock held by Epic are convertible as of the record date for determining the stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Series E Designation, Epic will vote together with the holders of Common Stock, as a single class. In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, we may conduct our operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, we must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein. Accordingly, as a result of such concentration of ownership, Epic will have the ability to exert further influence over us and may have the effect of preventing a change of control of Elite. For more detailed information about the Epic Strategic Alliance Agreement please see “*Description of Business; Epic Strategic Alliance Agreement.*”

Also, as disclosed above in “*The issuance of additional shares and securities convertible into or exercisable for shares of Commons Stock pursuant to existing agreements or otherwise will cause existing holders of our Common Stock to experience substantial dilution*”, we may issue significant additional shares of Common Stock, Common Stock Warrants and convertible Series E Preferred Stock to Epic upon the happening of certain events. If we are required to issue such securities, Epic may beneficially own in excess of 50% of our issued and outstanding shares of Common Stock or other voting securities. Under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of our issued and outstanding Common Stock or other voting securities, the number of Epic Directors that Epic will be entitled to designate will be equal to a majority of the Board of Directors.

***Holders of our preferred stock may exercise their veto rights to make it more difficult for us to take an action or consummate a transaction that may be deemed by the Board to be in our best interest or the best interest of the other stockholders.***

The holders of Series B Preferred Stock, Series C Preferred Stock and Series E Preferred Stock have certain veto rights and the selling stockholder pursuant to any Series F Preferred Stock it acquires will have certain veto rights that may be exercised to prevent us from taking an action or consummating a transaction that may be deemed by the Board to be in our best interest and the best interest of the holders of our Common Stock if the holders of our preferred stock believe such action or transaction would be adverse to their own interests. If the holders of our preferred stock exercise their veto rights to prevent us from taking any such action or consummating any such transaction, our ability to achieve our strategic objectives may be hindered. The ability of holders of our preferred stock to affect our actions through use of their veto rights might limit the price that certain investors would be willing to pay in the future for shares of our Common Stock. See also, “*Epic has the ability to exert substantial influence over us*” above.

***Our Common Stock is considered a “penny stock”. The application of the “penny stock” rules to our Common Stock could limit the trading and liquidity of our Common Stock, adversely affect the market price of our Common Stock and increase the transaction costs to sell shares of our Common Stock.***

Our common stock is a “low-priced” security or “penny stock” under rules promulgated under the Securities Exchange Act of 1934, as amended. In accordance with these rules, broker-dealers participating in transactions in low-priced securities must first deliver a risk disclosure document which describes the risks associated with such stocks, the broker-dealers duties in selling the stock, the customer’s rights and remedies and certain market and other information. Furthermore, the broker-dealer must make a suitability determination approving the customer for low- priced stock transactions based on the customer’s financial situation, investment experience and objectives. Broker-dealers must also disclose these restrictions in writing to the customer, obtain specific written consent from the customer, and provide monthly account statements to the customer. The effect of these restrictions will likely decrease the willingness of broker-dealers to make a market in our Common Stock, will decrease liquidity of our Common Stock and will increase transaction costs for sales and purchases of our Common Stock as compared to other securities.

***We voluntarily delisted our Common Stock from NYSE Amex in May 2009. Our Common Stock is now quoted on the Over-the- Counter Bulletin Board. The Over-the-Counter Bulletin Board is a quotation system, not an issuer listing service, market or exchange, therefore, buying and selling stock on the Over-the-Counter Bulletin Board is not as efficient as buying and selling stock through an exchange. As a result, it may be difficult to sell our Common Stock for an optimum trading price or at all.***

The Over-the-Counter Bulletin Board (the “OTCBB”) is a regulated quotation service that displays real-time quotes, last sale prices and volume limitations in over-the-counter securities. Because trades and quotations on the OTCBB involve a manual process, the market information for such securities cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and intervening price fluctuations may result in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmations may be delayed significantly. Consequently, one may not be able to sell shares of our Common Stock at the optimum trading prices.



When fewer shares of a security are being traded on the OTCBB, volatility of prices may increase and price movement may outpace the ability to deliver accurate quote information. Lower trading volumes in a security may result in a lower likelihood of an individual's orders being executed, and current prices may differ significantly from the price one was quoted by the OTCBB at the time of the order entry. Orders for OTCBB securities may be canceled or edited like orders for other securities. All requests to change or cancel an order must be submitted to, received and processed by the OTCBB. Due to the manual order processing involved in handling OTCBB trades, order processing and reporting may be delayed, and an individual may not be able to cancel or edit his order. Consequently, one may not be able to sell shares of Common Stock at the optimum trading prices.

The dealer's spread (the difference between the bid and ask prices) may be large and may result in substantial losses to the seller of securities on the OTCBB if the Common Stock or other security must be sold immediately. Further, purchasers of securities may incur an immediate "paper" loss due to the price spread. Moreover, dealers trading on the OTCBB may not have a bid price for securities bought and sold through the OTCBB. Due to the foregoing, demand for securities that are traded through the OTCBB may be decreased or eliminated.

## **FORWARD LOOKING STATEMENTS**

This prospectus contains “forward-looking statements”. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this prospectus, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words “plan”, “intend”, “may,” “will,” “expect,” “believe”, “could,” “anticipate,” “estimate,” or “continue” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. All statements other than statements of historical fact included in this prospectus regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note, without limitation, that statements regarding the preliminary nature of the clinical program results and the potential for further product development, that involve known and unknown risks, delays, uncertainties and other factors not under our control, the requirement of substantial future testing, clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities prior to the commercialization of products under development, and our ability to manufacture and sell any products, gain market acceptance earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature. These risks and other factors are discussed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

## **USE OF PROCEEDS**

The shares of Common Stock issued to the selling stockholder upon exercise of the Socius Warrant and Additional Investment Right will be paid for by the selling stockholder using promissory notes, rather than cash. Accordingly, we will not receive any cash proceeds from the sale of the Common Stock to Socius. We will not receive any of the proceeds resulting from the sale of Common Stock by the selling stockholder. However, we will generate proceeds from the sale of Series F Preferred Stock by the selling stockholder, if any. We intend to use those proceeds for general corporate purposes.

**SELLING STOCKHOLDER**

This prospectus relates to the resale from time to time by the selling stockholder of any or all of the shares of Common Stock that may be issued by us to Socius under the Securities Purchase Agreement and the Socius Warrant. For additional information regarding the issuance of Common Stock covered by this prospectus, see “Description of Transaction and Securities to be Registered” below. We are registering the shares of Common Stock pursuant to the provisions of the Securities Purchase Agreement we entered into with Socius on in order to permit the selling stockholder to offer the shares for resale from time to time.

The table below presents information regarding the selling stockholder and the shares of Common Stock that it may offer from time to time under this prospectus. This table is prepared based on information supplied to us by the selling stockholder, and reflects holdings as of February 21, 2012. As used in this prospectus, the term “selling stockholder” includes Socius and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge, or other non-sale related transfer. The number of shares in the column “Shares of Common Stock Included in Prospectus” represents all of the shares of Common Stock that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares in this offering. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares. The fourth column assumes the sale of all of the shares offered by the selling stockholder pursuant to this prospectus.

Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Securities Exchange Act of 1943, as amended (the “Exchange Act”), and includes shares of Common Stock with respect to which the selling stockholder has voting and investment power.

Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us during the past three years. The following table has been prepared on the assumption that all shares offered under this prospectus will be sold to parties unaffiliated with the selling stockholder.

Name Of Selling Stockholder	Beneficial Ownership Before the Offering(1)	Percentage Of Ownership Before the Offering(1)(2)	Shares of Common Stock Included in Prospectus	Beneficial Ownership After the Offering (5)	Percentage Of Ownership After Completion of the Offering
Socius CG II, Ltd (3)	-0-		* <b>71,071,429</b>	<b>(4)</b> -0-	0.0 % (1)(2)

\*

Less than 1%

In accordance with Rule 13d-3(d) under the Exchange Act, we have excluded from the number of shares beneficially owned prior to the offering all of the shares that Socius may be required to purchase under the Securities Purchase Agreement and the Socius Warrant because the issuance of such shares is solely at our discretion and is subject to certain conditions, the satisfaction of all of which are outside of Socius' control, (1) including the registration statement of which this prospectus is a part becoming and remaining effective. Also, under the terms of the Securities Purchase Agreement and the Socius Warrant, we may not issue shares of our Common Stock to Socius to the extent that Socius or any of its affiliates would, at any time, beneficially own more than 9.99% of our outstanding Common Stock. This beneficial ownership limitation may not be waived by the parties.

Applicable percentage ownership is based on 321,827,276 shares of our Common Stock outstanding as of February (2) 21, 2012. However, the selling stockholder's beneficial percentage ownership cannot exceed 9.99% of our outstanding Common Stock.

The sole stockholder of Socius CG II, Ltd. is Socius Capital Group, LLC. Sabra ICG, LLC holds all of the membership interests of Socius Capital Group, LLC and Patricia Peizer holds all of the membership interests of Sabra ICG, LLC. Voting and dispositive power with respect to the shares held by Socius CG II, Ltd. is exercised by Terren Peizer, the Managing Director of Sabra ICG, LLC, Socius Capital Group, LLC and Socius CG II, Ltd., who acts as investment advisor to these entities. Terren Peizer, Patricia Peizer, Sabra ICG, LLC and Socius Capital Group, LLC disclaim beneficial ownership with respect to the shares held by Socius CG II, Ltd. The Securities (3) Purchase Agreement contains a restrictive covenant under which Socius is prohibited from: (1) voting any shares of Common Stock owned or controlled by it or soliciting any proxies or seeking to advise or influence any person with respect to any of our voting securities; (2) engaging or participating in any actions, plans or proposals which relate to or would result in, among other things: (a) an extraordinary corporate transaction, such as a merger, (b) a sale of a material amount of assets, (c) any change in the present board of directors or management, (d) any change in capitalization, or (e) any other change in our business or corporate structure; or (3) requesting that we amend or waive any such covenants.

Represents shares of Common Stock issuable to Socius that includes (i) 17,500,000 shares of the Company's  
(4) Common Stock issuable upon exercise of the Socius Warrant, (ii) 50,000,000 shares of the Company's Common  
Stock issuable as Additional Investment Shares and (iii) 3,571,429 shares of the Company's Common Stock  
issuable upon payment of the Commitment Fee.

(5) Assumes the sale of all shares being offered pursuant to this prospectus.

## PLAN OF DISTRIBUTION

We are registering shares of Common Stock that may be issued by us from time to time to Socius under the Securities Purchase Agreement and the Socius Warrant to permit the resale of these shares of Common Stock after the issuance thereof by the selling stockholder from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholder of the shares of Common Stock. We will bear all fees and expenses incident to our obligation to register the shares of Common Stock.

Socius is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act. Socius may sell all or a portion of the shares of Common Stock beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder and/or the purchasers of the shares of Common Stock for whom they may act as agent. In effecting sales, broker-dealers that are engaged by the selling stockholder may arrange for other broker-dealers to participate. Socius has informed us that each such broker-dealer will receive commissions from Socius which will not exceed customary brokerage commissions. The securities may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices and by any other method permitted pursuant to applicable law. Socius will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales will be made on the OTC Bulletin Board or otherwise at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act. If the securities are sold through broker-dealers, Socius will be responsible for applicable discounts or commissions.

Socius may sell our shares in one or more of the following manners:

- ordinary brokerage transactions and transactions in which the broker solicits purchasers;

- a block trade in which the broker or dealer so engaged will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

- any other method permitted pursuant to applicable law; or

- a combination of any such methods of sale.

The selling stockholder may also sell shares of Common Stock covered by this prospectus pursuant to Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling

stockholder may transfer the shares of Common Stock by other means not described in this prospectus.

Socius has agreed that during the period beginning on the trading day immediately preceding the date of the Securities Purchase Agreement and ending on the trading day immediately following the termination of the Securities Purchase Agreement, neither Socius nor any of its affiliates nor any entity managed or controlled by Socius will, directly or indirectly, enter into or execute or cause or assist any person to enter into or execute any "short sale" (as such term is defined in Rule 200 of Regulation SHO, or any successor regulation, promulgated by the SEC under the Exchange Act) of the Common Stock or trading derivative securities to the same effect.

In addition, Socius and any unaffiliated broker-dealer will be subject to liability under the federal securities laws and must comply with the requirements of the Securities Act and the Exchange Act, including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of Common Stock by Socius or any unaffiliated broker-dealer. Under these rules and regulations:

- may not engage in any stabilization activity in connection with our securities,

- must furnish each broker that offers shares of our shares of Common Stock covered by the prospectus that is a part of our Registration Statement with the number of copies of such prospectus and any prospectus supplement which are required by each broker; and

- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities other than as permitted under the Exchange Act.

These restrictions may affect the marketability of the shares of Common Stock purchased and sold by Socius and any unaffiliated broker-dealer.

Under the securities laws of some states, the shares of Common Stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of Common Stock registered pursuant to the registration statement, of which this prospectus forms a part.

We have agreed to indemnify and hold harmless Socius and each person who controls Socius against certain liabilities, including liabilities under the Securities Act. We have also agreed to pay \$35,000 of attorneys' fees and expenses incurred by Socius in connection with the preparation, negotiation, execution and delivery of the Securities Purchase Agreement and related transaction documents. Further, we have agreed that each time we issue a tranche notice, we will pay by the tranche closing a \$10,000 non-refundable administrative fee to Socius' counsel with respect to the first tranche closing and a \$5,000 non-refundable administrative fee to Socius' counsel for each additional tranche closing, in each case, by offset against the amount of the tranche, or by wire transfer of immediately available funds. Socius has agreed to indemnify and hold harmless us and each of our directors, officers and persons who control us against certain liabilities relating to any breach of the representations, warranties, covenants, or agreements made by Socius in the Securities Purchase Agreement or in the other transaction documents.

We are required to pay all fees and expenses incident to the registration of the shares, including fees and disbursements of counsel to the selling stockholder, but excluding brokerage commissions or underwriter discounts.

For additional information regarding the issuance of Common Stock covered by this prospectus, see "Description of Transaction and Securities to be Registered" below and the disclosure set forth in our Current Report on Form 8-K relating to our transaction with Socius, filed with the SEC on January 5, 2012, as amended on February 29, 2012, pursuant to the Exchange Act, each of which is incorporated herein by reference.



## DESCRIPTION OF TRANSACTION AND SECURITIES TO BE REGISTERED

This prospectus includes 71,071,429 shares of our Common Stock offered by the selling stockholder. The following description of our Common Stock is only a summary. You should also refer to our articles of incorporation and bylaws, which have been filed as exhibits to the registration statement of which this prospectus forms a part.

### Securities Purchase Agreement

The Company entered into a securities purchase agreement on December 30, 2011 (the “Effective Date”), which was amended on February 28, 2012 (such securities purchase agreement as so amended, the “Securities Purchase Agreement”) with Socius CG II, Ltd., a Bermuda exempted company (“Socius”). Under the terms and subject to the conditions of the Securities Purchase Agreement, the Company has the right, in its sole discretion, over a term of two years, to demand through separate tranche notices that Socius purchase up to a total of \$5 million of redeemable Series F Preferred Stock (the “Series F Preferred Shares”). In order to effectuate such a sale, the Company will issue to Socius, subject to the terms and conditions of the Securities Purchase Agreement, one or more tranche notices to purchase a certain dollar amount of such Series F Preferred Shares. Each tranche notice after the first tranche notice may not be given sooner than five trading days after the date on which the closing for the prior tranche has occurred or the tranche has been cancelled. Upon receipt of a tranche notice, Socius will be obligated, subject to the terms and conditions specified in the Securities Purchase Agreement, to purchase the Series F Preferred Shares subject to such tranche notice on the tenth trading day after the date of the tranche notice.

Such conditions to the purchase and sale of the Series F Preferred Shares include, but are not limited to, the following: (i) the Common Stock must be listed for trading or quoted on the OTC Bulletin Board or another trading exchange or market, (ii) the representations and warranties of the Company set forth in the Securities Purchase Agreement must be true and correct as if made on the date of each tranche notice and each tranche closing (subject, however, to the Company’s ability to update disclosure exceptions to such representations and warranties through the Company’s SEC reports), (iii) the Company must not be in breach or default of the Securities Purchase Agreement or any agreement entered into in connection therewith, or any other material agreement of the Company, (iv) there shall have occurred no material adverse effect involving the Company or its business, operations or financial condition, (v) the absence of any law or judicial action prohibiting the transactions contemplated by the Securities Purchase Agreement, or any lawsuit seeking to prohibit or adversely affect such transactions, (vi) all necessary governmental, regulatory or third party approvals and consents must have been obtained and (vii) the Company must have a current, valid and effective registration statement and a prospectus shall be properly available for use to permit the lawful resale of all previously-issued and future issuable shares of Common Stock to Socius (including without limitation all shares of Common Stock issuable upon exercise of the warrant (the “Socius Warrant”) issued to Socius (the “Warrant Shares”) delivered in connection with such tranche and any previous tranches, all shares of Common Stock issuable upon exercise of any additional investment right (the “Additional Investment Right”) issued to Socius (the “Additional Investment Shares”) in connection with such tranche, and any shares of Common Stock issued to Socius as consideration for executing and delivering the Securities Purchase Agreement (the “Commitment Shares”). In the event the closing bid price of the Common Stock during any one or more of the nine (9) trading days on or immediately

following the delivery or deemed delivery of a tranche notice falls below 75% of the closing bid price of the Common Stock on the trading day immediately prior to the delivery or deemed delivery of a tranche notice, the tranche will be cancelled; provided, however, that upon such cancellation, Socius will redeem any outstanding promissory note tendered by Socius for Additional Investment Shares or Warrant Shares issued in connection with the applicable tranche notice for the principal amount of the promissory note plus accrued interest in exchange for (a) 92% of any gross proceeds received by the Socius upon the sale of such Additional Investment Shares or Warrant Shares issued to Socius in connection with such tranche notice and (b) the return to the Company of any unsold Additional Investment Shares or Warrant Shares issued to Socius in connection with such tranche notice.

At no time may the Company deliver a tranche notice if the number of Warrant Shares and/or Additional Investment Shares to be received pursuant to the automatic exercise of the Socius Warrant and the exercise of the Additional Investment Right, in each case, triggered by such tranche notice (including all other shares of Common Stock and other voting securities then owned or deemed beneficially owned by Socius and its affiliates), would result in Socius and/or its affiliates owning or being deemed the beneficial owner of more than 9.99% of the Common Stock. In addition, at no time may the Company deliver a tranche notice if the number of shares of Common Stock to be issued upon the automatic exercise of the Socius Warrant and the exercise of the Additional Investment Right, in each case, triggered by such tranche notice (together with any shares of Common Stock issued to Socius as a commitment fee and all shares of Common Stock issued pursuant to previous tranche notices) would exceed the aggregate number of shares of Common Stock which the Company may issue without breaching the Company's obligations under the rules or regulations of its applicable trading market. Finally, the Company may not deliver a tranche notice to Socius if, at such time, the closing bid price of the Company's Common Stock is less than \$0.10.

### Additional Investment Right

Under the Securities Purchase Agreement, in connection with the delivery of a tranche notice, Socius is obligated, pursuant to the automatic vesting and automatic exercise of the Additional Investment Right, to purchase a number of shares of our Common Stock equal in dollar amount to 100% of the amount of such tranche of Series F Preferred Shares at a per share price equal to \$0.10.

Upon automatic exercise of the Additional Investment Right, Socius must pay for the Additional Investment Shares, by delivering a full-recourse secured promissory note. Any such promissory note will bear interest at 2.0% per year calculated on a simple interest basis and be secured by securities owned by Socius with a fair market value equal to the principal amount of the promissory note. The entire principal balance and interest on each promissory note is due and payable on the fourth anniversary of the date of such promissory note or earlier in the case of an acceleration event under such promissory note; provided, however, that the promissory notes will not become due and payable so long as (a) the Company is in default of any of its material obligations under the Securities Purchase Agreement, or the Socius Warrant or other security of the Company issued pursuant to the Securities Purchase Agreement or the Socius Warrant, or any loan agreement or other material agreement between Socius and the Company, or (b) there are any Series F Preferred Shares issued or outstanding. In connection with a redemption of the Series F Preferred Shares by the Company, all outstanding promissory notes will be offset, exchanged and cancelled for all outstanding Series F Preferred Shares then held by Socius such that following such offset, exchange and cancellation, no further amounts shall be due or payable with respect to such Series F Preferred Shares or such promissory notes and all of such Series F Preferred Shares and promissory notes shall no longer be outstanding.

### Warrant

On the Effective Date and pursuant to the Securities Purchase Agreement, the Company issued to Socius the Socius Warrant which is initially exercisable for up to 17,500,000 shares of Common Stock at an initial exercise price of \$0.10. In connection with each tranche notice, a portion of the Socius Warrant equal to a number of shares calculated by dividing (1) 35% of the dollar amount of the tranche of Series F Preferred Shares by (2) the exercise price of the Socius Warrant then in effect will vest and be automatically exercised. The Socius Warrant issued to Socius will expire two years from the date it is first issued.

Upon automatic exercise of the Socius Warrant, Socius must pay for the Warrant Shares by delivering a full-recourse secured promissory note. Any such promissory note will bear interest at 2.0% per year calculated on a simple interest basis and be secured by securities owned by Socius with a fair market value equal to the principal amount of the promissory note. The entire principal balance and interest on each promissory note is due and payable on the fourth anniversary of the date of such promissory note or earlier in the case of an acceleration event under such promissory note; provided, however, that the promissory notes will not become due and payable so long as (a) the Company is in default of any of its material obligations under the Securities Purchase Agreement, or the Socius Warrant or other

security of the Company issued pursuant to the Securities Purchase Agreement or the Socius Warrant, or any loan agreement or other material agreement between Socius and the Company, or (b) there are any Series F Preferred Shares issued or outstanding. In connection with a redemption of the Series F Preferred Shares by the Company all outstanding promissory notes will be offset, exchanged and cancelled for all outstanding Series F Preferred Shares then held by Socius such that following such offset, exchange and cancellation, no further amounts shall be due or payable with respect to such Series F Preferred Shares or such promissory notes and all of such Series F Preferred Shares and promissory notes shall no longer be outstanding.

#### Series F Preferred Stock

In accordance with the Securities Purchase Agreement, the Company has created a new series of preferred stock - the Series F Preferred Stock. A summary of the terms of the Series F Preferred Stock is set forth below:

*Ranking and Voting.* The Series F Preferred Stock ranks, with respect to rights upon liquidation, winding-up or dissolution, (i) senior to the Company's Common Stock; and (ii) junior to all existing and future indebtedness of the company and any class or series of preferred stock of the Company. The Series F Preferred Stock has no voting rights other than as set forth in the Designation of Designations and as required by applicable law.

*No right of Conversion.* The Series F Preferred Stock is not convertible into shares of Common Stock.

*Dividends and Other Distributions.* Commencing on the date of issuance of any such shares of Series F Preferred Stock, and subject to the rights of senior securities, holders of Series F Preferred Stock shall be entitled to receive dividends on each outstanding share of Series F Preferred Stock, which shall accrue at a rate equal to 10% per annum from the date of issuance. Accrued dividends shall be payable upon redemption of the Series F Preferred Stock and shall be redeemed as part of such redemption.

*Liquidation.* Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company and any liquidation preferences to the senior securities, before any distribution or payment is made to the holders of any junior securities, the holders of Series F Preferred Stock shall first be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount with respect to the liquidation value per share equal to the original price per share thereof plus all accrued dividends thereon (the "Liquidation Value").

*Redemption.* The Company may redeem at any time (including on the closing date of a tranche), or may be required to redeem in certain circumstances, all (but not less than all) of the shares of Series F Preferred Stock by an offset, exchange and cancellation of all outstanding promissory notes issued by Socius to the Company in connection with the automatic exercise of each of the Socius Warrant and the Additional Investment Right such that following such offset, exchange and cancellation, no further amounts shall be due or payable with respect to such shares of Series F Preferred Stock or such promissory notes and all of such shares of Series F Preferred Stock and promissory notes shall no longer be outstanding.

The Series F Preferred Stock may not be transferred or sold except to an affiliate of Socius.

#### Commitment Fee

Under the terms of the Securities Purchase Agreement, the Company is obligated to pay Socius a commitment fee for committing to purchase the Series F Preferred Stock in the form of Commitment Shares or cash, at the Company's option (the "Commitment Fee"). The number of Commitment Shares payable will be determined by dividing \$250,000 by 85% of the Volume-Weighted Average Price of the Company's Common Stock for the five trading day period immediately preceding the date on which the Commitment Fee is paid, if paid in shares of Common Stock. Alternatively, the Company may pay \$250,000 in cash. If not earlier paid in connection with the first Tranche Notice, the Commitment Fee is payable in full six months after the Effective Date.

Company Lock-up Agreements with Key Officers and Directors

In connection with the transactions contemplated by the Securities Purchase Agreement and to facilitate the Company's ability to sell the Series F Preferred Stock in the future pursuant to the Securities Purchase Agreement, the Company is required to enter into certain Lock-Up Agreements with its key officers, directors and its 5% stockholders at or prior to the closing of the Securities Purchase Agreement. Such Lock-Up Agreements will provide that such persons agree with the Company on an irrevocable basis that they will not sell shares of Common Stock for at least ten trading days after the delivery or deemed delivery of a tranche notice. The Lock-up Agreements cover other transactions which have economic similarity to the sale of Common Stock.

Amendment

The Securities Purchase Agreement may not be amended.

## DESCRIPTION OF BUSINESS

### Business Overview and Strategy

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

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

- Phentermine 37.5 mg tablets
- Methadone 10 mg tablets
- Lodrane D® Immediate Release capsules
- Hydromorphone Hydrochloride 8 mg tablets (approved for commercial production on January 23, 2012)

During the fiscal years ended March 31, 2011 (“Fiscal 2011”) and March 31, 2010 (“Fiscal 2010”), the Company manufactured and sold Lodrane 24® and Lodrane 24D® (the “Lodrane Extended Release Products”). On March 3, 2011, the U.S. Food and Drug Administration (“FDA”) announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The Lodrane Extended Release Products were included in the FDA list of 500 products. After this announcement by the FDA, the Company’s customer for the Lodrane Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane Extended Release Products has ceased.

The Lodrane Extended Release Products were responsible for 97% and 100% of the Company’s revenues for Fiscal 2011 and Fiscal 2010, respectively.

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

Elite also purchased from Mikah Pharma LLC, an approved Abbreviated New Drug Applications (“ANDAs”) for Hydromorphone 8 mg and Naltrexone 50 mg tablets. Transfer of production of this product from the previous ANDA holder, Mikah Pharma to our manufacturing facilities is currently in process. Elite also completed a contract manufacturing agreement with Mikah Pharma for two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg.

The Company has a pipeline of additional generic drug candidates under active development, including, without limitation, ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-a-day oxycodone product.

Elite’s facility in Northvale, New Jersey (the “Facility”) operates under Good Manufacturing Practice (“GMP”) and is a United States Drug Enforcement Agency (“DEA”) registered facility for research, development and manufacturing.

## **Strategy**

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

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



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

### **Elite's Purchase of a Generic Hydromorphone HCl Product**

On May 18, 2010, Elite executed an asset purchase agreement with Mikah Pharma LLC ("Mikah") (the "Hydromorphone Agreement"). Pursuant to the Hydromorphone Agreement, the Company acquired from Mikah an ANDA for Hydromorphone Hydrochloride Tablets USP, 8 mg ("Hydromorphone 8 mg") for aggregate consideration of \$225,000, comprised of an initial payment of \$150,000, which was made on May 18, 2010. A second payment of \$75,000 was due to be paid to Mikah on June 15, 2010, with the Company having the option to make this payment in cash or by issuing to Mikah 937,500 shares of the Company's Common Stock. The Company elected and did issue 937,500 shares of Common Stock during the quarter ended December 31, 2010, in full payment of the \$75,000 due to Mikah pursuant to the asset purchase agreement dated May 18, 2010.

On May 31, 2011, the Company received a letter from the FDA responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 8 mg ANDA purchased from Mikah Pharma. The letter from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which has delayed the commercialization. On January 23, 2012, the Company received a letter from the FDA approving the application.

As a result of the delay in commercialization resulting from the reclassification of the Company's application, the Company recorded an impairment of the ANDA asset acquired from Mikah Pharma pursuant to the Hydromorphone Agreement in an amount equal to the entire purchase price of the acquisition on the consolidated financial statements contained herein.

### **Elite's Purchase of a Generic Naltrexone Product**

On August 27, 2010, Elite executed an asset purchase with Mikah (the "Naltrexone Agreement"). Pursuant to the Naltrexone Agreement, Elite acquired from Mikah the ANDA number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto, that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in this ANDA within the United States and its territories (including Puerto Rico) for aggregate consideration of \$200,000. In lieu of cash, Mikah agreed to accept from Elite product development services to be performed by Elite.

On December 14, 2011, the Company received an e-mail from the FDA responding to a Changes Being Effected in 30 Days (“CBE 30”) supplement filed by the Company with the agency to change the manufacturing and packaging location of the Naltrexone Hydrochloride Tablets USP, 50 mg ANDA purchased from Mikah Pharma. The e-mail from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which will delay the commercialization. The Company has been notified by the FDA that its filing is under review.

As a result of the delay in commercialization resulting from the reclassification of the Company’s application, the Company will record an impairment of the ANDA asset acquired from Mikah Pharma pursuant to the Naltrexone Agreement in an amount equal to the entire purchase price of the acquisition on the consolidated financial statements contained herein.

### **Elite’s Purchase of a Generic Phentermine Product**

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement (the “Phentermine Purchase Agreement”) with Epic for the purpose of acquiring from Epic an ANDA for a generic phentermine product (the “Phentermine ANDA”), with such being filed with the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the FDA approved the Phentermine ANDA. The acquisition of the Phentermine ANDA closed on March 31, 2011 and Elite paid the full acquisition price of \$450,000 from the purchase agreement with Epic Pharma.

This product is being marketed and distributed by Precision Dose Inc (“Precision Dose”) and its wholly owned subsidiary, TAGI Pharma Inc. (“TAGI”) pursuant license and manufacturing agreements dated September 10, 2010. A description of such manufacturing and licensing agreement with Precision Dose is set forth immediately following this paragraph.

### **Licensing Agreement with Precision Dose Inc.**

Pursuant to Elite's License Agreement with Precision Dose, Precision Dose is to market and sell four Elite generic products, consisting of Hydromorphone, Naltrexone, Phentermine 37.5 mg tablets ("Phentermine 37.5 mg") and one additional generic products for which an ANDA has been filed but not yet approved by the FDA, through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada. Precision Dose has the exclusive right to market the products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada. Pursuant to the License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years.

### **Research and Development**

During each of the last two fiscal years, we have focused on research and development activities. We spent \$1,385,211 during Fiscal 2011 and \$794,433 during Fiscal 2010 on research and development activities.

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

### **Commercial Products**

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

On September 27, 2011, Elite made the initial shipment of Lodrane D® immediate release capsules to ECR. Lodrane D is an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl. Elite will manufacture this product for ECR and will receive revenues for the manufacturing, packaging and laboratory stability study

services for this product as well as royalties on sales.

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

### **Contract Manufacturing**

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

Transfer of the manufacturing site to Elite's Facility is in progress as of the date of this Prospectus.

In June 2011, Elite entered into a commercial manufacturing and supply agreement with ThePharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories LLC (together "TPN"). Under the terms of the agreement, Elite will perform manufacturing and packaging for TPN's Methadone Hydrochloride, 10 mg tablets. The FDA has approved the manufacturing of Methadone 10 mg at the Northvale Facility and commercial launch of this product is expected during this fiscal year. The initial shipment to TPN of Methadone 10 mg was made on January 17, 2012.

### **Manufacturing Site Transfers in Progress**

Elite is currently engaged in the transfer of the manufacturing site for the following generic product for which it purchased approved ANDA's during the fiscal year ended March 31, 2011: Naltrexone 50 mg tablets.

Please refer to the sections above titled "*Elite's Purchase of a Generic Naltrexone Product*" for further details on the transfer of the manufacturing site for Naltrexone 50 mg.

### **Discontinued Products**

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

Lodrane 24®, was first commercially offered in November 2004 and Lodrane 24D® was first commercially offered in December, 2006. Elite's revenues for manufacturing these products and a royalty on sales for the years ended March 31, 2011 and 2010 aggregated \$3,917,721 and, \$3,339,870, respectively.

Since January, 2010, the Company has performed laboratory stability studies of Lodrane 24® and Lodrane 24D®, for ECR, on a contract basis. Elite's revenues from such contract laboratory services were \$348,242 and \$4,429 for Fiscal 2011 and Fiscal 2010, respectively.

On March 3, 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The Lodrane Extended Release Products were included in the FDA list of 500 products. After this announcement by the FDA, the Company's customer for the Lodrane Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane Extended Release Products has ceased.

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

### **Products Under Development**

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

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

For ELI-154, Elite has developed a once-daily oxycodone formulation using its proprietary technology. An investigational new drug application, or IND, has been filed and Elite has completed two pharmacokinetic studies in healthy subjects that compared blood levels of oxycodone from dosing ELI-154 and the twice-a-day product that is on the market currently, OxyContin® marketed in the U.S. by Purdue Pharma LP. The Company believes that these studies confirmed that ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hour period and equivalent blood levels to the twice-a-day product at the end of 24 hours. Elite has successfully manufactured multiple batches on commercial scale equipment and it is looking for a partner who can complete the clinical studies required for Europe and who can sell and distribute the product in key European territories. An interested party was identified that would fund half of the clinical costs for Europe, however, Elite is not able to find a way to fund the remaining costs at this time.

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

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

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

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

### **Epic Strategic Alliance Agreement**

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

### ***Use of Facility and Joint Development of Drug Products***

Pursuant to the Epic Strategic Alliance Agreement, on June 3, 2009 (the "*Initial Closing Date*"), Elite and Epic conducted the initial closing (the "*Initial Closing*") of the transactions contemplated by the Epic Strategic Alliance Agreement, and Epic and its employees and consultants commenced use of a portion of Elite's facility located at 165 Ludlow Avenue, Northvale, New Jersey (the "*Facility*"), for the purpose of developing new generic drug products, all at Epic's sole cost and expense for a period of at least three years (the "*Initial Term*"), unless sooner terminated or extended pursuant to the Epic Strategic Alliance Agreement or by mutual agreement of Elite and Epic (the Initial Term, as shortened or extended, the "*Term*"). In addition to the use of the Facility, Epic uses Elite's machinery, equipment, systems, instruments and tools residing at the Facility (collectively the "*Personal Property*") in connection with its joint drug development project at the Facility. Under the Epic Strategic Alliance Agreement, Epic has the right, exercisable in its sole discretion, to extend the Initial Term for two periods of one year each by giving written notice to Elite of such extension within ninety days of the end of the Initial Term or any extension thereof. Any such extension will be on the same terms and conditions contained in the Epic Strategic Alliance Agreement. Elite will be responsible for (and Epic will have no responsibility for) any maintenance, services, repairs and replacements in, to or of the Facility and the Personal Property, unless any such maintenance, service, repair or replacement is required as a result of the negligence or misconduct of Epic's employees or representatives, in which case Epic will be responsible for the costs and expenses associated therewith.



During the Term, Epic will use and occupy a portion of the Facility and use the Personal Property for the purpose of developing (i) at least four controlled-release products (the “*Identified CR Products*”) and (ii) at least four immediate-release products (the “*Identified IR Products*”), the identity of each have been agreed upon by Epic and Elite. If, during the Term, Epic determines, in its reasonable business judgment, that the further or continuing development of any Identified CR Product and/or Identified IR Product is no longer commercially feasible, Epic may, upon written notice to Elite, eliminate from development under the Epic Strategic Alliance Agreement such Identified CR Product and/or Identified IR Product, and replace such eliminated product with another controlled-release or immediate-release product, as applicable.

Pursuant to the Epic Strategic Alliance Agreement, Epic will also use a portion of the Facility and use the Personal Property for the purpose of developing (x) additional controlled-release products of Epic (the “*Additional CR Products*”), subject to the mutual agreement of Epic and Elite, and/or (y) additional immediate-release products of Epic (the “*Additional IR Products*”), subject to the mutual agreement of Elite and Epic (each Identified CR Product, Identified IR Product, Additional CR Product and Additional IR Product, individually, a “*Product*,” and collectively, the “*Products*”). Under the Epic Strategic Alliance Agreement, Epic may not eliminate an Identified CR Product or an Identified IR Product unless it replaces such Product with an Additional CR product or Additional IR Product, as the case may be. Subject to the mutual agreement of Elite and Epic as to additional consideration and other terms, Epic may use and occupy the Facility for the development of other products (in addition to the Products).

As additional consideration for Epic’s use and occupancy of a portion of the Facility and its use of the Personal Property during the Term and the issuance and delivery by Elite to Epic of the Milestone Shares (as defined below) and Milestone Warrants (as defined below), for the period beginning on the First Commercial Sale (as defined in the Epic Strategic Alliance Agreement) of each Product and continuing for a period of ten years thereafter (measured independently for each Product), Epic will pay Elite a cash fee (the “*Product Fee*”) equal to fifteen percent of the Profit (as defined in the Epic Strategic Alliance Agreement), if any, on each of the Products.

With respect to each Identified CR Product and Additional CR Product developed by Epic at the Facility: (i) Elite will issue and deliver to Epic a seven-year warrant to purchase up to 10,000,000 shares of Common Stock, at an exercise price of \$0.0625, following the receipt by Elite from Epic of each written notice of Epic’s receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified CR Products and/or Additional CR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 40,000,000 shares of Common Stock (such warrants, the “*CR Related Warrants*”), and (ii) Elite will issue and deliver to Epic 7,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic’s receipt from the FDA of approval for such Identified CR Products and/or Additional CR Products, up to a maximum of an aggregate of 28,000,000 shares of Common Stock (such shares, the “*CR Related Shares*”).

With respect to each Identified IR Product and Additional IR Product developed by Epic at the Facility, (i) Elite will issue and deliver to Epic a seven year warrant to purchase up to 4,000,000 shares of Common Stock, at an exercise price of \$0.0625, following the receipt by Elite from Epic of each written notice of Epic’s receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified IR Products and/or

Additional IR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 16,000,000 shares of Common Stock (such warrants, together with the CR Related Warrants, the “*Milestone Warrants*”), and (ii) Elite will issue and deliver to Epic 3,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic’s receipt from the FDA of approval for such Identified IR Products and/or Additional IR Products, up to a maximum of an aggregate of 12,000,000 shares of Common Stock (such shares, together with the CR Related Shares, the “*Milestone Shares*”). The Milestone Warrants may only be exercised by payment of the applicable cash exercise price. Elite will have no obligation to register with the United States Securities and Exchange Commission (the “*SEC*”) or any state securities commission the resale of the Milestone Shares, Milestone Warrants or the shares of Common Stock issuable upon exercise of the Milestone Warrants.

Subject to the mutual agreement of Epic and Elite with respect to the selection of Additional CR Products and/or Additional IR Products pursuant to the Epic Strategic Alliance Agreement, Epic will have the sole right to make all decisions regarding all aspects of the Products, including, but not be limited to, (i) research and development, formulation, studies and validation of each Product, (ii) identifying, evaluating and obtaining ingredients for each Product, (iii) preparing and filing the ANDA for each Product with the FDA and addressing and handling all regulatory inquiries, audits and investigations pertaining to the ANDA, and (iv) the manufacture, marketing, supply and commercialization of each Product. In addition, Epic would be the sole and exclusive owner of all right, title and interest in and to each of the Products.

Pursuant to the Epic Strategic Alliance Agreement, the use by each of Elite and Epic of the other party's confidential and proprietary information is restricted by customary confidentiality provisions. Elite and Epic also agreed in the Epic Strategic Alliance Agreement to indemnify and hold each other harmless from certain losses under the Epic Strategic Alliance Agreement.

Under certain circumstances Epic will be entitled to terminate the Term early in the event that the Facility is totally damaged or destroyed such that the Facility is rendered wholly untenable. In addition, subject to certain exceptions, either Elite or Epic may terminate the Term at any time if the other party is in breach of any material obligations under Article V of the Epic Strategic Alliance Agreement and has not cured such breach within sixty days after receipt of written notice requesting cure of such breach.

Elite may also terminate the Term by written notice to Epic if (i) all conditions precedent that Elite is obligated to satisfy pursuant to Article II of the Epic Strategic Alliance Agreement on or prior to a Closing (as defined in the Epic Strategic Alliance Agreement) have been, or will have been, satisfied by Elite in accordance with the terms thereof and (ii) Epic does not consummate such Closing in accordance with Article II. Notwithstanding the foregoing, if Elite terminates the Epic Strategic Alliance Agreement as described in this paragraph, then any and all product fees to which it would otherwise be entitled will remain the obligation of Epic and must be paid to Elite in accordance with the terms of Epic Strategic Alliance Agreement.

### ***Infusion of Additional Capital Necessary for Product Development***

In order to provide Elite with the additional capital necessary for the product development and synergies presented by the strategic relationship with Epic, Epic agreed to invest \$3.75 million in Elite through the purchase of Elite's Series E Preferred Stock and Common Stock warrants. At the Initial Closing, which occurred on June 3, 2009, in order to fund the continued development of Elite's drug products, Elite issued and sold to the Epic, in a private placement, pursuant to an exemption from registration under Section 4(2) of the Securities Act, 1,000 shares of its Series E Convertible Preferred Stock, par value \$0.01 per share (the "*Series E Preferred Stock*"), at a price of \$1,000 per share, each share convertible, at \$0.05 per share (the "*Conversion Price*"), into 20,000 shares of Common Stock, par value \$0.001 per share (the "*Common Stock*"). The Conversion Price is subject to adjustment for certain events, including, without limitation, dividends, stock splits, combinations and the like. The Conversion Price is also subject to adjustment for (a) the sale of Common Stock or securities convertible into or exercisable for Common Stock, for which Epic's consent was not required under the Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock, at a price less than the then applicable Conversion Price, (b) the issuance of Common Stock in lieu of cash in satisfaction of Elite's dividend obligations on outstanding shares of its Series B 8% Convertible Preferred Stock, par value \$0.01 per share, Series C 8% Convertible Preferred Stock, par value \$0.01 per share, and/or Series D 8% Convertible Preferred Stock, par value \$0.01 per share (the "*Series D Preferred Stock*"), and (c) the issuance of Common Stock as a result of any holder of Series D Preferred Stock exercising its right to require Elite to redeem all of such holder's shares of Series D Preferred Stock pursuant to the terms thereof. Epic also acquired a warrant to purchase 20,000,000 shares of Common Stock (the "*Initial Warrant*"), exercisable on or prior to June 3, 2016, at a per share exercise price of \$0.0625 (the "*Exercise Price*"), subject to adjustments for certain events, including, but not limited to,

dividends, stock splits, combinations and the like. The Exercise Price of the Initial Warrant will also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock, for which Epic's consent was not required under the Epic Strategic Alliance Agreement, at a price less than the then applicable Exercise Price of the Initial Warrant. Epic paid an aggregate purchase price of \$1,000,000 for the shares of Series E Preferred Stock and the Initial Warrant issued and sold by Elite to the Epic at the Initial Closing, of which \$250,000 was received by Elite, in the form of a cash deposit, on April 30, 2009, pursuant to the First Amendment. The remaining \$750,000 of such aggregate purchase price was paid to Elite by Epic at the Initial Closing.

On October 30, 2009, Elite completed the second closing of the Strategic Alliance Agreement with Epic. Epic paid to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, and a warrant to purchase an additional 40,000,000 shares of Common Stock. The warrant is to be exercisable until the date that is the seventh anniversary of the Second Closing Date and is to have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, without limitation, dividends, stock splits, combinations and the like.

On March 31, 2011, Elite completed the third closing of the Strategic Alliance Agreement with Epic (the "Third Closing Date"), Epic paid to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, and a warrant to purchase an additional 40,000,000 shares of Common Stock. The warrant is to be exercisable until the date that is the seventh anniversary of the Second Closing Date and is to have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, without limitation, dividends, stock splits, combinations and the like.

In addition, within ten business days following the last day of each calendar quarter, beginning with the first calendar quarter following the Initial Closing Date and continuing for each of the eleven calendar quarters thereafter, Epic will pay to Elite a sum of \$62,500, for an aggregate purchase price over such period of \$750,000, in exchange for an additional 62.5 shares of Series E Preferred Stock per quarter and 750 shares of Series E Preferred Stock, in the aggregate, over such period, which such shares will be convertible into 1,250,000 shares of Common Stock per quarter and 15,000,000 shares of Common Stock, in the aggregate, over such period, subject to adjustment. To date, Epic has only made three payments.

Pursuant to the Epic Strategic Alliance Agreement, if Elite determines, in its reasonable judgment, that additional funding is required for the development of its pharmaceutical products, then, either (i) Elite will issue, and Epic will purchase, such additional number of shares of Series E Preferred Stock or Common Stock from Elite, upon such terms and conditions as may be agreed upon by Elite and Epic at the time of such determination; or (ii) on or after September 15, 2011, Epic will provide a loan to Elite, in an aggregate principal amount not to exceed \$1,000,000, which such loan will (A) have an interest rate equal to the then prime interest rate as published in the Wall Street Journal on the date of such loan, (B) mature on the second anniversary of date of such loan, and (C) be on such other terms and conditions which are customary and reasonable to loans of a similar nature and which are mutually agreed upon between Epic and Elite. As of the date of this Prospectus, Epic has neither made such an additional investment nor made such a loan.

Elite believes, which as to such belief there can be no assurances, the completion of the transactions contemplated by the Epic Strategic Alliance Agreement creates value for our stockholders by adding a new revenue source for Elite upon the commercialization of the Epic products developed at our facility, providing an experienced partner to assist in the development, manufacture and licensing of our pharmaceutical products, and contributing funding for the products. Importantly, Elite will continue the development of its pain products and, with the help of Epic, work towards securing licensing arrangements for such pain products.

### ***Board of Directors Composition and Voting Rights***

As of the Initial Closing Date and at all times thereafter, except as otherwise set forth in the Epic Strategic Alliance Agreement, Elite and its Board of Directors is required to take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the “*Epic Directors*”) will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the period commencing on the Initial Closing Date and ending on the date immediately following the first anniversary of the Third Closing Date Epic owns less than (i) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by Epic at all of the then applicable Closings or (ii) following the conversion by Epic of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither Elite nor its Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be

removed from office for cause unless such removal is directed or approved by (x) a majority of the independent members of the Board of Directors and (y) all of the non-affected Epic Director (s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the request of Epic, with or without cause. At such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that Epic will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a majority of the Board of Directors.

The Series E Designation provides that on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), Epic, as a holder of Series E Preferred Stock, will be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Series E Preferred Stock held by Epic are convertible as of the record date for determining the stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Series E Designation, Epic will vote together with the holders of Common Stock, as a single class.

In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, Elite may conduct its operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein.

## Novel Labs Investment

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

## Patents

Since our incorporation, we have secured seven United States patents of which two have been assigned for a fee to another pharmaceutical company. Elite's patents are:

PATENT	EXPIRATION DATE
U.S. patent 5,871,776	October 28, 2016
U.S. patent 5,902,632	July 31, 2017
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 17, 2018
U.S. patent 6,620,439	October 3, 2020
U.S. patent 6,635,284 (assigned to Celgene Corporation)	March 11, 2018
U.S. patent 6,926,909	April 4, 2023
U.S. patent 6,984,402	April 10, 2023

We have pending applications for four additional U.S. patents.

The pending patent applications relate to two different controlled-release pharmaceutical products on which we are working. Three of these patents are for an opioid agonist and antagonist product that we are developing to be used with oxycodone and other opioids to minimize the abuse potential for the opioids. Another U.S. patent is for formulation of oral sustained-release opioids intended to improve the delivery of the opioids. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade (“GATT”), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured

from the date of grant. Under GAAT, the term of any U.S. Patent granted on an application filed subsequent to June 8, 1995 terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price Competition Act, a U.S. product patent or use patent may be extended for up to five years under certain circumstances to compensate the patent holder for the time required for FDA regulatory review of the product. Such benefits under the Drug Price Competition Act are available only to the first approved use of the active ingredient in the drug product and may be applied only to one patent per drug product. There can be no assurance that we will be able to take advantage of this law.

Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention, or that any judicial interpretation of the validity, enforceability, or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

We also rely upon unpatented proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we will have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology.



## **Trademarks**

We currently plan to license our products to other entities engaged in the marketing of pharmaceuticals and not to sell under our own brand name and so we do not currently intend to register any trademarks related to our products.

## **Government Regulation and Approval**

The design, development and marketing of pharmaceutical compounds, on which our success depends, are intensely regulated by governmental regulatory agencies, in particular the FDA. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecution based on products or manufacturing practices that violate statutory requirements. In addition, administrative remedies can involve voluntary withdrawal of products, as well as the refusal of the FDA to approve ANDAs and NDAs. The FDA also has the authority to withdraw approval of drugs in accordance with statutory due process procedures.

Before a drug may be marketed, it must be approved by the FDA either by an NDA or an ANDA, each of which is discussed below.

Please note that, as discussed in “*Discontinued Products*” above, in March 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with such list of 500 products including the Lodrane Extended Release Products. After this announcement by the FDA, the Company’s customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products has ceased.

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

## **NDAs and NDAs under Section 505(b) of the Drug Price Competition Act**

The FDA approval procedure for an NDA is generally a two-step process. During the Initial Product Development stage, an investigational new drug application (“IND”) for each product is filed with the FDA. A 30-day waiting period after the filing of each IND is required by the FDA prior to the commencement of initial clinical testing. If the FDA does not comment on or question the IND within such 30-day period, initial clinical studies may begin. If, however, the FDA has comments or questions, they must be answered to the satisfaction of the FDA before initial clinical testing may begin. In some instances this process could result in substantial delay and expense. Initial clinical studies generally constitute Phase I of the NDA process and are conducted to demonstrate the product tolerance/safety and pharmacokinetic in healthy subjects.

After Phase I testing, extensive efficacy and safety studies in patients must be conducted. After completion of the required clinical testing, an NDA is filed, and its approval, which is required for marketing in the United States, involves an extensive review process by the FDA. The NDA itself is a complicated and detailed application and must include the results of extensive clinical and other testing, the cost of which is substantial. However, the NDA filings contemplated by us, which are already marketed drugs, would be made under Sections 505 (b)(1) or 505 (b)(2) of the Drug Price Competition Act, which do not require certain studies that would otherwise be necessary; accordingly, the development timetable should be shorter. While the FDA is required to review applications within a certain timeframe, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. It is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product.

Whether or not FDA approval has been obtained, approval of the product by comparable regulatory authorities in any foreign country must be obtained prior to the commencement of marketing of the product in that country. We intend to conduct all marketing in territories other than the United States through other pharmaceutical companies based in those countries. The approval procedure varies from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further delays may be encountered before the products become commercially available.

## **ANDAs**

The FDA approval procedure for an ANDA differs from the procedure for a NDA in that the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. “Bioavailability” indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. “Bioequivalence” compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods, during which the FDA may be prohibited from accepting applications for, or approving, generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date.

In May 1992, Congress enacted the Generic Drug Enforcement Act of 1992, which allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Act requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Drug Enforcement Act allows for civil penalties and withdrawal of previously approved applications. Neither we nor any of our employees have ever been subject to debarment. We do not believe that we receive any services from any debarred person.

## **Controlled Substances**

We are also subject to federal, state, and local laws of general applicability, such as laws relating to working conditions. We are also licensed by, registered with, and subject to periodic inspection and regulation by the Drug Enforcement Agency (“DEA”) and New Jersey state agencies, pursuant to federal and state legislation relating to drugs and narcotics. Certain drugs that we currently develop or may develop in the future may be subject to regulations under the Controlled Substances Act and related statutes. As we manufacture such products, we may become subject to the Prescription Drug Marketing Act, which regulates wholesale distributors of prescription drugs.

## **GMP**

All facilities and manufacturing techniques used for the manufacture of products for clinical use or for sale must be operated in conformity with GMP regulations issued by the FDA. We engage in manufacturing on a commercial basis for distribution of products, and operate our facilities in accordance with GMP regulations. If we hire another company to perform contract manufacturing for us, we must ensure that our contractor’s facilities conform to GMP regulations.

## **Compliance with Environmental Laws**

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices of corporations as to which we are the legal successor or in possession. We do not expect that compliance with such environmental laws will have a material effect on our capital expenditures, earnings or competitive position in the foreseeable future. There can be no assurance, however, that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on our capital expenditures, earnings or competitive position.

## Competition

We have competition with respect to our two principal areas of operation. We develop and manufacture generic products and products using controlled-release drug technology for other pharmaceutical companies, and we develop and market (either on our own or by license to other companies) generic and proprietary controlled-release pharmaceutical products. In both areas, our competition consists of those companies which develop controlled-release drugs and alternative drug delivery systems. We do not represent a significant presence in the pharmaceutical industry.

An increasing number of pharmaceutical companies have become interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will significantly increase in the future since smaller specialized research and development companies are beginning to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many of these companies have greater financial and other resources as well as more experience than we do in commercializing pharmaceutical products. Certain companies have a track record of success in developing controlled-release drugs. Significant among these are Sandoz (a Novartis company), Durect Corporation, Mylan Laboratories, Inc., Par Pharmaceuticals, Inc., Alkermes, Inc., Teva Pharmaceuticals Industries Ltd., Aptalis Pharma, Impax Laboratories, Inc., and Watson Pharmaceuticals. Each of these companies has developed expertise in certain types of drug delivery systems, although such expertise does not carry over to developing a controlled-release version of all drugs. Such companies may develop new drug formulations and products or may improve existing drug formulations and products more efficiently than we can. In addition, almost all of our competitors have vastly greater resources than we do. While our product development capabilities and, if obtained, patent protection may help us to maintain our market position in the field of advanced drug delivery, there can be no assurance that others will not be able to develop such capabilities or alternative technologies outside the scope of our patents, if any, or that even if patent protection is obtained, such patents will not be successfully challenged in the future.

In addition to competitors that are developing products based on drug delivery technologies, there are also companies that have announced that they are developing opioid abuse-deterrent products that might compete directly or indirectly with Elite's products. These include, but are not limited to Pfizer Inc., Pain Therapeutics (which has an agreement with Durect Corporation and Pfizer Inc.), Collegium Pharmaceuticals, Inc., Purdue Pharma LP, and Acura Pharmaceuticals, Inc.

We also face competition in the generic pharmaceutical market. The principal competitive factors in the generic pharmaceutical market include: (i) introduction of other generic drug manufacturers' products in direct competition with our products under development, (ii) introduction of authorized generic products in direct competition with any of our products under development, particularly if such products are approved and sold during exclusivity periods, (iii) consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups, (iv) ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods,

diminishing the amount and duration of significant profits, (v) the willingness of generic drug customers, including wholesale and retail customers, to switch among pharmaceutical manufacturers, (vi) pricing pressures and product deletions by competitors, (vii) a company's reputation as a manufacturer and distributor of quality products, (viii) a company's level of service (including maintaining sufficient inventory levels for timely deliveries), (ix) product appearance and labeling and (x) a company's breadth of product offerings.

### **Sources and Availability of Raw Materials; Manufacturing**

A significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

Please see the Risk Factor entitled “*We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products*” above.

While we currently obtain the raw materials that we need from over 20 suppliers, some materials used in our products are currently available from only one supplier or a limited number of suppliers. The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

We have acquired pharmaceutical manufacturing equipment for manufacturing our products. We have registered our facilities with the FDA and the DEA.

### **Dependence on One or a Few Major Customers**

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have agreements with ECR and Precision Dose for the sales and distribution of products that we manufacture. We receive revenues to manufacture these products and also receive a profit split or royalties based on in-market sales of the products.

In April 2011, we ceased production of the Lodrane Extended Release Products, which are the subject of the agreements with ECR, pursuant to the FDA’s announcement of its intention to remove approximately 500 cough/cold and allergy related products from the US market, including the Lodrane Extended Release Products. While the announcement by the FDA had a minimal effect on the Company’s results for Fiscal 2011, the Lodrane Extended Release Products for which production has ceased were responsible for 97% of the Company’s revenues. The announcement by the FDA accordingly has a material adverse effect on the Company’s revenues for periods beginning after March 31, 2011.

### **Employees**

As of the date of this Prospectus, we had 18 full time employees. Full-time employees are engaged in operations, administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the continued service of our senior management and key

personnel.

35



## DESCRIPTION OF PROPERTY

We own a facility located at 165 Ludlow Avenue, Northvale, New Jersey (“165 Ludlow”) which contains approximately 15,000 square feet of floor space. This real property and the improvements thereon are encumbered by a mortgage in favor of the New Jersey Economic Development Authority (“NJEDA”) as security for a loan through tax-exempt bonds from the NJEDA to Elite. The mortgage contains certain customary provisions including, without limitation, the right of NJEDA to foreclose upon a default by Elite. The NJEDA has declared the payment of this bond to be in default. We are currently using the Facility as a laboratory, manufacturing, storage and office space.

We entered into a lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey (“135 Ludlow”), consisting of approximately 15,000 square feet of floor space. The lease term began on July 1, 2010. The lease includes an initial term of 5 years and 6 months and we have the option to renew the lease for two additional terms, each of 5 years. The property related to this lease will be used for the storage of pharmaceutical finished goods, raw materials, equipment and documents as well as engaging in manufacturing, packaging and distribution activities. This property requires significant construction and qualification as a prerequisite to achieving suitability for such intended future use. Approximately 3,500 square feet of this property was constructed and qualified as suitable for use for storage of pharmaceutical finished goods, raw materials, equipment and documents and was placed into service on or before the expiration of the lease for the warehouse at 80 Oak Street, as noted below. Construction and qualification as suitable for manufacturing, packaging and distribution operations are expected to be achieved within two years from the beginning of the lease term. These are estimates based on current project plans, which are subject to change. There can be no assurance that the construction and qualification will be accomplished during the estimated time frames, or that the property located at 135 Ludlow Avenue, Northvale, New Jersey will ever achieve qualification for intended future utilization.

165 Ludlow and 135 Ludlow are hereinafter referred to as the “Facilities”.

Properties used in our operation are considered suitable for the purposes for which they are used, at the time they are placed into service, and are believed adequate to meet our needs for the reasonably foreseeable future.

**LEGAL PROCEEDINGS**

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

**MARKET PRICE OF AND DIVIDENDS ON REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market Information**

Our Common Stock was traded on NYSE Amex (formerly, the American Stock Exchange) under the symbol "ELI" until May 21, 2009, at which time Elite's Common Stock began to be quoted on the Over-the-Counter Bulletin Board ("OTCBB") under the ticker symbol "ELTP". The following table shows, for the periods indicated, the high and low bid prices per share of our Common Stock as reported by OTCBB. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
Fiscal Year Ending March 31, 2012		
December 31, 2011	\$0.10	\$0.07
September 30, 2011	\$0.14	\$0.07
June 30, 2011	\$0.24	\$0.07
Fiscal Year Ending March 31, 2011		
March 31, 2011	\$0.09	\$0.04
December 31, 2010	\$0.07	\$0.04
September 30, 2010	\$0.08	\$0.05
June 30, 2010	\$0.10	\$0.07
Fiscal Year Ending March 31, 2010		
March 31, 2010	\$0.12	\$0.08
December 31, 2009	\$0.25	\$0.06
September 30, 2009	\$0.09	\$0.06
June 30, 2009	\$0.20	\$0.05

As of February 28, 2012, the last reported sale price of our Common Stock, as reported by the OTCBB, was \$0.09

### **Holders**

As of February 28, 2012, there were, respectively, approximately 125, 6, 10 and 1 holders of record of our Common Stock, Series B Preferred Stock, Series C Preferred Stock and Series E Preferred Stock.

### **Dividends**

We have never paid cash dividends on our Common Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business. We do, however, pay dividends on our outstanding shares of Series B and Series C Preferred Stock and these dividends, generally, are paid in shares of our Common Stock.

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

### **General**

The following discussion and analysis should be read with the financial statements and accompanying notes, included elsewhere in this Prospectus and the information described under the captions “*Description of Business*”, “*Risk Factors*” and “*Special Note Regarding Forward Looking Statements*” above. The following discussion is intended to assist the reader in understanding and evaluating our financial position.

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

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

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

## **LIQUIDITY AND CAPITAL RESOURCES**

## Going concern considerations

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

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

Revenues and operating profits for the foreseeable future are expected to be significantly and adversely effected by the FDA removal of the Lodrane® Extended Release Products from the market. The Lodrane® Extended Release Products, which constituted approximately 97% of the Company's revenues in the periods immediately preceding the nine month period ended December 31, 2011, were included on a list of approximately 500 cough/cold and allergy products which are being removed from the U.S. market pursuant to a directive from the FDA.

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

As of December 31, 2011, we had cash reserves of \$0.6 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that we will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. We also anticipate obtaining funds pursuant to the Securities Purchase Agreement with Socius (see "Description of Transaction and Securities to be Registered" above). Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement and obtain funds pursuant to the Socius Securities Purchase Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all.

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

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

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

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

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

#### NJEDA Bonds

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing \$4,155,000, evidenced by a 6.5% Series A Note in the principal amount of \$3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of \$495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of 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 \$10,599 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 \$225,000 and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling \$225,000 was not made.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2011, totaling \$470,000, with such amount including the principal payments due on September 1, 2010 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling \$470,000 was not made.

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

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

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

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



## **Off-Balance Sheet Arrangements**

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

## **Effects of Inflation**

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

## **Results of Consolidated Operations**

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

Our revenues for the nine months ended December 31, 2011 were \$1,774,000 a decrease of \$1,279,000 or approximately 42% over revenues for the comparable period of the prior year, and consisted of \$848,000 in manufacturing fees, \$496,000 in lab and product development fees and \$430,000 in royalties and license fees. Revenues for the nine months ended December 31, 2010, consisted of \$2,236,000 in manufacturing fees, \$234,000 in lab and product development fees, and \$583,000 in royalties and license fees. Manufacturing fees decreased by approximately 62% due to the removal from the market of the Lodrane® Extended Release Products, pursuant to a directive from the FDA issued in March 2011. Lab and product development fees increased by approximately 112% due to product development fees earned from the Hi-Tech Development Agreement and the Mikah Development Agreement, offset by decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees decreased by 26% due to the removal from the market of the Lodrane® Extended Release Products as of August 30, 2011, offset by milestone payments received pursuant to the Precision Dose Agreement and related to the April 2011 launch of Phentermine 37.5 mg tablets. In-market sales of the Lodrane® Extended Release Products were only permitted for five of the nine months in the nine month period ended December 31, 2011, as compared with a full nine months of sales occurring during the comparable period of the prior year.

Research and development costs for the nine months ended December 31, 2011 were \$1,030,000, an increase of \$535,000 or approximately 108% from \$495,000 of such costs for the comparable period of the prior year. The increase was primarily due to the shifting of personnel and operational resources from commercial manufacturing to product development as a result of the discontinuance of the Lodrane® Extended Release Products.

General and administrative expenses for the nine months ended December 31, 2011, were \$1,090,000, an increase of \$142,000, or approximately 15% from \$948,000 of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to overhead costs related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products, increased real estate taxes at the Northvale Facility and increased legal fees related to the conversion of Series B, C, D and E Preferred Shares to Common Shares and preparation of the preliminary and final proxy statements which were filed during the nine month period ended December 31, 2011.

Depreciation and amortization for the nine months ended December 31, 2011 was \$336,000, an increase of \$223,000, or approximately 197%, from \$113,000 for the comparable period of the prior year. The increase was primarily due to depreciation expense related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products.

Non-cash compensation through the issuance of stock options and warrants for the nine months ended December 31, 2011 was \$18,000, a decrease of \$15,000, or approximately 45% from \$33,000 for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for the nine months ended December 31, 2011 was \$1,359,000, compared to a loss from operations of \$155,000 for the nine months ended December 31, 2010.

Other expenses for the nine months ended December 31, 2011 were a net expense of \$6,692,000, an increase in other net expenses of \$9,878,000 from the net other income of \$3,186,000 for the comparable period of the prior year. The increase in other expenses was due to derivative expenses relating to changes in the fair value of our preferred shares and outstanding warrants during the nine months ended December 31, 2011 totaling \$6,166,000, as compared to a net derivative income of \$4,376,000 for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company's convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company's Common Stock as of December 31, 2011 was \$0.07, as compared to a closing price of \$0.08 as of March 31, 2011. Closing prices on the various dates on which shares of convertible preferred stock were converted to common stock ranged from \$0.07 to \$0.22 during the nine months ended December 31, 2011. These variances in the closing price of the Company's

Common Stock as compared with the closing price at the end of the immediately preceding fiscal year end were significant factors in the derivative income recorded during the nine months ended December 31, 2011.

As a result of the foregoing, our net loss for the nine months ended December 31, 2011 was \$8,051,000, compared to a net income of \$3,023,000 for the nine months ended December 31, 2010.

### **Material Changes in Financial Condition – Nine Months Ended December 31, 2011**

Our working capital (total current assets less total current liabilities), decreased to a deficit of 3.2 million as of December 31, 2011 from a working capital deficit of \$1.5 million as of March 31, 2011, primarily due to our net loss from operations, exclusive of non-cash charges. In addition, it should be noted that current liabilities includes the entire principal amount due on the Company's NJEDA Bonds Payable. This amount, totaling \$3.4 million has been classified as a current liability as a result of the Company receiving a notice of default from the Trustee of the NJ-EDA Bonds. Please refer to Note 5 to our December 31, 2011 unaudited consolidated financial statements included herein for further details.

Net cash used by operations was \$789,000 for the nine months ended December 31, 2011, primarily due to our net loss of \$8,053,000, offset by non-cash charges totaling \$7,264,000, which included, without limitation, depreciation and amortization of \$363,000, net expense from the change in fair value of derivative liabilities of \$6,166,000, derivative interest payments satisfied through the issuance of common shares in lieu of cash of \$550,000, non-cash compensation satisfied by the issuance of common stock and options of \$18,000, decreases in inventories of \$185,000, decreases in accounts receivable of \$88,000 and increases in accounts payable and other current liabilities of \$41,000.

**Year Ended March 31, 2011 as compared to the Year Ended March 31, 2010**

Elite's revenues for the year ended March 31, 2011 were \$4,265,963, an increase of \$921,664 over revenues for the prior year, and consisted of \$3,086,183 in manufacturing fees, \$831,538 in royalty fees and \$348,242 in contract lab service fees. Revenues for the year ended March 31, 2010 consisted of \$2,575,942 in manufacturing fees, \$763,928 in royalty fees and \$4,429 in contract lab service fees. Manufacturing fees increased by approximately 20% and royalties increased by approximately 9% due to growth of product sales.

Research and development costs for the year ended March 31, 2011 were \$1,385,211, an increase of \$590,778, or approximately 74%, from \$794,433 of such costs for the prior year. Increases in research and development costs were mainly attributable to charges recorded as a result of the FDA's reclassification of the Company's application for transferring of the site of manufacture of Hydromorphone 8 mg, costs related to the transfer of production of new products acquired by the Company during the year and an increase in research and development activities. Research and development costs are expected to increase, in future periods, once Phase III and other clinical trials for ELI-216 are initiated.

General and administrative expenses for the year ended March 31, 2011, were \$876,012, a decrease of \$965,413, or approximately 52% from \$1,841,425 of general and administrative expenses for the prior year. The decrease was primarily attributable to decreases in salaries and fringe benefits from Elite's force reduction and management's continued cost reduction efforts.

Non-cash compensation satisfied by the issuance of stock options and warrants decreased \$82,987 to \$42,017 for the year ended March 31, 2011 from \$125,004 for the year ended March 31, 2010. Decreases were the result of previously issued options becoming vested and forfeitures as a result of the reduction in workforce.

Depreciation and amortization decreased by \$40,631, or approximately 19%, from \$213,955 for the prior year to \$173,363. While depreciation expense for the year ended March 31, 2011 decreased from the prior year, please note that during the year ended March 31, 2011, we acquired equipment costing approximately \$180,000 and invested approximately \$340,000 in leasehold improvements. Neither the equipment nor the leasehold improvements were placed in service during the year ended March 31, 2011, but we anticipate both to be placed in service during the year immediately subsequent to March 31, 2011. Accordingly, depreciation expenses in future years are expected to increase. Other income (expenses) for the year ended March 31, 2011 were \$(12,997,812) compared to (expenses) of \$(6,120,553) for the year ended March 31, 2010. The decrease in other income (expenses) was due to derivative expenses related to changes in the fair value of our preferred shares and outstanding warrants of \$(11,714,374), derivative interest expense of \$(1,259,480) and discount in Series E issuance attributable to beneficial conversion features of (\$292,213), impairment of intangible assets of (\$440,000), offset by sales of New Jersey Net Operating Losses of \$311,835 and proceeds received pursuant to the settlement of litigation with The Pharma Network totaling \$500,000.

As a result of the foregoing, Elite's net loss for the year ended March 31, 2011 was \$13,582,159 compared to a net loss of \$8,056,874 for the year ended March 31, 2010.

### **Material Changes in Financial Condition – Year Ended March 31, 2011**

Our working capital (total current assets less total current liabilities), increased to a working capital deficiency of \$1,521,959 as of March 31, 2011 from a working capital deficiency of \$2,274,572 as of March 31, 2010, primarily due to net proceeds received as a result of our private placement of Series E Convertible Preferred Stock, and by net cash provided by operations.

We experienced positive cash flows from operations of \$1,552,815 for the year ended March 31, 2011, primarily due to our net loss of \$13,582,159, offset by non-cash expenses totaling \$14,474,751, included in the net loss, combined with a decrease in inventory of \$754,931.

On November 15, 2004 and on December 18, 2006, Elite's partner, ECR, launched Lodrane 24® and Lodrane 24D®, respectively. Under its agreement with ECR, Elite manufactured, through April 2011, commercial batches of Lodrane 24® and Lodrane 24D® in exchange for manufacturing margins and royalties on product revenues. Manufacturing revenues and royalty income earned for the year ended March 31, 2011 was \$3,086,183 and \$831,538, respectively. In addition, the Company earned \$348,242 from contract lab services related to the Lodrane Products. Gross revenues earned in relation to the Lodrane Products equaled 98% of the Company's revenues for the year ended March 31, 2011.

On March 3, 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with Lodrane 24® and Lodrane 24D® being included in such list. According to the press release issued by the FDA, manufacturers must stop manufacturing the affected products within 90 days of March 3, 2011 and distribution of the affected products must stop within 180 days of March 3, 2011. Elite's customer for Lodrane 24® and Lodrane 24D® cancelled all outstanding orders, other than those orders for which manufacturing had commenced, citing the announcement by the FDA and advising that existing stocks of Lodrane 24® and Lodrane 24D® were sufficient and that additional quantities could not be sold prior to the 180 day distribution deadline announced by the FDA.

While the timing of the announcement by the FDA resulted in such having a minimal effect on the Company's results for the year ended March 31, 2011, the Company's inability to manufacture Lodrane 24® and Lodrane 24D® has a material and adverse effect on its revenues for period beginning after March 31, 2011.

#### **CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

As reported in our Current Report on Form 8-K filed with the SEC on January 15, 2010, effective January 1, 2009, Miller, Ellin & Company, LLP ("Miller Ellin"), the independent accountant of Elite, and the principal accountant engaged to audit Elite's financial statements, consummated a merger of its practice into the practice of Rosen Seymour, with Rosen Seymour Shapss Martin & Company LLP ("*Rosen Seymour*") succeeding to the business and operations of Miller Ellin, subject to certain conditions and exceptions, as agreed upon by the parties under the terms of the Merger. Upon consummation of the Merger on January 1, 2009, Miller Ellin effectively resigned as Elite's independent accountant, and Rosen Seymour, pursuant to the terms of its agreement with Miller Ellin, became Elite's new independent accountant and principal accountant to audit its financial statements, as the successor in interest of Miller Ellin. On January 14, 2010, the Audit Committee engaged Demetrius & Company LLC ("*Demetrius*") as its new independent registered public accounting firm and dismissed Rosen Seymour as the Company's independent registered public accounting firm.

During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no disagreements with Rosen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Rosen's satisfaction, would have caused Rosen to make reference to the subject matter of the disagreement in connection with its report. During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K.

**DIRECTORS AND EXECUTIVE OFFICERS**

The following sets forth biographical information about each of our directors and executive officers:

Name	Age	Position	Director / Officer Since
Jerry Treppel <sup>1</sup>	57	Chairman and Chief Executive Officer	November 2008
Barry Dash, Ph. D.	80	Director	April 2005
Chris Dick <sup>2</sup>	56	President, Chief Operating Officer and Director	October 2009 <sup>3</sup>
Ashok G. Nigalaye, Ph.D.	59	Chief Scientific Officer and Director	June 2009 <sup>4</sup>
Jeenarine Narine	61	Director	June 2009
Ram Potti	58	Director	June 2009
Jeffrey Whitnell	55	Director	October 2009
Carter J. Ward	47	Chief Financial Officer, Secretary and Treasurer	July 2009

(1) Mr. Treppel also served as Chairman of the Board since November 6, 2008 and CEO since September 15, 2009.

(2) Mr. Dick also serves as our Chief Operating Officer and, President.

(3) Mr. Dick previously served on our Board of Directors from October 2008 to June 2009, and was re-nominated and re-elected to the Board at the 2009 Stockholder meeting held on October 23, 2009.

(4) Dr. Nigalaye has served as a Director since June 2009 and as Chief Scientific Officer since September 2009.

The principal occupations and employment of each Director during the past five years is set forth below. In each instance in which dates are not provided in connection with a nominee's business experience, such nominee has held the position indicated for at least the past five years.

**Jerry Treppel** has served as a Director since October 28, 2008, Chairman of the Board since November 6, 2008 and Chief Executive Officer since September 15, 2009. Mr. Treppel served as the managing member of Wheaton Capital Management LLC, a capital management company focusing on investment in the health care sector from 2003 to 2009. In October 2008, Mr. Treppel was appointed managing director of Ledgemont Capital Group LLC, a boutique merchant bank that provides access to capital and corporate advisory services to public and private companies. Over the past 20 years, Mr. Treppel was an equity research analyst focusing on the specialty pharmaceuticals and generic drug sectors at several investment banking firms including Banc of America Securities, Warburg Dillon Read LLC (now UBS), and Kidder, Peabody & Co. He previously served as a healthcare services analyst at various firms, including Merrill Lynch & Co. He also held administrative positions in the healthcare services industry early in his career. From 2003 to 2009, Mr. Treppel served as a member of the board of directors of Akorn, Incorporated (NASDAQ: AKRX), a specialty pharmaceutical company engaged in the development, manufacturing and marketing of branded and multi-source pharmaceutical products and vaccines. Mr. Treppel also served as the Chair of Akorn's Nominating and Corporate Governance Committee and as a member of its Audit Committee and Compensation Committee. Mr. Treppel holds a BA in Biology from Rutgers College in New Brunswick, N.J., an MHA in Health Administration from Washington University in St. Louis, Mo., and an MBA in Finance from New York University. Mr. Treppel has been a Chartered Financial Analyst (CFA) since 1988. Mr. Treppel's knowledge of the pharmaceutical industry as well as his education credentials and his experience as a member of the board of directors of Akorn, Incorporated led to the conclusion that he is qualified to serve as a director.

**Dr. Barry Dash** has served as a Director since April 2005, Member of the Audit Committee since April 2005, Member of the Nominating Committee since April 2005 and Member and Chairman of the Compensation Committee since June 2007. Dr. Dash has been, since 1995, President and Managing Member of Dash Associates, LLC., an independent consultant to the pharmaceutical and health industries. From 1983 to 1996 he was employed by Whitehall-Robins Healthcare, a division of American Home Products Corporation (now known as Wyeth), initially as Vice President of Scientific Affairs, then as Senior Vice President of Scientific Affairs and then as Senior Vice President of Advanced Technologies, during which time he personally supervised six separate departments: Medical and Clinical Affairs, Regulatory Affairs, Technical Affairs, Research and Development, Analytical R&D and Quality Management/Q.C. Dr. Dash had been employed by the Whitehall Robins Healthcare from 1960 to 1976, during which time he served as Director of Product Development Research, Assistant Vice President of Product Development and Vice President of Scientific Affairs. Dr. Dash had been employed by J.B. Williams Company (Nabisco Brands, Inc.) from 1978 to 1982. From 1976 to 1978 he was Vice President and Director of Laboratories of the Consumer Products Division of American Can Company. He currently serves on the board of directors of GeoPharma, Inc. (NASDAQ: GORX). Dr. Dash holds a Ph.D. from the University of Florida and M.S. and B.S. degrees from Columbia University where he was Assistant Professor at the College of Pharmaceutical Sciences from 1956 to 1960. He is a member of the American Pharmaceutical Association, the American Association for the Advancement of Science and the Society of Cosmetic Chemist, American Association of Pharmaceutical Scientists, Drug Information Association, American Foundation for Pharmaceutical Education, and Diplomate American Board of Forensic Examiners. He is the author of scientific publications and patents in the pharmaceutical field. Dr. Dash's extensive education in pharmaceutical sciences and his experience in the development of scientific products, including his experience in regulatory affairs, led to the conclusion that he is qualified to serve as a director.



**Chris Dick** has served as Chief Operating Officer since October 2008, acting Chief Executive Officer from November 2008 to September 15, 2009, and President since April 2009; Director from October 20, 2008 to June 24, 2009, and since October 23, 2009. Mr. Dick began at Elite in November 2002 as Vice President of Business Development. Since March 2006, Mr. Dick has been Executive Vice President of Corporate Development. From 1999 to 2002, Mr. Dick served as Director of Business Development for Elan Drug Delivery, Inc. responsible for licensing and business development of Elan's portfolio of drug delivery technologies. From 1978 to 1999, he held various business and technical positions at FMC Corporation which included responsibility for business development and marketing for EnTec, a drug delivery business unit within FMC Corporation's Pharmaceutical Division and marketing for its pharmaceutical functional coatings product line. Mr. Dick holds an M.B.A. from the Stern School of Business, New York University, and a B.S. and M.S. in Chemical Engineering from Cornell University. Mr. Dick's experience and qualifications in the pharmaceutical industry, specifically in the area of business and product development, provides specific attributes and qualifications to serve as a director, President and COO for the Company.

**Dr. Ashok G. Nigalaye** has served as a Director since June 24, 2009, member of the Compensation Committee since October 23, 2009 and Chief Scientific Officer since September 15, 2009. Dr. Nigalaye was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since December 2010, Dr. Nigalaye has been the Chairman and Chief Executive Officer of Epic Pharma, LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement. From July 2008 to December 2010, Dr. Nigalaye served as Epic Pharma's President and Chief Executive Officer. From August 1993 to February 2008, Dr. Nigalaye served as Vice President of Scientific Affairs and Operations of Actavis Totowa LLC, a manufacturer of generic pharmaceuticals, where he was responsible for directing and organizing company activities relating to pharmaceutical drug manufacturing, regulatory affairs and research and development. Dr. Nigalaye currently serves as a director of GTI Inc., a privately held company. Dr. Nigalaye holds a B.S. in Pharmacy from the University of Bombay, an M.S. in Industrial Pharmacy from Long Island University, and a Ph.D. in Industrial Pharmacy from St. John's University. Dr. Nigalaye is also a licensed pharmacist in the State of New York. Dr. Nigalaye's extensive education in pharmaceutical sciences and experience as a director and officer of pharmaceutical companies led to the conclusion that he is qualified to serve as a director.

**Jeenarine Narine** has served as a Director since June 24, 2009 and member of the Nominating Committee since October 23, 2009. Mr. Narine was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since December 2010, Mr. Narine has been the President and Chief Operating Officer of Epic Pharma, LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement, in which capacity he oversees all manufacturing operations. From July 2008 to December 2010, Mr. Narine served as Epic Pharma's Executive Vice President of Manufacturing and Operations. Mr. Narine is also the current President of Eniran Manufacturing Inc., a contract manufacturer of dietary and nutritional supplements, and has held such office since 2000. In addition, Mr. Narine has been since 1989 the President of A&J Machine Inc., a company owned by Mr. Narine that is engaged in the sales of new and used pharmaceutical manufacturing equipment. In addition to this professional experience, Mr. Narine graduated from the Guyana Industrial Institute, where he studied Metallogy and Welding. Mr. Narine's experience as President and Chief Operating Officer and, previously, as Executive Vice President of Manufacturing and Operations of Epic Pharma LLC and his knowledge of pharmaceutical manufacturing equipment led to the conclusion that he is qualified to serve as a director.

**Ram Potti** has served as a Director since June 24, 2009, chairman of the Nominating Committee since October 23, 2009 and member of the Audit Committee since October 23, 2009. Mr. Potti was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since December 2010, Mr. Potti has been the Vice President of Epic Pharma, LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement, in which capacity he handles the company's new ventures and products. From July 2008 to December 2010, Mr. Potti served as Epic Pharma's Vice President of Business Development. Mr. Potti is also the founder and current President of RSMB Investments LLC, an investment company that specializes in startup ventures in the healthcare and technology sectors. In addition, from 2002 to 2006, Mr. Potti was the President and Chief Operating Officer of Trigen Laboratories, a company which he founded that manufactures generic pharmaceutical products. Mr. Potti holds a B.S. in Chemistry from the University of Kerala, St. Albert's College. Mr. Potti's experience in developing business and products for Epic Pharma LLC led to the conclusion that he is qualified to serve as a director.

**Jeffrey Whitnell** has served as a Director since October 23, 2009, Chairman of the Audit Committee since October 23, 2009, member of the nominating committee since October 23, 2009 and designated by the Board as an “audit committee financial expert” as defined under applicable rules under the Securities Exchange Act of 1934, as amended, since October 23, 2009. Since June 2010, Mr. Whitnell has been the Vice President, Finance for Neurowave Medical Technologies, a medical device company. From June 2009 to June 2010, Mr. Whitnell provided financial consulting services to various healthcare companies, including Neurowave Medical Technologies. From June 2004 to June 2009, Mr. Whitnell was Chief Financial Officer and Senior Vice President of Finance at Akorn, Inc. From June 2002 to June 2004, Mr. Whitnell was Vice President of Finance and Treasurer for Ovation Pharmaceuticals. From 1997 to 2001, Mr. Whitnell was Vice President of Finance and Treasurer for MediChem Research. Prior to 1997, Mr. Whitnell held various finance positions at Akzo Nobel and Motorola. Mr. Whitnell began his career as an auditor with Arthur Andersen & Co. He is a certified public accountant and holds an M.B.A. in Finance from the University of Chicago and a B.S. in Accounting from the University of Illinois. Mr. Whitnell’s qualifications as an accounting and audit expert provide specific experience to serve as a director for the Company.

**Carter J. Ward** has served as Chief Financial Officer, Secretary and Treasurer of the Company since July 1, 2009. Prior to joining the Company, from July 2005 to April 2009, Mr. Ward filled multiple finance and supply chain leadership roles with the Actavis Group and its U.S. subsidiary, Amide Pharmaceuticals. From September 2004 to June 2005, Mr. Ward was a consultant, mainly engaged in improving internal controls and supporting Sarbanes Oxley compliance of Centennial Communications Inc., a NASDAQ listed wireless communications provider. From 1999 to September 2004, Mr. Ward was the Chief Financial Officer for Positive Healthcare/Ceejay Healthcare, a U.S.-Indian joint venture engaged in the manufacture and distribution of generic pharmaceuticals and nutraceuticals in India. Mr. Ward began his career as a certified public accountant in the audit department of KPMG and is a Certified Supply Chain Professional (“CSCP”). Mr. Ward holds a B.S. in Accounting from Long Island University, Brooklyn, NY, from where he graduated *summa cum laude*. Mr. Ward’s experience and expertise in the area of finance and more specifically, as a Certified Supply Chain Professional, provides the qualifications, attributes and skills to serve as an officer for the Company.

## **EXECUTIVE COMPENSATION**

### **Compensation discussion and analysis summary**

Our approach to executive compensation, one of the most important and complex aspects of corporate governance, is influenced by our belief in rewarding people for consistently strong execution and performance. We believe that the ability to attract and retain qualified executive officers and other key employees is essential to our long-term success.

### **Compensation Linked to Attainment of Performance Goals**

Our plan to obtain and retain highly skilled employees is to provide significant incentive compensation opportunities and market competitive salaries. The plan was intended to link individual employee objectives with overall company strategies and results, and to reward executive officers and significant employees for their individual contributions to those strategies and results. Furthermore, we believe that equity awards serve to align the interests of our executives with those of our stockholders. As such, equity is a key component of our compensation program.

### **Role of the Compensation Committee and its Advisors**

The Company formed the Compensation Committee in June 2007. Since the formation of the Compensation Committee all elements of the executives' compensation are determined by the Compensation Committee, which is comprised of a two independent non-employee directors, and one director who is also the Company's Chief Scientific Officer. However, the Compensation Committee's decisions concerning the compensation of the Company's Chief Executive Officer are subject to ratification by the independent directors of the Board of Directors. As of March 31, 2011, the members of the Compensation Committee were Barry Dash, Ashok Nigalaye and Jeffrey Whitnell. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants.

### **Our executive compensation program**

#### **Overview**

The primary elements of our executive compensation program are base salary, incentive cash and stock bonus opportunities and equity incentives typically in the form of stock option grants or payment of a portion of annual salary as stock. Although we provide other types of compensation, these three elements are the principal means by which we provide the Named Executive Officers with compensation opportunities.

The annual bonus opportunity and equity compensation components of the executive compensation program reflect our belief that a portion of an executive's compensation should be performance-based. This compensation is performance-based because payment is tied to the achievement of corporate performance goals. To the extent that performance goals are not achieved, executives will receive a lesser amount of total compensation.

### **Elements of our executive compensation program**

#### ***Base Salary***

We pay a base salary to certain of the Named Executive Officers, with such payments being made in either cash, Common Stock or a combination of cash and Common Stock. In general, base salaries for the Named Executive Officers are determined by evaluating the responsibilities of the executive's position, the executive's experience and the competitive marketplace. Base salary adjustments are considered and take into account changes in the executive's responsibilities, the executive's performance and changes in the competitive marketplace. We believe that the base salaries of the Named Executive Officers are appropriate within the context of the compensation elements provided to the executives and because they are at a level which remains competitive in the marketplace.

***Bonuses***

The Board of Directors may authorize us to give discretionary bonuses, payable in cash or shares of Common Stock, to the Named Executive Officers and other key employees. Such bonuses are designed to motivate the Named Executive Officers and other employees to achieve specified corporate, business unit and/or individual, strategic, operational and other performance objectives.

***Stock Options***

Stock options constitute performance-based compensation because they have value to the recipient only if the price of our Common Stock increases. Stock options for each of the Named Executive Officers generally vest over time, obtainment of a corporate goal or a combination of the two.

The grant of stock options at Elite is designed to motivate our Named Executive Officers to achieve our short-term and long-term corporate goals.

***Retirement and Deferred Compensation Benefits***

We do not presently provide the Named Executive Officers with a defined benefit pension plan or any supplemental executive retirement plans, nor do we provide the Named Executive Officers with retiree health benefits. We have adopted a deferred compensation plan under Section 401(k) of the Code. The plan provides for employees to defer compensation on a pretax basis subject to certain limits, however, Elite does not provide a matching contribution to its participants.

The retirement and deferred compensation benefits provided to the Named Executive Officers are not material factors considered in making other compensation determinations with respect to Named Executive Officers.

***Post-Termination/Change of Control Compensation***

We do not presently provide the Named Executive Officers with any plan or arrangement in connection with any termination, including, without limitation, through retirement, resignation, severance or constructive termination (including a change in responsibilities) of such Named Executive Officer's employment with the Company. We also do not presently provide the Named Executive Officers any plan or arrangement in connection with a change in control of the Company.

### **Perquisites**

As described in more detail below, the perquisites provided to certain of the Named Executive Officers consist of car allowances and life insurance premiums. These perquisites represent a small fraction of the total compensation of each such Named Executive Officer. The value of the perquisites we provide are taxable to the Named Executive Officers and the incremental cost to us of providing these perquisites is reflected in the Summary Compensation Table. The Board of Directors believes that the perquisites provided are reasonable and appropriate. For more information on perquisites provided to the Named Executive Officers, please see the "*All Other Compensation*" column of the Summary Compensation Table and "*Agreements with Named Executive Officers,*" below.

**Compensation of named executive officers**Summary Compensation Table

Name And Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
<u>Jerry Treppel</u>						
Chairman of the Board and Chief Executive Officer	2011 <sup>(1)</sup>	—	—	—	30,000	<sup>(2)</sup> 30,000
	2010 <sup>(1)</sup>	—	—	—	27,500	<sup>(3)</sup> 27,500
 Chris Dick						
President and Chief Operating Officer	2011 <sup>(1)</sup>	200,000 <sup>(4)</sup>	—	—	8,400	<sup>(7)</sup> 208,400
	2010 <sup>(1)</sup>	218,817 <sup>(5)</sup>	—	18,690 <sup>(6)</sup>	8,400	<sup>(7)</sup> 245,907
 Carter J. Ward						
Chief Financial Officer Secretary and Treasurer	2011 <sup>(1)</sup>	150,000 <sup>(8)</sup>	600 <sup>(10)</sup>	—	—	150,600
	2010 <sup>(1)</sup>	105,000 <sup>(9)</sup>	500 <sup>(10)</sup>	18,690 <sup>(11)</sup>	—	124,190

(1) Represents the fiscal years ended March 31, 2011 and 2010.

Represents compensation due to Mr. Treppel for his service as Chairman of the Board of Directors. Mr. Treppel receives no salary or additional compensation for his service as Chief Executive Officer. Compensation due to Mr. Treppel is paid via the issuance of Common Stock, pursuant to the Company's Director compensation policy.

(2) During Fiscal Year 2011, a total of 366,401 shares of Common Stock were issued to Mr. Treppel in satisfaction of Director's fees totaling \$22,500 earned during the year ended March 31, 2011. Mr. Treppel is owed an additional 136,845 shares of Common Stock in payment of Director's fees totaling \$7,500 due and owing for the three months ended March 31, 2011.

Represents compensation due to Mr. Treppel for his service as Chairman of the Board. \$12,500 of the total amount results from cash compensation due pursuant to the First Treppel Agreement and \$15,000 of the total amount results from compensation due for Mr. Treppel's service as Chairman of the Board. Mr. Treppel receives no salary (3) or additional compensation for his service as Chief Executive Officer. During Fiscal Year 2011, a total of 221,434 shares of Common Stock were issued to Mr. Treppel in satisfaction of Director's fees totaling \$20,417 which were due and payable as of the end of Fiscal Year 2010. As of March 31, 2011, the Company has no remaining liability to Mr. Treppel for Director's fees earned during Fiscal Year 2010.



(4) Represents total salaries due to Mr. Dick pursuant to the Second Dick Agreement. Of the total salary amount, \$175,000 was paid in cash as salary in accordance with the Company's payroll practices, and \$25,000 is to be paid via the issuance of Common Shares in lieu of cash. During Fiscal Year 2011, a total of 305,334 shares of Common Stock were issued to Mr. Dick in payment of salaries totaling \$18,750 earned during the year ended March 31, 2011. Mr. Dick is owed an additional 114,038 shares of Common Stock in payment of salaries earned and owing during the three months ended March 31, 2011.

(5) Represents salaries paid to Mr. Dick pursuant to the First Dick Agreement for the period April 2009 to November 2009, and pursuant to the Second Dick Agreement thereafter. Of the total salary amount, \$208,400 was paid in cash as salary in accordance with the Company's payroll practices, and \$10,417 was paid via the issuance of 120,859 shares of Common Stock, with such shares of Common Stock being issued during Fiscal Year 2011.

(6) Represents the value of incentive stock options granted to Mr. Dick under the Elite Pharmaceutical Inc. 2004 Stock Option Plan on January 18, 2010. Mr. Dick was granted options to purchase 200,000 shares of the Company's Common Stock at 10 cents per share. The options vest in equal increments of one-third of the total grant each on January 18, 2011, 2012 and 2013, respectively. The options expire on January 17, 2020. The options were valued using the Black Scholes Method. Please refer to note 19 of the audited financial statements as and for the fiscal year ended March 31, 2011 attached hereto for further detail on the valuation assumptions.

(7) Represents amounts paid for auto allowance.

(8) Represents total salaries due to Mr. Ward pursuant to the Second Ward Agreement. Of the total salary amount, \$125,000 was paid in cash as salary in accordance with the Company's payroll practices, and \$25,000 is to be paid via the issuance of Common Shares in lieu of cash. During Fiscal Year 2011, a total of 305,334 shares of Common Stock were issued to Mr. Ward in payment of salaries totaling \$18,750 earned during the year ended March 31, 2011. Mr. Ward is owed an additional 114,038 shares of Common Stock in payment of salaries earned and owing during the three months ended March 31, 2011.

(9) Represents salaries paid to Mr. Ward pursuant to the First Ward Agreement for the period July 2009 to October 2009, and pursuant to the Second Ward Agreement thereafter. Of the total salary amount, \$94,583 was paid in cash as salary in accordance with the Company's payroll practices and \$10,417 was paid via the issuance of 120,859 shares of Common Stock, with such shares of Common Stock being issued during Fiscal Year 2011.

(10) Represents discretionary bonuses award to Mr. Ward by the Chief Executive Officer

(11) Represents the value of incentive stock options granted to Mr. Ward under the Elite Pharmaceutical Inc. 2004 Stock Option Plan on January 18, 2010. Mr. Ward was granted options to purchase 200,000 shares of the Company's Common Stock at 10 cents per share. The options vest in equal increments of one-third of the total grant each on January 18, 2011, 2012 and 2013, respectively. The options expire on January 17, 2020. The options were valued using the Black Scholes Method. Please refer to note 19 of the audited financial statements as and for the fiscal year ended March 31, 2011 attached hereto for further details on the valuation assumptions.

### ***Agreements with Named Executive Officers***

#### **Jerry Treppel**

On December 1, 2008, Elite entered into a compensation agreement with Mr. Treppel (the "*First Treppel Agreement*") providing for the terms under which Mr. Treppel will serve as the non-executive Chairman of the Board. Pursuant to the First Treppel Agreement, Mr. Treppel will serve as the non-executive Chairman of the Board until immediately prior to the next annual meeting of the Company's stockholders; provided, however, that following such annual meeting, and each subsequent annual meeting of the Company's stockholders, if the Board elects Mr. Treppel as the non-executive Chairman of the Board, the term of the First Treppel Agreement will be extended through the earlier of (a) the date of the next subsequent annual meeting of the Company's stockholders and (b) the date upon which Mr. Treppel no longer serves as the non-executive Chairman.

During the term of the First Treppel Agreement, including any applicable extensions thereof, Mr. Treppel is entitled to cash compensation of \$2,083.33 on a monthly basis in lieu of, and not in addition to, any cash directors' fees and other compensation paid to other non-employee members of the Board. Mr. Treppel is also entitled to reimbursement of any expenses reasonably incurred in the performance of his duties under the First Treppel Agreement upon presentation of

proper written evidence of such expenditures.

In addition, pursuant to the terms of the First Treppel Agreement, Elite granted to Mr. Treppel under its 2004 Stock Option Plan non-qualified stock options to purchase 180,000 shares of Common Stock of Elite, par value \$0.001 per share, exercisable for a period of 10 years at an exercise price per share of \$0.06, subject to the terms and conditions of the related option agreement.

Under the First Treppel Agreement, Elite has also agreed to indemnify Mr. Treppel to the fullest extent permitted by law in accordance with the By-Laws of Elite against (a) reasonable expenses, including attorneys' fees, incurred by him in connection with any threatened, pending, or completed civil, criminal, administrative, investigative, or arbitrative action, suit, or proceeding (and any appeal therein) seeking to hold him liable for actions taken in his capacity as Chairman of the Board, and (b) reasonable payments made by him in satisfaction of any judgment, money decree, fine (including assessment of excise tax with respect to an employee benefit plan), penalty or settlement for which he may have become liable in any such action, suit or proceeding, provided that any such expenses or payments are not the result of Mr. Treppel's gross negligence, willful misconduct or reckless actions.

Either party may terminate the First Treppel Agreement, effective immediately upon the giving of written notice to the other party. If no such written notice is given, then the term of the First Treppel Agreement shall end immediately prior to the next annual meeting of the Company's stockholders (the "Treppel Term"), provided however, that following such annual meeting, and each subsequent meeting of the Company's stockholders, if the Board elects Mr. Treppel to continue to serve as the non-executive Chairman of the Board, the Treppel Term shall be extended through the earlier of (a) the date of the next subsequent annual meeting of the Company's stockholders and (b) the date upon which Mr. Treppel shall no longer serve as the non-executive Chairman of the Board.

On September 15, 2009, Mr. Treppel was appointed Chief Executive Officer of the Company. He continues to also serve as Chairman of the Board and he has agreed to forego any additional compensation related to his activities and Chief Executive Officer. Accordingly, Mr. Treppel's compensation as Chief Executive Officer and Chairman of the Board remains unchanged from the First Treppel Agreement.

On October 23, 2009, at the meeting of the Board held immediately after the annual stockholders meeting, Mr. Treppel's compensation as Chairman of the Board was revised to an annual amount of \$30,000, payable in common shares of the Company. The amount of common shares to be issued to Mr. Treppel in payment of compensation due to him as Chairman of the Board is calculated on a quarterly basis, and is equal to the quotient of the quarterly amount due of \$7,500, divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

Mr. Treppel agreed to forego any additional compensation for his services as Chief Executive Officer of the Company.

Chris C. Dick

In November 13, 2009, we entered into an employment agreement with Mr. Dick as our President and Chief Operating Officer (the "Dick Agreement"). The Dick Agreement is terminable at the will of either the Company or Mr. Dick, with or without notice and for any reason or no reason.

The Dick Agreement provides for a base salary of \$200,000, with \$175,000 of this amount being paid in cash and \$25,000 of this amount being paid in restricted shares of the Company's Common Stock. The Common Stock component of Mr. Dick's compensation is to be paid on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of \$6,250 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

In addition, the Dick Agreement provides for 25 days of paid vacation, the right to participate in all health insurance plans maintained by the Company for its employees, a monthly auto allowance of \$700 and term life insurance in the amount of \$500,000 payable to Mr. Dick's estate.

The Dick Agreement also required Mr. Dick's execution of a Proprietary Rights Agreement.

Carter J. Ward

On July 1, 2009, the Company appointed Carter J. Ward as Chief Financial Officer and entered into a letter agreement with Mr. Ward (the "*First Ward Agreement*") wherein Mr. Ward became an at-will employee as the Company's Chief Financial Officer. Under the terms of the First Ward Agreement, Mr. Ward will dedicate at least two business days per week toward fulfilling his responsibilities as Chief Financial Officer and will receive an annual base salary of \$60,000, payable in accordance with the Company's payroll practices. Mr. Ward is entitled to generally the same benefits offered to other employees of the Company, subject to applicable eligibility requirements and may become eligible for cash and/or equity based awards that may be granted by the Company in the future, with any such awards being granted in the discretion of the Company and its Chief Executive Officer.

On November 12, 2009, the Company entered into an employment agreement replacing the First Ward Agreement (the "*Second Ward Agreement*"). Pursuant to the terms of the Second Ward Agreement, Mr. Ward continues as an at-will employee of the Company as its Chief Financial Officer. Mr. Ward receives a base salary of \$150,000, with \$125,000 of such amount being paid in accordance with the Company's payroll practices and \$25,000 of such amount being paid by the issuance of restricted shares of Common Stock, in lieu of cash. The Common Stock component of Mr. Ward's compensation is to be paid on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of \$6,250 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

The following table sets forth information concerning stock option awards held by Named Executive Officers as of March 31, 2011:

Name	Number of securities underlying unexercised options Exercisable (#)	Number of securities underlying unexercised options Unexercisable (#)	Equity Incentive Plan Awards: Number of securities underlying unexercised unearned options (#)	Options Exercise Price (\$)	Option Expiration Date
<u>Chris Dick</u>	10,000	(1) —	—	2.34	10/31/2012
	10,000	(1) —	—	2.34	10/31/2012
	10,000	(1) —	—	2.34	10/31/2012
	10,000	(2) —	—	2.21	6/13/2012
	10,000	(2) —	—	2.21	6/13/2012
	10,000	(2) —	—	2.21	6/13/2012
	40,000	(3) —	—	2.80	7/14/2015
	250,000	(4) —	—	2.25	11/13/2016
	—	—	150,000	(5) 2.25	11/13/2016
	—	—	150,000	(6) 2.25	11/13/2016
	—	—	200,000	(7) 2.25	11/13/2016
	66,667	(8) —	133,333	(8) 0.10	1/17/2020
<u>Jerry Treppel</u>	60,000	(9) —	—	0.06	12/1/2018
	60,000	(10) —	—	0.06	12/1/2018
		60,000	(11) —	0.06	12/1/2018
<u>Carter J. Ward</u>	66,667	(8) —	133,333	(8) 0.10	1/17/2020

(1) Options vested on November 1, 2003, 2004 and 2005, respectively

(2) Options vested on June 13, 2004, 2005 and 2006, respectively

(3) Options vested on July 14, 2005

(4)

Options vested on November 3, 2006

These options vest upon the closing of an exclusive product license for the first of the United States national (5) market, the entire European Union market or the Japan market or product sale transaction of all of our ownership rights in the United States (only once for each individual product) for our first Non-Generic Opioid Product.

These options vest upon the closing of an exclusive product license for the United States national market, the entire (6) European Union market or the Japan market or product sale transaction of all of our ownership rights in the United States (only once for each individual product) for our second Non-Generic Opioid Product.

These options vest as follows: upon the commencement of the first Phase III clinical trial relating to the first (7) "Non-Generic Opioid Product" developed by the Company as to 125,000 options and relating to the second "Non-Generic Opioid Product" developed by the Company as to 75,000 options.

(8) Total of 200,000 options granted with such options vesting in annual increments on January 18, 2011, 2012 and 2013, with each increment equal to one-third of the total options granted.

(9) Options vested on December 1, 2009

(10) Options vested on December 1, 2010

(11) Options vest on December 1, 2011

## DIRECTOR COMPENSATION

The following table sets forth information concerning director compensation for the year ended March 31, 2011:

Name	Fees Earned or Paid In Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compen- sation Earnings (\$)	Non- qualified Deferred Compen- sation Earnings (\$)	All Other Compen- sation (\$)	Total (\$)
Barry Dash	9,125 (1)	25,000 (2)	—	—	—	5,000 (3)	39,125
Ashok Nigalaye	—	29,750 (4)	—	—	—	5,000 (3)	34,750
Jeenarine Narine	—	29,750 (4)	—	—	—	5,000 (3)	34,750
Ram Potti	—	29,750 (4)	—	—	—	5,000 (3)	34,750
Jeffrey Whitnell	—	25,000 (2)	—	—	—	5,000 (3)	30,000

(1) Represents directors fees earned and owing pursuant to the Company's policy with regards to directors fees in effect prior to October 23, 2009 which were paid in cash during the year ended March 31, 2011.

(2) Represents directors fees earned and owing pursuant to the Company's policy with regards to directors fees in effect since October 23, 2009. In accordance with such policy, all directors are to be paid via the issuance of Common Stock in lieu of cash. A total of 340,954 shares of Common Stock were issued during Fiscal 2011 to each Director in payment of the listed stock award.



Represents directors fees earned during the quarter ended March 31, 2011 for which 91,250 shares of Common  
(3) Stock is due and owing to each Director. As of the date of this Proxy Statement, such shares have not yet been issued.

Represents Directors fees earned and owing prior to October 23, 2009, which each Director elected to receive in  
Common Stock in lieu of cash and Directors fees earned and owing pursuant to the Company's policy with regards  
(4) to Directors' fees in effect since October 23, 2009. In accordance with such policy, all directors are to be paid via the issuance of Common Stock in lieu of cash. A total of 407,949 shares of Common Stock were issued during Fiscal 2011 in payment of the listed stock award.

### ***Director Fee Compensation***

As of October 23, 2009, the Company's policy regarding director fees was as follows: (i) Directors who are employees or consultants of the Company (and/or any of its subsidiaries), except for Mr. Jerry Treppel, Chief Executive Officer and Dr. Ashok Nigalaye, Chief Scientific Officer, receive no additional remuneration for serving as directors or members of committees of the Board; (ii) all Directors are entitled to reimbursement for out-of-pocket expenses incurred by them in connection with their attendance at the Board or committee meetings; (iii) Directors who are not employees or consultants of the Company (and/or any of its subsidiaries) receive \$20,000 annual retainer fee, payable on a quarterly basis, in arrears, for their service on the Board and all committees; (iv) The Chairman of the Board receives a \$30,000 annual retainer fee, payable on a quarterly basis, in arrears; (v) Directors and the Chairman do not receive any additional compensation for attendance at or chairing of any meetings. (vi) Mr. Jerry Treppel receives no additional compensation, above the annual retainer fee due to the Chairman of the Board, for his services as Chief Executive Officer (vii) Dr. Ashok Nigalaye receives no additional compensation, above the annual retainer fee due to Directors, for his services as Chief Scientific Officer. (viii) All Director and Chairman fees are paid via the issuance of Common Stock of the Company, in lieu of cash, as described below.

### ***Director Equity Compensation***

As of October 23, 2009, Members of the Board of Directors and the Chairman are paid their annual retainer fees via the issuance of restricted shares of Common Stock of the Company, in lieu of cash. The number of shares to be issued to each Director and the Chairman is equal to the quotient of the quarterly amount due to each Director and the Chairman, respectively, divided by the average daily closing price of the Company's stock for the quarter just ended.

Members of the Board of Directors during the fiscal years ended March 31, 2011 and March 31, 2010 did not receive any options or equity compensation for serving as directors other than the grant of grant of 180,000 options to the Chairman of the Board in December 2008 and shares of Common Stock earned in lieu of cash in relation to Director and Chairman fees due since October 23, 2009.

### ***Other***

The Company has entered into indemnification agreements with each of its directors to indemnify them to the fullest extent permitted under Delaware General Corporation Law.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information, as of February 21, 2012 (except as otherwise indicated), regarding beneficial ownership of our Common Stock by (i) each person who is known by us to own beneficially more than 5% of the Common Stock, (ii) each of our directors and nominees for director, (iii) each of the Named Executive Officers (as defined below) and (iv) all our directors and executive officers as a group. As of February 21, 2012, we had 321,827,276 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 1,937.5 shares of Series E Preferred Stock outstanding as of February 21, 2012 are entitled to vote, on an as-converted basis, with the Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting). The 796.6 shares of Series B Preferred Stock and 2,966 shares of Series C Preferred Stock outstanding as of February 21, 2012 are nonvoting. As of February 21, 2012, none of the individuals listed below beneficially owned any shares of Series B Preferred Stock, Series C Preferred Stock or Series E Preferred Stock, except for the following (as further described in the footnotes to the table): (a) 1,937.5 shares of Series E Preferred Stock were beneficially owned by Messrs. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti.

As used in the table below and elsewhere in this Proxy Statement, the term beneficial ownership with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the 60 days immediately following February 20, 2012. Except as otherwise indicated, the stockholders listed in the table have sole voting and investment powers with respect to the shares indicated.

Name and Address Of Beneficial Owner of Common Stock	Amount and Nature of Beneficial Ownership***		Percent (%) of Class Beneficially Owned	
Chris Dick, President and Chief Operating Officer*	1,723,873	(1)	48	**
Barry Dash, Director*	743,346	(2)	48	**
Jerry Treppel, Chairman of the Board and Chief Executive Officer*	3,291,452	(3)	48	**
Ashok G. Nigalaye, Chief Scientific Officer and Director *	255,221,491	(4)	48	%
Jeenarine Narine, Director *	255,221,491	(4)	48	%
Ram Potti, Director *	254,813,542	(4)	48	%
Jeffrey Whitnell *	572,585	(5)	48	**
Carter J. Ward, Chief Financial Officer *	849,065	(6)	48	**

Epic Investments LLC 227-15 North Conduit Ave. Laurelton, NY 11413	246,674,934	(4)	48	%
All Directors and Officers as a group	255,366,046	(7)	50	%

\* The address is c/o Elite Pharmaceuticals Inc., 165 Ludlow Avenue, Northvale, NJ 07647.

\*\* Less than 1%

Includes options to purchase 850,000 shares of Common Stock, 24,808 shares of Common Stock and 426,192 shares of Common Stock issued to Mr. Dick pursuant to the employment agreement between the Company and Mr. Dick dated November 13, 2009 (the "Dick Agreement"), 289,539 shares of Common Stock due and owing to Mr. Dick as of December 31, 2011 for salaries earned for the 12 month period ended on such date, pursuant to the Dick (1) Agreement and options to purchase 133,334 shares of Common Stock granted to Mr. Dick under the Company's 2004 Equity Incentive Plan. In addition, Mr. Dick has been granted options to purchase 66,666 shares of Common Stock under the Company's 2004 Equity Incentive Plan which were not vested as on February 20, 2012 and accordingly not included as part of Mr. Dick's beneficial ownership. These options are scheduled to vest on January 18, 2013.

Includes options to purchase 120,000 shares of Common Stock, warrants to purchase 14,829 shares of Common Stock, 35,932 shares of Common Stock, 340,954 shares of Common Stock issued to Dr. Dash in payment of (2) Director Fees pursuant to the Company's policy regarding payment of Director's Fees and 231,631 shares of Common Stock due and owing to Dr. Dash as of December 31, 2011 for Director's fees earned by Dr. Dash for the 12 month period ended on such date, pursuant to the Company's policy regarding payment of Director's Fees.

Includes 419,059 shares of restricted Common Stock, 500,000 shares of unrestricted Common Stock, warrants to purchase up to 1,257,113 of Common Stock, an option to purchase up to 180,000 shares of Common Stock, (3) 587,834 shares of Common Stock issued to Mr. Treppel in payment of Chairman of the Board Fees earned pursuant to the Company's policy regarding payment of the Chairman's Fees and 347,446 shares of Common Stock due and owing to Mr. Treppel as of December 31, 2011 for Chairman's Fees earned by Mr. Treppel for the 12 month period ended on such date, pursuant to the Company's policy regarding payment of the Chairman's Fees.

Represents 1,937.5 shares of Series E Preferred Stock convertible into 78,760,163 shares of Common Stock, 55,821,718 shares of Common Stock and warrants to purchase 120,000,000 shares of Common Stock held by Epic Investments, LLC, a Delaware limited liability company. Messrs. Nigalaye, Narine and Potti are executive officers and equity owners of Epic Pharma, LLC, a Delaware limited liability company, and Epic Investments, LLC, a Delaware limited liability company. Epic Pharma, LLC is an equity owner of Epic Investments, LLC. Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti share voting and investment control over, and are indirect beneficial (4) owners of, the shares. The interest of Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti in the shares is limited, and each disclaims beneficial ownership of such shares except to the extent of its pecuniary interest in Epic Investments, LLC. In addition to beneficial interests related to Epic Investments, Messrs. Nigalaye and Narine each own 407,949 shares of Common Stock which were issued in payment of Director's Fees pursuant to the Company's policy regarding payment of Director's Fees and Messrs. Nigalaye, Narine and Potti have 231,631 shares of Common Stock due and owing to them as of December 31, 2011 for Director's Fees earned by each of Dr. Nigalaye, Mr. Potti and Mr. Narine, for the 12 month period ended on such date, pursuant to the Company's policy regarding payment of Director's Fees.

Includes 340,954 shares of Common Stock issued to Mr. Whitnell in payment of Director Fees pursuant to the (5) Company's policy regarding payment of Director's Fees and 231,631 shares of Common Stock due and owing to Mr. Whitnell as of December 31, 2011 for Director's fees earned by Mr. Whitnell for the 12 month period ended on such date, pursuant to the Company's policy regarding payment of Director's Fees.

Includes 426,192 shares of Common Stock issued to Mr. Ward pursuant to the employment agreement between the Company and Mr. Ward dated November 13, 2009 (the "Ward Agreement"), 289,539 shares of Common Stock due and owing to Mr. Ward as of December 31, 2011 for salaries earned for the 12 month period ended on such date, (6) pursuant to the Ward Agreement and options to purchase 133,334 shares of Common Stock granted to Mr. Ward under the Company's 2004 Equity Incentive Plan. In addition, Mr. Ward has been granted options to purchase 66,666 shares of Common Stock under the Company's 2004 Equity Incentive Plan which were not vested as on February 21, 2012 and accordingly not included as part of Mr. Ward's beneficial ownership. These options are scheduled to vest on January 18, 2013.

Includes 2,085,640 shares of Common Stock issued to the Chairman and Directors in payment of Chairman and Director Fees pursuant to the Company's policy regarding payment of Chairman and Directors Fees, 852,384 shares of Common Stock issued pursuant to employment contracts with Officers, 3,112.5 shares of Series E Preferred Stock convertible into 126,674,934 shares of Common Stock, Warrants to purchase 121,271,942 shares of Common Stock, Options to purchase 1,416,668 shares of Common Stock, 979,799 shares of Common Stock, 1,505,601 of Common Shares due and owing to the Chairman and Directors as of December 31, 2011 for (7) Chairman's and Director's Fees earned during the 12 month period ending on such date pursuant to the Company's policy regarding payment of Chairman and Director's Fees, and 579,078 shares of Common Stock due and owing to Officers as of December 31, 2011 for salaries earned during the 12 month period ended on such date pursuant to the employment contracts of each Officer. In addition, there are options to purchase 133,332 shares of Common Stock which have been granted to Officers of the Company but which were not vested as on February 21, 2012, and accordingly not included in the beneficial ownership amounts. These options are scheduled to vest on January 18, 2013.

### **Changes in Control**

The following information is provided with respect to any arrangements known to the Company the operation of which may at a subsequent date result in a change of control of the Company. As of February 21, 2012, Epic held a beneficial interest in 1,937.5 shares of Series E Preferred Stock convertible into 78,760,163 shares of Common Stock, 55,821,718 shares of Common Stock and warrants to purchase up to 120,000,000 shares of Common Stock representing its beneficial ownership of approximately 48% of the Company's outstanding Common Stock as of such date (calculated in accordance with Rule 13d-3 of the Exchange Act). Further, the 1,937.5 shares of Series E Preferred Stock in which Epic has a beneficial interest as of February 21, 2012 are entitled to vote 78,760,163 shares of Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting).

In addition, in connection with subsequent closings of the transactions contemplated by the Epic Strategic Alliance Agreement, Epic could acquire an additional 437.5 shares of Series E Preferred Stock. Further, with respect to the products developed by Epic at the Facility under the Epic Strategic Alliance Agreement, the Company would also be obligated to issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of its Common Stock upon the receipt by Elite from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at Elite's facility and (b) up to an aggregate of 40,000,000 additional shares of its Common Stock following the receipt by Elite from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and immediate-release products developed by Epic at the Facility.

If Elite is required to issue such additional securities to Epic in accordance with the Epic Strategic Alliance Agreement, Epic could beneficially own in excess of 50% of the issued and outstanding Common Stock or other voting securities of the Company. Further, under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that Epic will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a

majority of the Board of Directors.

57

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND CORPORATE GOVERNANCE

### Certain Related Person Transactions

#### *Transactions with Epic Pharma LLC and Epic Investments LLC*

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, each were elected as members of our Board of Directors, effective June 24, 2009, as the three directors that Epic is entitled to designate for appointment to the Board pursuant to the terms of the Epic Strategic Alliance Agreement. Messrs. Nigalaye, Narine and Potti are also officers of Epic Pharma, LLC, in the following capacities:

- Mr. Nigalaye, Chairman and Chief Executive Officer of Epic Pharma, LLC;
- Mr. Narine, President and Chief Operating Officer of Epic Pharma, LLC;
- Mr. Potti, Vice President of Epic Pharma, LLC.

As part of the operation of the strategic alliance, the Company and Epic identified areas of synergy, including, without limitation, raw materials used by both entities, and various regulatory and operational resources existing at Epic that could be utilized by the Company.

With regards to synergies related to raw materials usage, the strategic alliance allowed the Company to purchase such raw materials from Epic, at the Epic acquisition cost, without markup. In all cases, the acquisition cost of Epic was lower than those costs available to the Company, mainly as a result of efficiencies of scale generated by significantly larger volumes purchased by Epic during the course of their normal operations. During the fiscal year ended 3/31/2011, an aggregate amount of \$232,305 in such materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma's acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC's acquisition cost.

With regards to synergies related to regulatory and operational resources, the strategic alliance allowed the Company to utilize Epic's substantial resources and technical competencies on an "as needed" basis at a cost equal to Epic's actual cost for only the resources utilized by the Company. Without such access to Epic's resources, the Company would have to invest significant amounts in human resources and fixed assets as well as incur substantial costs with third party providers to provide the same resources provided by Epic and necessary for the operations of the Company. During the fiscal year ended 3/31/2011, an aggregate amount of \$73,440 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company as well as



\$140,000 in manufacturing equipment.

The Company also purchased an ANDA for Phentermine 37.5 mg tablets from Epic Pharma LLC for a cost of \$450,000.

Total purchases from Epic by the Company during the fiscal year ended 3/31/2011 were \$895,745.

During the fiscal year ended 3/31/2011, the Company also performed method development services for Epic Pharma LLC, for which it was paid \$25,000, sold retired equipment to Epic for \$30,000 and sold excess raw materials to Epic for a total of \$2,903.

Total payments from Epic Pharma LLC to the Company during the fiscal year ended 3/31/2011 were \$57,903.

### **Director Independence**

All related person transactions are reviewed and, as appropriate, may be approved or ratified by the Board of Directors. If a Director is involved in the transaction, he or she may not participate in any review, approval or ratification of such transaction. Related person transactions are approved by the Board of Directors only if, based on all of the facts and circumstances, they are in, or not inconsistent with, our best interests and the best interests of our stockholders, as the Board of Directors determines in good faith. The Board of Directors takes into account, among other factors it deems appropriate, whether the transaction is on terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related person's interest in the transaction. The Board of Directors may also impose such conditions as it deems necessary and appropriate on us or the related person in connection with the transaction.

In the case of a transaction presented to the Board of Directors for ratification, the Board of Directors may ratify the transaction or determine whether rescission of the transaction is appropriate.

## **ADDITIONAL INFORMATION**

Federal securities laws require us to file information with the Commission concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, and other information with the Commission. You can inspect and copy this information at the public reference facility maintained by the Commission at 100 F Street, NE, Washington, D.C. 20549.

You can get additional information about the operation of the Commission's public reference facilities by calling the Commission at 1-800-SEC-0330. The Commission also maintains a web site (<http://www.sec.gov>) at which you can read or download our reports and other information.

We have filed with the Commission a registration statement on Form S-1 under the Securities Act of 1933 with respect to the Common Stock being offered hereby. As permitted by the rules and regulations of the Commission, this prospectus does not contain all the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to Elite Pharmaceuticals, Inc. and the Common Stock offered hereby, reference is made to the registration statement, and such exhibits and schedules. A copy of the registration statement, and the exhibits and schedules thereto, may be inspected without charge at the public reference facilities maintained by the Commission at the addresses set forth above, and copies of all or any part of the registration statement may be obtained from such offices upon payment of the fees prescribed by the Commission. In addition, the registration statement may be accessed at the Commission's web site.

## **LEGAL MATTERS**

The validity of the Common Stock offered in this Prospectus has been passed upon for us by Richard Feiner, Esq., 381 Park Avenue South, Suite 1601, New York, New York 10016.

## **EXPERTS**

The consolidated balance sheets of Elite Pharmaceuticals, Inc. as of March 31, 2011 and 2010 and the related consolidated statements of operations, stockholder's deficit, and cash flows for each of the two years in the period ended March 31, 2011, included in this registration statement on Form S-1, have been audited by Demetrius & Company, LLC, an independent registered public accounting firm, as stated in their report appearing with the financial statements. These financial statements are included in reliance upon the report of Demetrius & Company, LLC. given upon their authority as experts in accounting and auditing.



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

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

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

***CONDENSED CONSOLIDATED BALANCE SHEETS***

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

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

F-2

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

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	December 31,		December 31,	
	2011	2010	2011	2010
<b>REVENUES</b>				
Manufacturing Fees	\$ 170,099	\$ 901,653	\$ 847,832	\$ 2,236,064
Royalties & Profit Splits	20,127	231,742	430,228	582,677
Lab Fee Revenues	319,712	92,902	495,987	234,123
<b>Total Revenues</b>	<b>509,938</b>	<b>1,226,297</b>	<b>1,774,047</b>	<b>3,052,864</b>
<b>COSTS OF REVENUES</b>	<b>156,590</b>	<b>641,524</b>	<b>658,289</b>	<b>1,618,820</b>
<b>Gross Profit</b>	<b>353,348</b>	<b>584,773</b>	<b>1,115,758</b>	<b>1,434,044</b>
<b>OPERATING EXPENSES</b>				
Research and Development	386,430	179,525	1,030,141	494,968
General and Administrative	288,416	315,537	1,089,909	947,761
Non-cash compensation through issuance of stock options	6,113	7,580	18,340	33,268
Depreciation and Amortization	103,339	9,200	336,454	113,490
<b>Total Operating Expenses</b>	<b>784,298</b>	<b>511,842</b>	<b>2,474,844</b>	<b>1,589,487</b>
<b>PROFIT / (LOSS) FROM OPERATIONS</b>	<b>(430,950 )</b>	<b>72,931</b>	<b>(1,359,086 )</b>	<b>(155,443 )</b>
<b>OTHER INCOME / (EXPENSES)</b>				
Interest expense, net	(57,138 )	(58,059 )	(172,438 )	(173,867 )
Change in fair value of warrant derivatives	4,586,076	2,064,745	1,499,682	4,788,493
Change in fair value of preferred share derivatives	4,749,332	4,156,097	(7,665,268 )	(412,908 )
Interest expense attributable to preferred share derivatives	(86,325 )	(306,440 )	(353,500 )	(976,799 )
Discount in Series E issuance attributable to beneficial conversion features	—	—	—	(39,132 )
<b>Total Other Income / (Expense)</b>	<b>9,191,945</b>	<b>5,856,343</b>	<b>(6,691,524 )</b>	<b>3,185,787</b>
<b>INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES</b>	<b>8,760,995</b>	<b>5,929,274</b>	<b>(8,050,610 )</b>	<b>3,030,344</b>
<b>PROVISION FOR INCOME TAXES</b>	<b>—</b>	<b>1,062</b>	<b>2,500</b>	<b>7,302</b>

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 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 through the issuance of stock options			18,339				18,339

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 consolidated financial statements**

F-4

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

	NINE MONTHS ENDED DECEMBER	
	30,	2010
	2011	
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net (Loss) Income	\$ (8,053,110	) \$ 3,023,042
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	363,542	362,381
Change in fair value of warrant derivative liability	(1,499,682	) (4,788,493 )
Change in fair value of preferred share derivative liability	7,665,268	412,908
Discount in Series E issuance attributable to embedded beneficial conversion feature	—	39,132
Preferred share derivative interest satisfied by the issuance of common stock	549,854	897,680
Non-cash compensation satisfied by the issuance of common stock and options	18,339	33,268
Non-cash rent expense	8,686	22,584
Non-cash lease accretion	949	601
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
<b>NET CASH (USED IN) / PROVIDED BY OPERATING ACTIVITIES</b>	<b>(789,098</b>	<b>) 318,456</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(78,427	) (35,398 )
Cost of leasehold improvements	(390,845	) (176,645 )
Costs incurred for intellectual property assets	(32,406	) (191,274 )
Proceeds from sale of retired equipment	—	30,000
Deposits to restricted cash, net	(41,826	) (51,464 )
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(543,504</b>	<b>) (424,781 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of Series E Convertible Preferred Stock	125,000	
Other loan payments	(9,565	) (56,669 )
Costs associated with raising capital	(40,000	)
<b>NET CASH PROVIDED BY / (USED IN) FINANCING ACTIVITIES</b>	<b>75,435</b>	<b>(56,669 )</b>

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 consolidated financial statements**

F-5

**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 these condensed consolidated financial statements 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 audited consolidated financial statements and notes thereto as and for the fiscal year ended March 31, 2011 included herewith. 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.

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

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

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

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

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

As of December 31, 2011, we had cash reserves of \$0.6 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first three of a total of twelve quarterly payments of \$62,500 each, there can be no assurances that Elite will be able to consummate the remaining nine quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of \$0.5625 million. Even if we were to receive the remaining nine quarterly payments due pursuant to the Epic Strategic Alliance Agreement, we still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all.

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.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50 mg 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:

Intangible assets at March 31, 2011 (audited)	
Patent application costs	147,556
ANDA acquisitions	450,000
Total Intangible Assets at March 31, 2011 (audited)	597,556

Intangible asset costs capitalized during the nine months ended December 31, 2011	
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 1<sup>st</sup> of varying amounts as specified in the loan documents and semi-annual interest payments on March 1<sup>st</sup> and September 1<sup>st</sup>, equal to interest due on the outstanding principal at the applicable rate for the semi-annual period just ended.

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

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

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

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

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

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

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

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

**NOTE 6 - PREFERRED STOCK DERIVATIVE LIABILITIES**

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

Preferred Stock Derivative Liability as of December 31, 2011

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

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.

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	154,153,308	153,674,610
Fair Value of Warrant Derivative Liability	\$ 10,543,145	\$ 24,126,576	\$ 13,629,540	\$ 9,043,464

## CHANGE IN VALUE OF WARRANT DERIVATIVE LIABILITY

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

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

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

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

**NOTE 8 - OPERATING LEASES**

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

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

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

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

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

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

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



## RENT EXPENSE

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

## DEFERRED RENT LIABILITY (LONG-TERM LIABILITY)

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

F-12

**NOTE 9 - DEFERRED REVENUES**

Deferred revenues totaling \$182,224 represents the unamortized amount of a \$200,000 advance payment received from Precision Dose Inc. for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license. The current portion of deferred revenues, totaling \$13,333 represents the revenue that will be recognized over the 12 months immediately subsequent to December 31, 2011. The long term portion of deferred revenues, totaling \$168,891, represents the revenue that will be recognized during the period that begins more than twelve months subsequent to December 31, 2011.

**NOTE 10 - STOCKHOLDERS' EQUITY****Common Stock**

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

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

Common shares issued pursuant to the conversion of Series D Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$9,473,715 at the time of their conversion	58,042,857
Common shares issued pursuant to the conversion of Series E Preferred Share derivatives, with such derivative liabilities being valued at an aggregate of \$386,905 at the time of their conversion	2,976,190
Total Common Shares issued during the nine months ended December 31, 2011	84,285,078

**Options**

At December 31, 2011, the Company had 1,943,605 options fully vested and outstanding with exercise prices ranging from \$0.06 to \$3.00 per share; each option representing the right to purchase one share of common stock. In addition, there are 1,065,395 options issued pursuant to the Company's 2004 Stock Option Plan which are outstanding and not vested, with exercise prices ranging from \$0.06 to \$2.50 per share. These options are scheduled to vest in equal annual increments on January 18, 2012 and 2013 or upon the occurrence of certain defined events and require that employees awarded such options be employed by the Company on the vesting date.

**NOTE 11 - PER SHARE INFORMATION**

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

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

**NOTE 12 - SUBSEQUENT EVENTS****Common shares issued in lieu of cash in payment of derivative interest expense**

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

**Reincorporation in Nevada**

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

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

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

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

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

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

### **Methadone shipment**

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

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

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

**Approval of Hydromorphone 8 mg**

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

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

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

## AUDITED FINANCIAL STATEMENTS

### Report of Independent Registered Public Accounting Firm

To The Board of Directors and

Shareholders of Elite Pharmaceuticals, Inc. & Subsidiaries

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiaries (“the Company”) as of March 31, 2011 and 2010 and the related consolidated statements of operations, stockholders' deficit and cash flows for each of the years in the two-year period ended March 31, 2011. The Company’s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2011 and 2010 and the results of their operations and their cash flows for each of the years in the two year period ended March 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that Elite Pharmaceuticals, Inc. and Subsidiaries will continue as a going concern. As shown in the consolidated financial statements, the Company has experienced significant losses resulting in a working capital deficiency and shareholders’ deficit. These conditions raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are more fully described in Note 2. The consolidated financial statements do not include any adjustments that might



result from the outcome of these uncertainties.

/s/Demetrius & Company, L.L.C.

Wayne, New Jersey 07470

June 29, 2011

F-16

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****MARCH 31, 2011 and 2010**

	2011	2010
<b>ASSETS</b>		
<b><u>CURRENT ASSETS</u></b>		
Cash and cash equivalents	\$1,825,858	\$578,187
Accounts receivable (net of allowance for doubtful accounts of -0-)	571,667	404,961
Inventories (net of reserve of \$1,047,456 and \$494,425, respectively)	616,362	1,371,292
Prepaid expenses and other current assets	133,471	131,507
 Total Current Assets	 3,147,358	 2,485,947
 <b><u>PROPERTY AND EQUIPMENT</u></b> - net of accumulated depreciation of \$4,189,618 and \$3,840,279, respectively	 4,118,274	 4,095,814
 <b><u>INTANGIBLE ASSETS</u></b> – net of accumulated amortization of \$-0- and \$-76,434-, respectively	 597,556	 96,407
 <b><u>OTHER ASSETS</u></b>		
Investment in Novel Laboratories, Inc.	3,329,322	3,329,322
Security deposits	28,377	14,652
Restricted cash – debt service for EDA bonds	291,420	294,836
EDA bond offering costs, net of accumulated amortization of \$78,898 and \$64,767, respectively	275,554	289,685
 Total Other Assets	 3,924,673	 3,928,495
 TOTAL ASSETS	 \$11,787,862	 \$10,606,663

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****MARCH 31, 2011 and 2010**

	2011	2010
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b><u>CURRENT LIABILITIES</u></b>		
EDA bonds payable	\$3,385,000	\$3,385,000
Short term loans and current portion of long-term debt	13,105	82,302
Accounts payable and accrued expenses	935,797	986,777
Customer Deposits	39,400	—
Deferred revenues – current	13,333	—
Preferred share derivative interest payable	282,680	306,440
 Total Current Liabilities	 4,669,315	 4,760,519
<b><u>LONG TERM LIABILITIES</u></b>		
Deferred revenues	178,890	—
Long term debt, less current portion	6,717	19,823
Other long term liabilities	68,746	
Derivative liability – preferred shares	14,192,329	7,924,763
Derivative liability – warrants	10,543,145	8,499,423
 Total Long Term Liabilities	 24,989,827	 16,444,009
 TOTAL LIABILITIES	 29,659,142	 21,204,528
<b><u>STOCKHOLDERS' DEFICIT</u></b>		
Common stock – par value \$0.001, Authorized 355,516,558 shares Issued and outstanding – 180,545,657 shares and 83,950,168 shares, respectively	180,546	83,950
 Additional paid-in-capital	 97,116,044	 90,903,896
 Accumulated deficit	 (114,861,029)	 (101,278,870)
 Treasury stock at cost (100,000 common shares)	 (306,841 )	 (306,841 )
 TOTAL STOCKHOLDERS' DEFICIT	 (17,871,280 )	 (10,597,865 )
 TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	 \$11,787,862	 \$10,606,663

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



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended March 31,	
	2011	2010
<b>REVENUES</b>		
Manufacturing Fees	\$ 3,086,183	\$ 2,575,942
Royalties	831,538	763,928
Lab Fee Revenues	348,242	4,429
Total Revenues	4,265,963	3,344,299
<b>COSTS OF REVENUES</b>	2,675,118	2,305,763
Gross Profit	1,590,845	1,038,536
<b>OPERATING EXPENSES</b>		
Research and Development	1,385,211	794,433
General and Administrative	876,014	1,841,425
Non-cash compensation through issuance of stock options	42,016	125,004
Depreciation and Amortization	173,364	213,995
Total Operating Expenses	2,476,605	2,974,857
<b>(LOSS) FROM OPERATIONS</b>	(885,760 )	(1,936,321 )
<b>OTHER INCOME / (EXPENSES)</b>		
Interest expense, net	(231,745 )	(260,337 )
Change in fair value of warrant derivatives	(1,297,998 )	(3,792,130 )
Change in fair value of preferred share derivatives	(10,416,376 )	(283,920 )
Interest expense attributable to preferred share derivatives	(1,259,480 )	(1,271,254 )
Discount in Series E issuance attributable to beneficial conversion features	(292,213 )	(512,912 )
Proceeds from litigation settlement	500,000	—
Total Other Income / (Expense)	(12,997,812 )	(6,120,553 )
<b>(LOSS) BEFORE PROVISION FOR INCOME TAXES</b>	(13,883,572 )	(8,056,874 )
<b>CREDIT FOR INCOME TAXES</b>	301,413	—
<b>NET (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	\$(13,582,159 )	\$(8,056,874 )
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	\$(0.14 )	\$(0.11 )
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>	100,020,520	75,581,345

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

F-19

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEAR ENDED MARCH 31, 2010**

(page 1 of 2)

	Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Common Stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at March 31, 2009	1,046	\$ 11	13,705	\$ 137	9,154	\$ 91	60,839,374	\$ 608,394
Cumulative effect of reclassification of preferred stock and warrants		(11 )		(137 )		(91 )		
Proceeds received in exchange for beneficial conversion features embedded in Series E Preferred Shares								
Conversion of Series B, Series C and Series D Preferred Shares into Common Shares	(150 )		(8,287 )		(146 )		5,383,010	53,830
Costs associated with raising capital								
Non-cash compensation through the issuance of stock options and warrants								
Net income for the year ended March 31, 2010								
Dividends							3,914,944	39,149
Common shares issued in lieu of cash in payment of preferred share derivative interest expense							12,699,749	93,504
Reduction in par value								(712,040)
Common shares issued in lieu of cash in payment of legal and consulting expenses							1,113,091	1,113

Write-off of subscription  
receivable from defunct company

Balance at March 31, 2010	896	—	5,418	—	9,008	—	83,950,168	\$83,950
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**The accompanying notes are an integral part of the consolidated financial statements**

F-20



**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEAR ENDED MARCH 31, 2010**

(page 2 of 2)

	Subscription Receivable	Additional Paid-In Capital	Treasury Stock Shares	Amount	Accumulated Deficit	Stockholders (Deficit) Equity
Balance at March 31, 2009	\$ (75,000 )	\$95,718,082	(100,000)	\$(306,841)	\$(90,001,793 )	\$ 5,943,081
Cumulative effect of reclassification of preferred stock and warrants		(7,144,131 )			(3,220,203 )	(10,364,573 )
Proceeds received in exchange for beneficial conversion features embedded in Series E Preferred Shares		512,912				512,912
Conversion of Series B, Series C and Series D Preferred Shares into Common Shares	(150 )	14,000				67,830
Costs associated with raising capital		(183,456 )				(183,456 )
Non-cash compensation through the issuance of stock options and warrants		125,004				125,004
Net income for the year ended March 31, 2010					(8,056,874 )	(8,056,874 )
Dividends		319,472				358,621
Common shares issued in lieu of cash in payment of preferred share derivative interest expense		805,882				899,386
Reduction in par value		712,040				
Common shares issued in lieu of cash in payment of legal		99,091				100,204

and consulting expenses

Write-off of subscription receivable from defunct company	75,000	(75,000 )
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Balance at March 31, 2010	—	\$90,903,896	(100,000)	\$(306,841)	\$(101,278,870)	\$(10,597,865 )
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**The accompanying notes are an integral part of the consolidated financial statements**

F-21

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEAR ENDED MARCH 31, 2011**

	Common Stock		Additional	Treasury Stock		Accumulated	Stockholders'
	Shares	Amount	Paid-In Capital	Shares	Amount	Deficit	Deficit
Balance at Mar 31, 2010	83,950,168	\$83,950	\$90,903,896	100,000	\$(306,841)	\$(101,278,870)	\$(10,597,865)
Net Income						(13,582,159 )	(13,582,159)
Common shares issued in lieu of cash in payment of preferred share derivative interest expense	21,241,590	21,242	1,261,999				1,283,240
Common shares issued pursuant to the conversion of Series D Convertible Preferred Derivatives	70,649,154	70,649	4,394,935				4,465,584
Non-cash compensation through the issuance of stock options			42,017				42,017
Common shares issued pursuant to ANDA purchase agreement dated 5/18/2010	937,500	938	74,062				75,000
Common shares issued in lieu of cash in payment of consulting expenses	343,425	343	13,394				13,737
Common shares issued in payment of	2,493,589	2,494	97,249				99,743

Director's Fees

Common shares issued in payment of employee salaries	930,231	930	36,280				37,210
Proceeds received in exchange for beneficial conversion features embedded in Series E Preferred Shares			292,213				292,213
Balance at Mar 31, 2011	180,545,657	\$ 180,546	\$ 97,116,044	100,000	\$(306,841)	\$(114,861,029)	\$(17,871,280)

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

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

(page 1 of 2)

	Years Ended March 31,	
	2011	2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Loss from continuing operations	\$(13,582,159)	\$(8,056,874)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	483,473	508,610
Inventory adjustment	—	311,986
Change in fair value of warrant derivative liability	1,297,997	3,792,130
Change in fair value of preferred shares derivative liability	10,416,375	283,920
Discount in Series E issuance attributable to embedded beneficial ownership feature	292,213	512,912
Preferred shares derivative interest satisfied by the issuance of common stock	1,283,240	964,814
Legal and consulting expenses satisfied by the issuance of common stock	13,737	100,204
Salaries and Directors Fees satisfied by the issuance of common stock	136,953	—
Non-cash compensation satisfied by the issuance of common stock, options and warrants	42,017	125,004
Non-cash rent expense	48,064	—
Impairment of Intangible Assets	440,000	—
Non-cash lease accretion	20,682	—
Changes in assets and liabilities:		
Accounts and interest receivable	(166,706 )	(395,245 )
Inventories	754,931	20,488
Prepaid expenses and other current assets	(1,962 )	16,659
Security deposit	(13,725 )	12,909
Accounts payable, accrued expenses and other current liabilities	87,686	437,734
<b>NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES</b>	<b>1,552,815</b>	<b>(1,364,748)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(178,169 )	—
Cost of leasehold improvements	(343,631 )	—
Proceeds from sale of retired equipment	30,000	—
Costs incurred for intellectual property assets	(866,150 )	(96,404 )
Withdrawals from restricted cash, net	3,416	32,599
<b>NET CASH (USED IN ) INVESTING ACTIVITIES</b>	<b>(1,354,533 )</b>	<b>(63,805 )</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Other loan payments	(13,106 )	(65,839 )
NJEDA bond principal payments	—	(210,000 )
Proceeds from issuance of Series E Convertible Preferred Stock and Warrants	1,062,500	2,000,000
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>1,049,394</b>	<b>1,724,161</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>1,247,676</b>	<b>295,609</b>

CASH AND CASH EQUIVALENTS – beginning of period	578,187	282,578
CASH AND CASH EQUIVALENTS – end of period	\$1,825,858	\$578,187

**Schedule continues on next page The accompanying notes are an integral part of the consolidated financial statements**

F-23

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(page 2 of 2)

	Years Ended March 31,	
	2011	2010
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
Cash paid for interest	226,150	\$262,685
Cash paid for income taxes	7,822	—
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Cumulative effect of reclassification of Preferred Stock and Warrants as Derivative Liabilities		10,364,573
Reduction in par value of common stock from \$0.01 per share to \$0.001 per share		712,954
Common stock issued for purchase of intangible assets	75,000	

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 2011 AND 2010**

**NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**BASIS OF PRESENTATION**

The accompanying audited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”)

**PRINCIPLES OF CONSOLIDATION**

The consolidated financial statements include the accounts 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 years ended March 31, 2011 (“Fiscal Year 2011”) and 2010 (“Fiscal Year 2010”). Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2011, the financial statements of all wholly-owned entities are consolidated and all significant intercompany accounts are eliminated upon consolidation.

**NATURE OF BUSINESS**

Elite Pharmaceuticals, Inc. was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. was incorporated on August 23, 1990 under the laws of the State of Delaware. Elite Labs engages primarily in researching, developing and licensing proprietary controlled-release drug delivery systems and products. The Company is also equipped to manufacture controlled-release products on a contract basis for third parties and itself if and when the products are approved; however the Company has concentrated on developing orally administered controlled-release products. These products include drugs that cover therapeutic areas for pain, allergy and infection. The Company also engages in research and development activities for the purpose of obtaining Food and Drug Administration approval, and, thereafter, commercially exploiting generic and new controlled-release pharmaceutical products. The Company also engages in contract research and development on behalf of other pharmaceutical companies.

**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.

### INVENTORIES

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

### LONG-LIVED ASSETS

The Company periodically evaluates the fair value of long-lived assets, which include property and equipment and intangibles, whenever events or changes in circumstances indicate that its carrying amounts may not be recoverable. Such conditions may include an economic downturn or a change in the assessment of future operations. A charge for impairment is recognized whenever the carrying amount of a long-lived asset exceeds its fair value. Management has determined that no impairment of long-lived assets has occurred.

Property and equipment are stated at cost. Depreciation is provided on the straight-line method based on the estimated useful lives of the respective assets which range from five to forty years. Major repairs or improvements are capitalized. Minor replacements and maintenance and repairs which do not improve or extend asset lives are expensed currently.

Upon retirement or other disposition of assets, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is recognized in income.

Costs incurred to acquire intangible assets such as for the application of patents and trademarks 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 and trademarks. Such costs are charged to expense if the patent or trademark is unsuccessful.

#### RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense as incurred.

#### CONCENTRATION OF CREDIT RISK

The Company maintains cash balances, which, at times, may exceed the amounts insured by the Federal Deposit Insurance Corp. Uninsured balances at March 31, 2011 are \$1,575,858. Management does not believe that there is any significant risk of losses.

The Company in the normal course of business extends credit to its customers based on contract terms and performs ongoing credit evaluations. An allowance for doubtful accounts due to uncertainty of collection is established based on historical collection experience. Amounts are written off when payment is not received after exhaustive collection efforts. During Fiscal 2010 and Fiscal 2011 the Company generated all its revenues from two companies. The termination of the contracts with either of such two companies will result in the loss of a significant amount of revenues currently being earned.

#### USE OF ESTIMATES

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, the recognition of revenue, the amount of the allowance for doubtful accounts receivable and the fair value of intangible assets, stock-based awards and derivatives.

#### INCOME TAXES

The Company uses the liability method for reporting income taxes, under which current and deferred tax liabilities and assets are recorded in accordance with enacted tax laws and rates. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Under the liability method, the amounts of deferred tax liabilities and assets at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or

recovered. Further tax benefits are recognized when it is more likely than not, that such benefits will be realized. Valuation allowances are provided to reduce deferred tax assets to the amount considered likely to be realized.

GAAP prescribes a recognition threshold and measurement attribute for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. GAAP requires that the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. No adjustments related to uncertain tax positions were recognized during the years ended March 31, 2011 and March 31, 2010.

The Company recognizes interest and penalties related to uncertain tax positions as a reduction of the income tax benefit. No interest and penalties related to uncertain tax positions were accrued as of March 31, 2011 and March 31, 2010.

The Company operates in multiple tax jurisdictions within the United States of America. Although we do not believe that we are currently under examination in any of our major tax jurisdictions, we remain subject to examination in all of our tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2011, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal and State – 2005 and forward. The Company does not expect to have a material change to unrecognized tax positions within the next twelve months.

### EARNINGS PER COMMON SHARE

Basic earnings per common share is calculated by dividing net earnings by the weighted average number of shares outstanding during each period presented. Diluted earnings per share are calculated by dividing earnings by the weighted average number of shares and common stock equivalents. The Company's common stock equivalents consist of options, warrants and convertible securities.

### REVENUE RECOGNITION

Revenues earned under manufacturing agreements with other pharmaceutical companies are recognized on the date of shipment of the product, when title for the goods is transferred, and for which the price is agreed to and it has been determined that collectability is reasonably assured.

Revenues derived from royalties are recognized when such are reasonably estimable and collectible. Revenues from royalties which cannot be reasonably estimated are recognized when the payment is received.

Revenues derived from providing research and development services under contracts with other pharmaceutical companies are recognized when earned. These contracts provide for non-refundable upfront and milestone payments. Because no discrete earnings event has occurred when the upfront payment is received, that amount is deferred until the achievement of a defined milestone. Each nonrefundable milestone payment is recognized as revenue when the performance criteria for that milestone have been met. Under each contract, the milestones are defined, substantive effort is required to achieve the milestone, the amount of the non-refundable milestone payment is reasonable, commensurate with the effort expended, and achievement of the milestone is reasonably assured.

Revenues earned by licensing certain pharmaceutical products developed by the Company are recognized at the beginning of a license term when the Company's customer has legal right to the use of the product. Revenues are recognized on licensing income on a straight line basis over the life of the licensing agreement.

### TREASURY STOCK

The Company records common shares purchased and held in treasury at cost.

### FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of current assets and liabilities approximate fair value due to the short-term nature of these instruments. The carrying amounts of noncurrent assets are reasonable estimates of their fair values based on

management's evaluation of future cash flows. The long-term liabilities are carried at amounts that approximate fair value based on borrowing rates available to the Company for obligations with similar terms, degrees of risk and remaining maturities.

### STOCK-BASED COMPENSATION

The Company accounts for all stock-based payments and awards under the fair value based method. Stock-based payments to non-employees are measured at the fair value of the consideration received, or the fair value of the equity instruments issued, or liabilities incurred, whichever is more reliably measurable. The fair value of stock-based payments to non-employees is periodically re-measured until the counterparty performance is complete, and any change therein is recognized over the vesting period of the award and in the same manner as if the Company had paid cash instead of paying with or using equity based instruments on an accelerated basis. The cost of the stock-based payments to nonemployees that are fully vested and non-forfeitable as at the grant date is measured and recognized at that date, unless there is a contractual term for services in which case such compensation would be amortized over the contractual term.

The Company accounts for the granting of share purchase options to employees using the fair value method whereby all awards to employees will be recorded at fair value on the date of the grant. Share based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition during the requisite service period. Such an award with a performance condition is accrued if it is probable that a performance condition will be achieved. Compensation costs for stock-based payments to employees that do not include performance conditions are recognized on a straight-line basis. The fair value of all share purchase options is expensed over their vesting period with a corresponding increase to additional capital surplus. Upon exercise of share purchase options, the consideration paid by the option holder, together with the amount previously recognized in additional capital surplus, is recorded as an increase to share capital

The Company uses the Black-Scholes option valuation model to calculate the fair value of share purchase options at the date of the grant. Option pricing models require the input of highly subjective assumptions, including the expected price volatility. Changes in these assumptions can materially affect the fair value estimate.

The compensation expense recognized for the years ended March 31, 2011 and 2010 was \$42,016 and \$125,004, respectively.

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position or results of operations upon adoption.

In October 2009, the Financial Accounting Standards Board (“FASB”) issued ASU 2009-13, *Multiple Deliverable Revenue Arrangements*. ASU 2009-13 provides principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This standard shall be applied prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. Alternatively, an entity may elect to adopt this standard on a retrospective basis. Adoption of this standard is not expected to have a material impact on the financial statements.

In March 2010, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 08-9, “Milestone Method of Revenue Recognition” (Issue 08-9). The Accounting Standards Update resulting from Issue 08-9 amends ASC 605-28.1. The Task Force concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the

only acceptable method of revenue recognition for milestone payments. The guidance in Issue 08-9 is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010, and may be applied: prospectively to milestones achieved after the adoption date, or retrospectively for all periods presented. Adoption of this standard is not expected to have a material impact on the financial statements.

#### NOTE 2 MANAGEMENT'S LIQUIDITY PLANS

The Company reported net losses of \$13,582,159 and \$8,056,874 for the fiscal years ended March 31, 2011 and 2010, respectively. At March 31, 2011, the Company had a working capital deficiency of approximately \$1.5 million and an accumulated deficit of approximately \$114.9 million, consolidated assets of approximately \$11.8 million, and negative stockholders' equity of approximately \$17.9 million. The Company has not generated any significant profits to date. During the fiscal year ended March 31, 2011, the Company raised \$1,062,500 of net proceeds from the sale of Series E Preferred Stock, and issued Series E Preferred Stock with a face value of \$1,062,500, with the payment for such Series E Preferred Stock being received during Fiscal 2010.

The Company's strategy is to continue to be engaged in the development and manufacturing of oral controlled-release products. It will continue to develop generic versions of controlled-release drug products with high barriers to entry and assist partner companies in the life cycle management of products to improve off-patent drug products. The Company has two products currently being sold commercially; a generic product recently purchased and being transferred to Elite but not yet being sold; an approval for a generic product not yet being sold; and a pipeline of products under development.

As of March 31, 2011, the Company's principal source of liquidity was approximately \$1.8 million of cash and cash equivalents. The Company may also receive funds through the exercise of outstanding stock options and warrants and \$0.6875 million from the issuance of the Company's Series E Convertible Preferred Stock pursuant to the Strategic Alliance Agreement with Epic Pharma. However, there can be no assurance of the exercise of any outstanding options or warrants, the performance of Epic Pharma under the Strategic Alliance Agreement, or that any cash received from such sources will be material to contribute sufficient amounts to continue operating activities.

As a result there is no assurance that the Company's business strategy will be successfully implemented, and with the Company's existing working capital levels, there can be no assurance that the Company will continue as a going concern.

#### NOTE 3 INVENTORIES

Inventories are recorded at the lower of cost or market. Inventories at March 31, 2011 and 2010 consist of the following:

	2011	2010
Finished Goods	\$ 156,399	\$ 164,529
Raw Materials	1,507,419	1,701,188
	1,663,818	1,865,717
Less: Inventory Valuation Reserve	(1,047,456)	(494,425 )
	\$ 616,362	\$ 1,371,292

The Inventory Valuation Reserve as of March 31, 2011, consists of raw materials with an aggregate cost of \$918,355 having no commercial value due to the FDA's decision to remove Lodrane from the market and the FDA's recent reclassification of the Company's application to transfer the manufacturing site of Hydromorphone to its facilities from CBE-30 to Prior Approval, as well as \$35,762 in expired raw materials which have not yet been destroyed and \$93,339 in mark-to-market adjustments required to fairly state the Company's raw materials inventory at the lower of cost or market, with current replacement cost being the standard upon which the market value is determined.



Please refer to the Current Reports on Form 8-K filed with the SEC on March 4, 2011 and June 6, 2011 for details on the FDA's decision to remove Lodrane from the market and the FDA's reclassification of the Company's application for transfer of manufacturing site, respectively, with such filings being herein incorporated by reference.

The Inventory Valuation Reserve as of March 31, 2010, consisted of \$494,425 in mark-to-market adjustments required to fairly state the Company's raw materials inventory at the lower of cost or market, with current replacement cost being the standard upon which the market value is determined.

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment at March 31, 2011 and 2010 consists of the following:

	2011	2010
Laboratory manufacturing, and warehouse equipment	\$5,117,709	\$5,089,540
Office equipment	56,961	56,961
Furniture and fixtures	62,406	62,406
Transportation equipment	66,855	66,855
Land, building and improvements	2,835,783	2,492,152
Equipment under capital lease	168,179	168,179
	8,307,893	7,936,093
Less: Accumulated depreciation and amortization	(4,189,619)	(3,840,279)
	\$4,118,274	\$4,095,814

Depreciation and amortization expense amounted to \$483,473 and \$508,610 for the years ended March 31, 2011 and 2010, respectively.

#### NOTE 5 - 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 March 31, 2011 and 2010, the following costs were recorded as intangible assets on the Company’s balance sheet:

	2011	2010
<u>Intangible assets at beginning of fiscal year</u>		
Patent application costs	172,841	151,300
Trademarks	—	8,120
ANDA acquisitions	—	—
Less: Accumulated Amortization	(76,434 )	(131,677)
Net Intangible Assets at beginning of fiscal year	96,407	27,743
<u>Intangible asset costs capitalized during the fiscal year</u>		
Patent application costs	51,152	96,404
Trademarks	—	—
ANDA acquisition costs	890,000	—
Total cost of intangible assets capitalized	941,152	96,404
<u>Amortization of intangible assets during fiscal year</u>		
Patent application costs	—	6,990
Trademarks	—	540
ANDA acquisition costs	—	—
Total amortization of intangible assets	—	7,530
<u>Impairment of intangible assets during the fiscal year</u>		
Patent application costs	76,434	74,863
Trademarks	—	8,120
ANDA acquisition costs	(440,000)	—
Accumulated amortization of impaired assets	(76,434 )	(62,773 )
Net impairment of intangible assets	(440,000)	20,210
<u>Intangible assets at end of fiscal year</u>		
Patent application costs	147,556	172,841

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Trademarks	—	—
ANDA acquisition costs	450,000	—
Less: Accumulated Amortization	—	(76,434 )
Net Intangible Assets	\$597,556	\$96,407

F-30

The costs incurred in patent applications totaling \$51,152 and \$96,404 for the 2011 and 2010 fiscal years, were all related to our abuse resistant and extended release opioid product lines. The Company is continuing its efforts to achieve approval of such patents. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

The ANDA acquisition costs of \$890,000 incurred during the 2011 fiscal year, are related to our acquisition of the ANDA's for Hydromorphone 8mg, Naltrexone 50mg and Phentermine 37.5mg tablets. For further details on these acquisitions, please refer to the current reports on Form 8-K filed with the SEC on May 24, 2010 for the Hydromorphone ANDA acquisition and September 1, 2010 for the Naltrexone and Phentermine ANDA acquisitions, such filings being herein incorporated by this reference. In addition, please refer to exhibits 10.4, 10.5 and 10.7 of the quarterly report on Form 10-Q filed with the SEC on November 15, 2010 for the purchase agreements for Hydromorphone, Naltrexone, and Phentermine, respectively, such filings being herein incorporated by this reference.

The Company has successfully transferred production of the Phentermine 37.5mg product to its facilities and has commenced commercial production of this product. Please refer to the current report on form 8-K, filed with the SEC on April 7, 2011, such filing being herein incorporated by reference.

On May 31, 2011, the Company received a letter from the FDA responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 8mg ANDA purchased from Mikah Pharma. The letter from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which will delay the commercialization of the product. The delay imposed by such reclassification is a significant detrimental factor to the value of the Hydromorphone ANDA. In accordance with GAAP, the Company recorded an impairment equal to the full historical cost.

The Company has also recorded an impairment equal to the full historical cost of the Naltrexone 50mg ANDA, as the reason given by the FDA for the reclassification of the Company's application filed with the FDA for Hydromorphone may also apply to a similar application filed by the Company with the FDA for the transfer of manufacturing and packaging for Naltrexone 50mg.

#### NOTE 6 INVESTMENT IN NOVEL LABORATORIES INC.

At the end of 2006, Elite entered into a joint venture with VGS Pharma, LLC ("VGS") and created Novel Laboratories, Inc. ("*Novel*"), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite's ownership interest in Novel's Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel. As of October 1, 2007, Elite deconsolidated its financial statements from Novel and the investment in Novel is accounted for under the cost method of accounting.

Since its inception, Novel has filed at least 11 Abbreviated New Drug Applications with the US Food and Drug Administration. The first ANDA approval for Novel was received in Dec 2008 and at least three additional ANDA approvals were received in 2009. Four of the Novel ANDAs have been granted first-to-file status.

In addition, Novel has acquired three ANDAs to supplement its own in-house product development and marketing strategy. Novel has publicly said that it has identified over 50 drug products which are in various stages of development that it plans to commercialize in the coming years.

We also know from public information that Perrigo Company acquired rights in 2010 for an undisclosed amount to an additional Novel ANDA approved in 2010 for the product HalfLytely®. Novel believes this is a first to file ANDA. Perrigo expects to be in a position to launch a generic version of this product later this year and they expect to have 180 days of generic exclusivity. Novel will manufacture the product exclusively for Perrigo. Annual sales for the branded product were approximately \$80 million according to Wolters Kluwer.

In accordance with GAAP, the company records an impairment write-down to such investments when the cost of the investment exceeds its fair value and when the decline in value is determined to be other-than temporary. Indicators of an other-than-temporary decline in value include, without limitation, the following:

A significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee

A significant adverse change in the regulatory, economic, or technological environment of the investee

A significant adverse change in the general market condition of either the geographic area or the industry in which the investee operates

A bona fide offer to purchase (whether solicited or unsolicited), an offer by the investee to sell, or a completed auction process for the same or similar security for an amount less than the cost of the investment

Factors that raise significant concerns about the investee's ability to continue as a going concern, such as negative cash flows from operations, working capital deficiencies, or noncompliance with statutory capital requirements or debt covenants.

A review and assessment of all documents available, public announcements by Novel and communications with the management of Novel does not indicate the existence of impairment indicators. Accordingly, the Company determined that no impairment is required in the valuation of its investment in Novel as of March 31, 2011. The valuation of the Company's investment in Novel remains at \$3,329,322, an amount equal to the valuation as of March 31, 2010 with no impairment write downs.

#### NOTE 7 - NJEDA BONDS

On September 2, 1999, the Company completed the issuance of tax exempt bonds by the New Jersey Economic Development Authority ("NJEDA" or the "Authority"). The aggregate proceeds from the issuance of the fifteen year term bonds were \$3,000,000. Interest on the bonds accrues at 7.75% per annum. A portion of the proceeds were used by the Company to refinance its land and building, and the remaining proceeds were intended to be used for the purchase of manufacturing equipment and building improvements.

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

Interest is payable semiannually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a \$415,500 Debt Service Reserve Fund consisting of \$366,000 from the Series A Notes proceeds and \$49,500 from the Series B Notes proceeds. The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets. \$1,274,311 of the proceeds had been deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company's facility. As of September 30, 2010, all of these proceeds were utilized to upgrade the Company's manufacturing facilities and for the purchase of manufacturing and laboratory equipment.

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$3,533 and \$10,598 for the three and nine months ended December 31, 2010, respectively.

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

The interest payment of \$120,775 due on September 1, 2009, and three separate interest payments of \$113,075 due on March 31, 2010, September 1, 2010 and March 1, 2011, 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 \$225,000 (the "2010 Principal Payment"), and requested the Trustee to withdraw the funds from debt service reserve held in the restricted cash account and to utilize such funds to make the principal payment due. The Company's request was denied by the Trustee. Accordingly, the principal payment due on September 1, 2010, totaling \$200,000 was not made.

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15<sup>th</sup> of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15<sup>th</sup> of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on September 1, 2009, March 1, 2010, September 1, 2010 and March 1, 2011. The Company is required to make two additional monthly payments of \$19,529 during the period June 29, 2011 through August, 2011, in order to fully replenish the March 1, 2011 withdrawal from the debt service reserve.

The Company does not expect to have sufficient available funds to make the interest payment of \$113,075 due on September 1, 2011 as well as principal payments totaling \$245,000 due on September 1, 2011 (the "2011 Principal Payment"). Please note that the 2011 Principal Payment is in addition to the 2010 Principal Payment, which has not yet been paid.

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



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

Bond financing consisting of the following, as of March 31,

	2011	2010
Refinanced NJEDA Bonds	\$3,385,000	\$3,385,000
Current portion	(3,385,000)	(3,385,000)
Long term portion, net of current maturities	\$—	\$—

**Maturities of Bonds for the next five years are as follows:**

YEAR ENDING MARCH 31,	AMOUNT
2012	\$470,000
2013	260,000
2014	185,000
2015	195,000
2016	210,000
Thereafter	2,065,000
	\$3,385,000

**NOTE 8 - LOANS PAYABLE AND LONG TERM DEBT**

Loans payable and long term debt consisted of the following:

	March 31, 2011		March 31, 2010	
	Current	Long-Term	Current	Long-Term
Note payable to First Niagara Bank in 60 monthly installments of \$1,180, including interest at the rate of 9.00% per annum; Final payment in September 2012 ; Secured by vehicle purchased with proceeds of loan	\$13,105	\$6,717	\$11,793	\$19,823
Short term loan to finance commercial insurance policy			9,701	
Short term loan to finance directors & officers insurance policy			60,808	
<b>TOTAL</b>	<b>\$13,105</b>	<b>\$6,717</b>	<b>\$82,302</b>	<b>\$19,823</b>

**NOTE 9 - LEASES OF RENTAL PROPERTIES**

The following leases for rental properties were operative during the year ended March 31, 2011:

	80 Oak Street Unit 102	135 Ludlow Ave (see note 10)
Effective Date	August 1, 2009	July 1, 2010
Termination Date	November 30, 2010	December 31, 2015

Lease term	Month-to-month	5 years with 2 tenant renewal options for 5 years each
Rent expense for the 2011 Fiscal Year	\$29,102	\$67,753
Minimum 5 Year Lease Payments*		
Fiscal year ended March 31, 2012	—	79,248
Fiscal year ended March 31, 2013	—	81,228
Fiscal year ended March 31, 2014	—	83,259
Fiscal year ended March 31, 2015	—	85,344
Fiscal year ended March 31, 2016	—	87,363
		\$416,442

\* Minimum lease payments are exclusive of additional expenses related to certain expenses incurred in the operation and maintenance of the premises, including, without limitation, real estate taxes and common area charges which may be due under the terms and conditions of the lease, but which are not quantifiable at June 29, 2011, the time of filing of the Company's annual report on Form 10-K.

The real estate leases are recorded as operating leases.

The lease for 80 Oak Street was a month-to-month lease, and accordingly the rent expense was equal to rent payments made during Fiscal Year 2011.

Rent expense related to the operating lease at 135 Ludlow was recorded using the straight line method and summarized as follows:

**Summary of Rent Expense – 135 Ludlow Avenue**

	Fiscal Year Ended March 31, 2011
Rent Expense	67,753
Actual lease payments	19,689
Increase in deferred rent liability	48,064
Balance of deferred rent liability	48,064

**NOTE 10 - LEASE OF 135 LUDLOW AVENUE**

The Company entered into a lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey, consisting of approximately 15,000 square feet of floor space. The lease term began on July 1, 2010 and is classified as an operating lease.

The lease includes an initial term of 5 years and 6 months and the Company has the option to renew the lease for two additional 5 year terms. The property related to this lease will be used for the storage of pharmaceutical finished

goods, raw materials, equipment and documents as well as pharmaceutical manufacturing, packaging and distribution activities.

This property requires significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use.

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

Please refer to Note 9 of these financial statements for details on minimum lease payments, rent expense and deferred rent liabilities.

F-35

**NOTE 11 - LEASE TERMINATION COSTS - 135 LUDLOW AVENUE**

The lease for the property located at 135 Ludlow Avenue, Northvale NJ, includes a requirement that, at termination, the Company return the property to its condition at the inception of the lease, with normal wear and tear excepted. Such requirement accordingly represents an unconditional obligation associated with the retirement of a long-lived asset and subject to ASC 410 of the Codification. The Company estimates such costs would amount to \$50,000, at lease termination, and pursuant to ASC 410 has recorded a liability and offsetting asset equal to the present value, at lease inception, of such obligation. This liability is accreted over the term of the lease (including extensions), using the interest method.

**NOTE 12 - DEFERRED REVENUES**

Deferred revenues in the aggregate amount of \$192,223, consisting of a current component of \$13,333 and a long term component of \$178,890 represents the unamortized amount of a \$200,000 advance payment received for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license. The current component is equal to the amount of revenue to be earned during the 12 month period immediately subsequent to the balance date and the long term component is equal to the amount of revenue to be earned thereafter.

**NOTE 13 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE**

Preferred share derivative interest payable as of March 31, 2011 consisted of \$282,680 in derivative interest accrued as of March 31, 2011. The full amount of derivative interest payable as of March 31, 2011 was paid via the issuance of 4,775,017 shares of Common Stock, in lieu of cash, in April 2011.

Preferred share derivative interest payable as of March 31, 2010 consisted of \$306,440 in derivative interest accrued as of March 31, 2010. The full amount of derivative interest payable as of March 31, 2011 was paid via the issuance of 3,402,813 shares of Common Stock, in lieu of cash, in April 2010.

**NOTE 14 - DERIVATIVE LIABILITIES – PREFERRED SHARES**

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

**Preferred Stock Derivative Liabilities – Fiscal Year 2011**

	Series B	Series C	Series D	Series E	Total
Preferred shares Outstanding as of March 31, 2011	896	5,418	4,063	3,062.5	13,439.5
Underlying common shares into which Preferred may convert	730,274	4,280,842	58,042,861	118,898,957	181,952,934
Closing price on valuation date	\$0.078	\$0.078	\$0.078	\$0.078	\$0.078
Preferred stock derivative liability at March 31, 2011	\$56,961	\$333,906	\$4,527,343	\$9,274,119	\$14,192,329
Change in preferred stock derivative liability for the 2011 Fiscal Year					<b>\$10,416,376</b>

The change of \$10,416,375 in value of the preferred stock derivative liability occurring during the 2011 Fiscal Year is included in the amount reported in the “Other Income/(Expense)” section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

**Preferred Stock Derivative Liabilities – Fiscal Year 2010**

	Series B	Series C	Series D	Series E	Total
Preferred shares Outstanding as of March 31, 2010	896	5,418	9,008	2,000	17,322
Underlying common shares into which Preferred may convert	574,076	3,365,217	45,037,200	44,256,006	93,232,499
Closing price on valuation date	\$0.085	\$0.085	\$0.085	\$0.085	\$0.085
Preferred stock derivative liability at March 31, 2010	\$48,797	\$286,043	\$3,828,162	\$3,761,761	\$7,924,763
<b>Change in preferred stock derivative liability for the 2010 Fiscal Year</b>					<b>\$283,920</b>

The change of \$283,920 in value of the preferred stock derivative liability occurring during the 2011 Fiscal Year is included in the amount reported in the “Other Income/(Expense)” section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.



## NOTE 15 - DERIVATIVE LIABILITIES - WARRANTS

To date, the Company has authorized the issuance of Common Stock Purchase Warrants, with terms of five to seven years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements. Exercise prices range from \$0.0625 to \$3.25 per warrant. The warrants expire at various times through March 31, 2018.

A summary of warrant activity for the fiscal years indicated below is as follows:

	Fiscal Year 2011		Fiscal Year 2010	
	Warrant Shares	Weighted Average Exercise Price	Warrant Shares	Weighted Average Exercise Price
Balance at beginning of year	125,299,740	\$ 0.25	39,667,853	\$ 0.63
Warrants issued	40,000,000	\$ 0.06	80,000,000	\$ 0.06
Exchange warrants issued	—	—	5,806,887	\$ 0.25
Warrant exercises, forfeited or expired	9,974,692	\$ 0.69	175,000	\$ 2.82
Ending Balance	155,325,048	\$ 0.15	125,299,740	\$ 0.25

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.

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

March 31

March 31

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	2011	2010
Risk-Free interest rate	.09% - 2.9%	2.4% - 3.3%
Expected volatility	138% - 194%	126% - 214%
Expected life (in years)	0.3 – 7.0	0.5 – 6.6
Expected dividend yield	—	—
Number of warrants	155,325,048	125,299,740
Fair value – Warrant Derivative Liability	\$ 10,543,145	\$ 8,499,423
Change in warrant derivative liability for the twelve months ended	\$ 1,297,998	\$ 3,792,130

F-38

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

The changes of \$1,297,998 and \$ 3,792,130 in value of the warrant derivative liability occurring during the years ended March 31, 2011 and 2010, respectively, are included in the amounts reported in the "Other Income/(Expense)" section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

#### NOTE 16 - BENEFICIAL CONVERSION FEATURES OF SERIES E PREFERRED SHARES

The Series E Preferred shares include an option, exercisable from the issuance date, to convert to common shares at prices which were less than the market price of the Company's Common Stock on the date such Series E Preferred shares were issued. The difference between the share price and option price represents a beneficial conversion feature existing on the issue date.

In accordance with GAAP, the beneficial conversion feature was valued separately and allocated to additional paid in capital. The valuations were calculated using the relative fair value method allocating the proceeds from each issuance of the Series E Preferred shares to the conversion option and detachable warrants, if such warrants were included with an issuance.

The beneficial conversion option is then required to be recognized as a discount and amortized over a period that begins on the date of issuance and ends on the earliest conversion date. As the conversion options were exercisable on their issue date, the full value assigned to the conversion option was immediately amortized and charged to interest expense.

During Fiscal Year 2011, the Company had two separate issuances of Series E Preferred Stock, consisting of 62.5 shares issued in September 2010 and 1,000 shares issued in March 2011.

The valuation of the beneficial conversion features, and detachable warrants, were applicable, for each issuance of Series E Preferred Stock occurring during Fiscal Year 2011 is summarized as follows:

Sept 2010	March 2011
Issuance	Issuance

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Allocation of proceeds to conversion option

Proceeds from issuance of Series E shares	\$62,500	\$1,000,000
Value of detachable warrants – March 2011 only (see Black-Scholes calculation below)	-0-	2,951,297
Total of proceeds plus warrants	62,500	3,951,297

Allocation % attributable to Series E shares (quotient of proceeds divided by proceeds plus warrant value)	100	%	25.3	%
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Proceeds allocated to conversion option	\$62,500	\$253,081
Proceeds allocated to warrants	—	\$746,919

Gross value of beneficial conversion option

Share price on date of issuance	\$0.0600	\$0.0780
Conversion option price	\$0.0369	\$0.0258
Beneficial conversion feature per share	\$0.0231	\$0.0522
Common shares on conversion	1,693,870	38,824,149
Gross value of beneficial conversion feature	\$39,132	\$2,028,284

Beneficial Conversion Feature Recorded (lesser of gross value or proceeds allocated)	\$39,132	\$253,081
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The warrants issued with the Series E Preferred shares were valued using the Black-Scholes option valuation model, with the following assumptions:

	March 2011 Issuance	
Risk-free interest rate	2.90	%
Expected volatility	138.4	%
Expected life (in years)	7	
Number of warrants	40 million	
Fair value	\$2,951,297	

During Fiscal Year 2010, the Company had two separate issuances of Series E Preferred Stock, consisting of 1,000 shares issued in June 2009 and 1,000 shares issued in October 2009.

The valuation of the beneficial conversion features, and detachable warrants, were applicable, for each issuance of Series E Preferred Stock occurring during Fiscal Year 2010 is summarized as follows:

	June 2009 Issuance	October 2009 Issuance
<u>Allocation of proceeds to conversion option</u>		
Proceeds from issuance of Series E shares	\$1,000,000	\$1,000,000
Value of detachable warrants – (see Black-Scholes calculation below)	2,869,361	2,931,983
Total of proceeds plus warrants	3,869,361	3,931,983
Allocation % attributable to Series E shares (quotient of proceeds divided by proceeds plus warrant value)	25.9	% 25.4
		%
Proceeds allocated to conversion option	\$258,700	\$254,212
Proceeds allocated to warrants	741,300	\$745,788
<u>Gross value of beneficial conversion option</u>		
Share price on date of issuance	\$0.0800	\$0.08
Conversion option price	\$0.0500	\$0.05
Beneficial conversion feature per share	\$0.0300	\$0.03
Common shares on conversion	20,000,000	20,000,000
Gross value of beneficial conversion feature	\$600,000	\$715,282
Beneficial Conversion Feature Recorded (lesser of gross value or proceeds allocated)	\$600,000	\$254,212

F-40

The warrants issued with the Series E Preferred shares were valued using the Black-Scholes option valuation model, with the following assumptions:

	June 2009 Issuance		October 2009 Issuance	
Risk-free interest rate	2.31	%	2.21	%
Expected volatility	115.2	%	123.3	%
Expected life (in years)	7		7	
Number of warrants	40 million		40 million	
Fair value	2,869,361		\$ 2,931,983	

#### NOTE 17 - COMMON STOCK

During Fiscal Year 2011, the Company issued a total of 96,595,489 shares of Common Stock, with such issuances of Common Stock being summarized as follows:

Description	Shares Of Common Stock
Common Shares issued in lieu of cash payment in payment of preferred share derivative interest expenses totaling \$1,283,240	21,241,590
Common Shares issued pursuant to the conversion of Series D Convertible Preferred Share derivatives, with such derivative liabilities totaling \$4,465,584 at the time of their conversion	70,649,154
Common Shares issued in payment of \$75,000 due and payable pursuant to the Asset Purchase Agreement dated 5/18/2010	937,500
Common Shares issued in lieu of cash in payment of consulting expenses totaling \$13,737	343,425
Common Shares issued in payment of Director's fees totaling \$99,743	2,493,589
Common shares issued in payment of employee salaries totaling \$37,210	930,231
Total Common Shares issued during Fiscal Year 2011	96,595,489
Common Shares outstanding at March 31, 2010	83,950,168
Common Shares outstanding at March 31, 2011	180,545,657

NOTE 18 - PER SHARE INFORMATION

Basic earnings per share of common stock ("Basic EPS") is computed by dividing the net income(loss) by the weighted-average number of shares of common stock outstanding. Diluted earnings per share of common stock ("Diluted EPS") is computed by dividing the net income(loss) by the weighted-average number of shares of common stock and dilutive common stock equivalents and convertible securities then outstanding. GAAP requires the presentation of both Basic EPS and Diluted EPS, if such Diluted EPS is not anti-dilutive, on the face of the Company's Consolidated Statements of Operations. As the Company had a net loss for Fiscal Year 2011 and Fiscal Year 2010, Diluted EPS is not presented as the effect of the Company's common stock equivalents and convertible securities is anti-dilutive.

Basic EPS is calculated as follows:

F-41



	Fiscal Year 2011	Fiscal Year 2010
<u>Numerator</u>		
Net (Loss) attributable to common shareholders	\$(13,582,159 )	\$(8,056,874 )
<u>Denominator</u>		
Weighted average shares of common stock outstanding	100,020,520	75,581,345
Net (Loss) per Share – Basic and Diluted	\$(0.14 )	\$(0.11 )
<u>Potentially dilutive securities excluded from the calculation of diluted loss per share (in accordance with GAAP)</u>		
Stock Options	3,057,000	3,287,000
Convertible Preferred Stock	180,881,120	94,370,379
Warrants	155,325,048	125,469,740

**NOTE 19 - STOCK-BASED COMPENSATION**

Part or all of the compensation paid by the Company to its Directors and employees consists of the issuance of Common Stock or via the granting of options to purchase Common Stock

Stock-based Director Compensation

The Company's Director compensation policy instituted in October 2009 includes provisions that Director's fees are to be paid via the issuance of shares of the Company's Common Stock, in lieu of cash, with the valuation of such shares being calculated on a quarterly basis and equal to the average closing price of the Company's common stock for the quarter just ended.

During Fiscal Year 2011, the Company issued 2,493,589 shares of Common Stock to its Directors in payment of Director's fees in the aggregate amount of \$99,743 and related to the period beginning on October 1, 2009 and ending on December 31, 2010. Please note that the shares issued during Fiscal Year 2011, include those shares owed and not yet issued at the end of Fiscal Year 2010.

As of March 31, 2011, the Company owes its Directors a total of 592,996 shares of Common Stock in payment of Directors Fees totaling \$32,500 for the three months ended March 31, 2011. The Company anticipates that these shares of Common Stock will be issued during the fiscal year ended March 31, 2012.

Stock-based Employee Compensation

Employment contracts with the Company's President, Chief Financial Officer and certain other employees includes provisions for a portion of each employees salaries to be paid via the issuance of shares of the Company's Common, in lieu of cash, with the valuation of such shares being calculated on a quarterly basis and equal to the average closing price of the Company's common stock for the quarter just ended.

During Fiscal Year 2011, the Company issued a total of 930,231 shares of Common Stock to its President, Chief Financial Officer and certain other employees in payment of salaries in the aggregate amount of \$37,210 and related to the period beginning on October 1, 2009 and ending on December 31, 2010. Please note that the shares issued during Fiscal Year 2011, include those shares owed and not yet issued at the end of Fiscal Year 2010.

F-42

As of March 31, 2011, the Company owes its President, Chief Financial Officer and certain other employees a total of 273,690 shares of Common Stock in payment of salaries totaling \$15,000 for the three months ended March 31, 2011, with such amount being recorded in accrued expenses. The Company anticipates that these shares of Common Stock will be issued during the fiscal year ended March 31, 2012.

#### Stock option based Employee Compensation

During the years ended March 31, 2011 and 2010, the Company issued zero and 1,000,000, respectively, options to purchase Common Stock to employees. The options issued during Fiscal 2010 have an exercise price of \$0.10, vest over a three year period which commences one year from the date of grant and expire ten years from the date of grant. The fair value of the options granted during Fiscal Year 2010 was \$93,452, computed using the Black-Scholes options pricing model on the grant date. Such fair value is being amortized by the Company, on a straight line basis, over the vesting period, and recorded on the Company's Statement of Income as "Non-cash compensation through the issuance of stock options".

In addition to the stock options granted in Fiscal 2010, the amount recorded on the Company's Statement of Income as non-cash compensation through the issuance of stock options includes amortization of the fair value of stock options granted prior to Fiscal Year 2010. The fair value of these options, totaling \$196,983 on the date of such grants, was fully amortized by the end of Fiscal Year 2011.

#### Stock option based employee compensation is summarized as follows:

	Fiscal Year 2011	Fiscal Year 2010
Non-cash compensation expense related to stock options granted prior to Fiscal Year 2010	\$ 17,056	\$ 118,514
Non-cash compensation expense related to stock options granted during Fiscal Year 2010	24,960	6,490
Total non-cash compensation through the issuance of stock options	\$ 42,016	\$ 125,004

#### NOTE 20 - STOCK OPTION PLANS

Under its 2004 Stock Option Plan and prior options plans, the Company may grant stock options to officers, selected employees, as well as members of the Board of Directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's Common Stock at the date of the grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant.

Transactions under the plans for years indicated were as follows:

	Fiscal Year 2011		Fiscal Year 2010	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of year	3,287,000	\$ 1.41	2,554,900	\$ 1.87
Options Granted	—	—	1,000,000	\$ 0.10
Options Exercised	—	—		
Options Expired	230,000	\$ 0.10	(267,900 )	\$ 0.87
Options Vested				
Outstanding at end of year	3,057,000	\$ 1.51	3,287,000	\$ 1.41

The following table summarizes information about stock options outstanding at March 31, 2011:

Range	Options Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price
\$ 0.01 – 1.00	968,000	8.58	\$ 0.09	444,667	\$ 0.08
1.01 – 2.00	99,000	6.82	\$ 1.08	95,999	\$ 1.08
2.01 – 3.00	1,990,000	6.06	\$ 2.22	1,490,000	\$ 2.22
\$ 0.01 – 3.00		6.88	\$ 1.51		\$ 1.69

There are 6,520,100 options available for future grant under our Stock Option Plan.

#### NOTE 21 - INCOME TAXES

The components of the credit for income taxes are as follows:

	Year Ended March 31,	
	2011	2010
Federal:		
Current	\$ —	\$ —
Deferred	—	—
State		
Current	\$ (10,422 )	\$ —
Deferred	—	—
Sale of New Jersey Net Operating Losses	\$ 311,835	\$ —
Net Credit for Income Taxes	\$ 301,413	\$ —

The Major components of deferred tax assets and liabilities at March 31, 2011 and 2010 are as follows:

	March 31,	
	2011	2010

Federal

Net Operating Loss Carry forward	\$ 17,789,382	\$ 17,604,348
Less: Deferred Tax Liability	(305,716 )	—
Subtotal	17,483,666	17,604,348
Valuation Allowance	(17,483,666)	(17,604,348)
	\$—	\$—

State

Net Operating Loss Carryforwards	2,223,278	2,481,065
Less: Deferred Tax Liability	(68,786 )	—
Subtotal	2,154,492	2,481,065
Valuation Allowance	(2,154,492 )	(2,481,065 )
	\$—	\$—

At March 31, 2011 and 2010, a 100% valuation allowance is provided, as it is uncertain if the deferred tax assets will provide any future benefits because of the uncertainty about the Company's ability to generate the future taxable income necessary to use the net operating loss carryforwards.

**NOTE 22 - REMOVAL OF LODRANE PRODUCTS FROM THE US MARKET**

On March 3, 2011, the U.S. Food and Drug Administration ("FDA") announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The Company manufactured two of the drugs impacted by the FDA's action. The affected products are:

Product	Active Ingredient , Strength
Lodrane® 24 Capsules	Brompheniramine maleate, 12mg
Lodrane® 24D Capsules	Brompheniramine maleate, 12mg/pseudoephedrine HCl, 90mg

According to the press release issued by the FDA, manufacturers must stop manufacturing the affected products within 90 days after March 3, 2011 and distribution of the effected products must stop within 180 days after March 3, 2011.

For the year ended March 31, 2011, gross revenues earned by the Company from the Lodrane® products equaled \$4.2 million, or approximately 97% of the Company's total income for the year.

Shortly after the announcement by the FDA, the Company's customer for the Lodrane® products cancelled all outstanding orders, other than those for which manufacturing had already begun, advising the Company that existing stocks of Lodrane® were sufficient and that additional quantities could not be sold prior to the 180 day deadline announced by the FDA.

The last shipment of Lodrane® products was made by the Company in April 2011 and manufacturing of Lodrane® has ceased.

While the timing of the announcement by the FDA resulted in such having a minimal effect on the Company's operations for the 2011 Fiscal Year, the Company's inability to manufacture Lodrane® has a material and adverse effect on its revenues for periods beginning after March 31, 2011.

Please refer to the Current Report on Form 8-K filed with the SEC on March 4, 2011, such filing being herein incorporated by reference, for further details on this announcement.

**NOTE 23 - MAJOR CUSTOMERS**

One customer accounted for approximately 97 percent and 100 percent of revenues for the years ended March 31, 2011 and 2010, respectively.

Please note that this major customer was the purchaser of the Lodrane® products, which have been discontinued pursuant to an announcement by the FDA.

Shortly after the announcement by the FDA, this customer cancelled all outstanding orders, other than those for which manufacturing had already begun, advising the Company that existing stocks of Lodrane® were sufficient and that additional quantities could not be sold prior to the 180 day deadline announced by the FDA.

The last shipment of Lodrane® products was made by the Company in April 2011 and manufacturing of Lodrane® has ceased.

F-45



While the timing of the announcement by the FDA resulted in such having a minimal effect on the Company's operations for the 2011 Fiscal Year, the Company's inability to manufacture Lodrane® has a material and adverse effect on its revenues for periods beginning after March 31, 2011.

Please refer to Note 22 to these financial statements and the Current Report on Form 8-K filed with the SEC on March 4, 2011, such filing being herein incorporated by reference, for further details on this announcement.

**NOTE 24 - SETTLEMENT OF MIDSUMMER INVESTMENTS, Ltd. Et al v. Elite Pharmaceuticals Inc.**  
*Midsummer Investments, Ltd., et al. v. Elite Pharmaceuticals, Inc.* – On or about September 22, 2009, Midsummer Investments, Ltd. (“Midsummer”) and Bushido Capital Master Fund, LP (“Bushido”, and together with Midsummer, the “Plaintiffs”) filed a complaint against Elite Pharmaceuticals, Inc., a Delaware corporation (the “Company”), in the United States District Court, Southern District of New York (Case No. 09 CIV 8074) (the “Action”). The Plaintiffs asserted claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (injunctive relief and damages), and attorneys' fees, arising out of a Securities Purchase Agreement, dated September 15, 2008, by and among the Company and certain purchasers of the Company's securities (including the Plaintiffs) and the Certificate of Designation of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, filed with the Secretary of State of the State of Delaware on September 15, 2009 (the “Series D Certificate”). Plaintiffs claimed that they were entitled to a reduced conversion price for their Series D 8% Convertible Preferred Stock, par value US\$0.01 per share (the “Series D Preferred Stock”), as a result of the Strategic Alliance Agreement, dated March 18, 2009, as amended (the “Epic SAA”), by and among the Company, on the one hand, and Epic Pharma, LLC (“Epic”) and Epic Investments, LLC (“Epic Investments”, and together with Epic, the “Epic Parties”). With their complaint, the Plaintiffs concurrently filed a request for preliminary injunction. Pursuant to an order of the Court entered into on October 16, 2009, the Plaintiffs' request for a preliminary injunction was denied. Thereafter, Plaintiffs filed an amended complaint (the “Complaint”), asserting claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (damages) and attorneys' fees, seeking compensatory damages of \$7,455,363.00, delivery of 1,000,000 shares of the Company's common stock, par value \$0.001 per share (the “Common Stock”), a declaration that all future conversions of the Series D Preferred Stock, held by Plaintiffs is at a conversion price of \$0.05, attorneys' fees, interest and costs.

The Company disputed the claims in the Complaint, believing the lawsuit to be without merit, and vigorously defended against them. The Company moved for summary judgment on the Complaint and the judge in the case did not issue an order on such motion. The Company proceeded with extensive, time-consuming and costly discovery. The court scheduled the trial to commence on June 28, 2010.

In order to avoid the delays, expense and risks inherent in litigation, after extensive negotiations, the Company entered into (i) a Stipulation of Settlement and Release, dated June 25, 2010 (the “Settlement Agreement”), with the Plaintiffs and the Epic Parties, (ii) an Amendment Agreement, dated June 25, 2010 (the “Series D Amendment Agreement”), with the Plaintiffs and (iii) an Amendment Agreement, dated June 25, 2010 (the “Series E Amendment Agreement”) with the Epic Parties. As part of the Settlement Agreement, the Action will be dismissed with prejudice.

Series D Amendment Agreement

Pursuant to the Series D Amendment Agreement, the Company and Plaintiffs agreed to amend the Series D Certificate. The holders of at least 50.1%, in the aggregate, of the Company's outstanding Series B Preferred 8% Convertible Preferred Stock, par value US\$0.01 per share, Series C 8% Convertible Preferred Stock, par value US\$0.01 per share, and Series D Preferred Stock, voting as one class, consented to the filing of the Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock (the "Amended Series D Certificate") with the Secretary of State of the State of Delaware. On June 29, 2010, pursuant to the authority of its Board of Directors, the Company filed with the Secretary of State of the State of Delaware the Amended Series D Certificate.

F-46

Pursuant to the terms of the Amended Series D Certificate, the terms of the Series D Preferred Stock have been amended as follows:

**Dividends:** The Series D Preferred Stock will continue 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 prior to giving effect to the Series D Amendment Agreement. In addition to being payable in cash and shares of Common Stock, as provided in the Series D Certificate, such dividends may also be paid in shares of Series D Preferred Stock (the “Dividend Payment Preferred Stock”) or a combination of cash, Common Stock and Dividend Payment Preferred Stock. Dividend Payment Preferred Stock will have the same rights, privileges and preferences as the Series D Preferred Stock, except that such Dividend Payment Preferred Stock will not be entitled to, nor accrue, any dividends pursuant to the Amended Series D Certificate.

**Conversion Price:** The conversion price of the Series D Preferred Stock shall be reduced from US\$0.20 per share to US\$0.07 per share (subject to adjustment as provided in the Amended Series D Certificate).

**Automatic Monthly Conversion:** On each Monthly Conversion Date (as defined below), a number of shares of Series D Preferred Stock equal to each holder’s pro-rata portion (based on the shares of Series D Preferred Stock held by each Holder on June 25, 2010) of the Monthly Conversion Amount (as defined below) will automatically convert into shares of 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 Series D Preferred Stock, the issuance of the shares will not cause a breach of the beneficial ownership limitations set forth in the Amended Series D Certificate, (iv) if requested by a holder of Series D 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 resold by such holder pursuant to an exemption under the Securities Act 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 Series D Certificate) that has not been consummated, (vi) the applicable holder of Series D 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 Series D Certificate) for the 20 trading days immediately prior to the applicable Monthly Conversion Date equals or exceeds the then-effective conversion price of the Series D Preferred Stock.** Shares of the Series D Preferred Stock issued to the holders of Series D Preferred Stock as Dividend Payment Preferred Stock shall be the last shares of Series D Preferred Stock to be subject to Monthly Conversion. As used herein, the following terms have the following meanings: (i) “Monthly Conversion Date” means the first day of each month, commencing on August 1, 2010, and terminating on the date the Series D Preferred Stock is no longer outstanding; (ii) “Monthly Conversion Amount” means an aggregate Stated Value of Series D Preferred Stock among all Holders that is equal to 25% 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 35% of the aggregate dollar trading volume during the Measurement Period if the average VWAP during such Measurement Period equals or exceeds \$0.12 (subject to adjustment for forward and reverse stock splits and the like that occur after June 25, 2010) and further increasing to 50% of the aggregate dollar trading volume during such Measurement Period if the average VWAP during such Measurement Period equals or exceeds \$0.16 (subject to adjustment for forward and reverse stock splits and the like that occur after June 25, 2010).

Change of Control Transaction: Epic and its affiliates were expressly excluded from any event which would otherwise constitute a “Change of Control Transaction” due to the acquisition in excess of 40% of the Company’s voting securities.

F-47

Pursuant to the Series D Amendment Agreement, the exercise price of the Warrants (the “Series D Warrants”) to purchase shares of Common Stock issued to the holders of Series D Preferred Stock pursuant to the Securities Purchase Agreement, dated as of September 15, 2008, by and among the Company and the purchasers of Series D Preferred Stock will be reduced from \$0.25 per share to US\$0.125. In addition, the exercise price of the Series D Warrants may be reduced as follows:

(i) by 20%, if on September 15, 2011, the holder of such Warrant still beneficially owns more than 50% of the Series D Preferred Stock beneficially owned by such holder as of June 25, 2010 (“Base Ownership”); and

(ii) by 20%, if (a) on September 15, 2011, such holder then beneficially owns more than 25% of the Base Ownership and 50% or less of the Base Ownership and (b) on September 15, 2012, such holder then beneficially owns more than 25% of the Base Ownership.

Notwithstanding the foregoing, (x) in no event will the exercise price of the Series D Warrants be reduced more than once as a result of the amendments to such Series D Warrants, and (y) in the event that on September 15, 2011 or, if the condition of clause (ii)(a) above is met, on September 15, 2012, the Holder beneficially owns 25% or less of the Base Ownership, then no adjustment shall occur pursuant to the Series D Warrants, as amended by the Series D Amendment Agreement. Additionally, there will be no corresponding increase in the number of shares of Common Stock issuable upon exercise of the Warrants solely as a result of the foregoing adjustments.

To the extent such issuance does not cause the breach of the beneficial ownership limitations set forth in the Amended Series D Certificate (any excess shares will be issued to the affected holder of Series D Preferred Stock upon written notice from such holder when such holder’s beneficial ownership is below 9.9% to the extent that such issuance does not cause such holder to exceed such amount), the Company agreed to issue certain shares of Common Stock to the Plaintiffs and their respective affiliates in satisfaction of the Company’s obligation to pay certain previously accrued but unpaid dividends through March 31, 2010 owing to the Plaintiffs and their respective affiliates.

#### Series E Amendment Agreement

Pursuant to the Series E Amendment Agreement, the Company agreed to amend the Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock, filed with Secretary of State of the State of Delaware on June 3, 2009 (the “Series E Certificate”). The Epic Parties, constituting all holders of Series E Preferred Stock, consented to the filing of the Amended Certificate of Designations of the Series E Convertible Preferred Stock (the “Amended Series E Certificate”) with the Secretary of State of the State of Delaware. On June 29, 2010, pursuant to the authority of its Board of Directors, Company filed with the Secretary of State of the State of Delaware the Amended Series E Certificate. Pursuant to the terms of the Amended Series E Certificate, the conversion

price of the Series E Preferred Stock will be adjusted downward to reflect, on a pro rata basis, the reduction in the conversion price of the Series D Preferred Stock as the result of the Series D Amendment Agreement, to the extent shares of Series D Preferred Stock are converted at the reduced conversion price set forth in the Amended Series D Certificate.

Pursuant to the Series E Amendment Agreement, the Epic SAA was amended so that the purchase of the 750 Additional Shares of Series E Preferred Stock described therein for an aggregate purchase price of \$750,000 would occur in 12 installments of 62.5 shares (for a purchase price of \$62,500) (i) on or prior to November 1, 2009 (which has been satisfied) and (ii) within 10 business days following the last day of each calendar quarter, beginning with the first calendar quarter ending on September 30, 2010 and continuing for each of the 10 calendar quarters thereafter.

F-48

### Settlement Agreement

Pursuant to the Settlement Agreement, Elite and the Epic Parties, individually and on behalf of each of their respective officers, directors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Elite Releasors") agreed to release and discharge each of the Plaintiffs, BCMF Trustees LLC, an affiliate of Bushido ("BCMF"), their respective owners, officers, directors, investors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Plaintiffs' Releases") from any and all actions, causes of action, claims, liens, suits, debts, accounts, liabilities, expenses, attorneys' fees, agreements, promises, charges, complaints and demands (collectively, "Loses") which the Elite Releasors have or may have against the Plaintiffs' Releasees that could have been asserted in the Action or any other court action, based upon any conduct up to and including the date of the Settlement Agreement. Notwithstanding the foregoing, the Elite Releasors will not release any claim of breach of the terms of the Settlement Agreement, breach of the terms of the Series D Amendment Agreement, or any cause of action arising from future conduct by the Plaintiffs' Releasees.

Pursuant to the Settlement Agreement, the Plaintiffs and BCMF, individually and on behalf of each of their respective owners, officers, directors, investors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Plaintiffs' Releasors") agreed to release and discharge Elite and the Epic Parties and each of their respective officers, directors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Elite Releasees"), from any and all Losses which the Plaintiffs' Releasors have or may have against the Elite Releasees that could have been asserted in the Action or any other court action, based upon any conduct up to and including the date of the Settlement Agreement. Notwithstanding the foregoing, the Plaintiffs' Releasors did not release any claim of breach of the terms of the Settlement Agreement, breach of the terms of the Series D Amendment Agreement or any cause of action arising from future conduct by the Elite Releasees.

In addition, concurrently with the execution of the Settlement Agreement, legal counsel for both the Company and the Plaintiffs executed a Stipulation of Discontinuance of the Action, which such counsel will file once all conditions precedent to the effectiveness of the Settlement Agreement have been satisfied.

The foregoing description of the Amended Series D Certificate, Amended Series E Certificate, Settlement Agreement, Series D Amendment Agreement and Series E Amendment Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such documents which are filed herewith and incorporated herein by reference.

On July 1, 2010, the Company filed with the SEC a Current Report on Form 8-K announcing the settlement of the litigation with the Plaintiffs, with such filing being incorporated by reference herein.

NOTE 25 - **SETTLEMENT OF *ThePharmaNetwork Inc. v. Elite Pharmaceuticals Inc.***

On March 17, 2011, Elite Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the settlement of a lawsuit filed in the Superior Court of New Jersey, Chancery Division: Bergen County entitled ThePharmaNetwork, LLC v. Elite Pharmaceuticals, Inc. (Index No. C-272-10) (the “Action”).

The Action was commenced on or about August 27, 2010 by ThePharmaNetwork, LLC (“TPN”). TPN alleged that the Company breached certain obligations in connection with a Product Collaboration Agreement (the “Collaboration Agreement”), made as of November 10, 2006, pursuant to which the Company and TPN agreed to collaborate in the development, commercialization, manufacturing and distribution of a generic pharmaceutical product, which the parties subsequently agreed would be methadone hydrochloride in a 10 mg. tablet (the “Product”). In the lawsuit, the Company asserted counterclaims against TPN arising out of the Collaboration Agreement, and sought damages of no less than \$1,125,000 from TPN. Both parties denied the other side’s allegations.

In order to fully and finally resolve the disputed claims arising in the Action, the Company and TPN have entered into a settlement agreement, dated March 11, 2011 (the “Settlement Agreement”), pursuant to which the Action, including all of TPN’s claims and the Company’s counterclaims, will be dismissed with prejudice. 3



Pursuant to the Settlement Agreement, the parties have agreed to terminate the Collaboration Agreement.

In addition, in consideration of the Company's agreement to terminate the Collaboration Agreement and to relinquish to TPN all rights and interest in the Abbreviated New Drug Application ("ANDA") for the Product approved by the U.S. Food and Drug Administration (FDA), TPN made a cash payment of \$500,000 to Elite.

As part of the Settlement Agreement, TPN also acknowledges that the Company may develop a generic product containing methadone of any strength (including the filing of an abbreviated new drug application relating to such product) and that nothing in the Settlement Agreement restricts the Company from developing, commercializing, manufacturing and distributing any pharmaceutical product similar to, or which may compete with, the Product or the ANDA filed in connection with the Product.

The Settlement Agreement also contained a mutual release pursuant to which the Company and TPN agreed to release and discharge each other and their respective affiliates from all claims arising before the date of the Settlement Agreement.

Please refer to the Current Report on Form 8-K filed with the SEC on March 17, 2011, such filing being herein incorporated by reference, for further details on this settlement of litigation.

#### NOTE 26 - TRANSACTIONS WITH RELATED PARTIES

##### Transactions with Epic Pharma LLC and Epic Investments LLC

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC, as disclosed in "Description of Business; Epic Strategic Alliance Agreement" in the prospectus. See also, "Directors and Executive Officers" in this prospectus. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, each were elected as members of our Board of Directors, effective June 24, 2009, as the three directors that Epic is entitled to designate for appointment to the Board pursuant to the terms of the Epic Strategic Alliance Agreement.

Mr. Nigalaye, Chairman and Chief Executive Officer of Epic Pharma, LLC;

Mr. Narine, President and Chief Operating Officer of Epic Pharma, LLC;

Mr. Potti, Vice President of Epic Pharma, LLC.

As part of the operation of the strategic alliance, the Company and Epic identified areas of synergy, including, without limitation, raw materials used by both entities, and various regulatory and operational resources existing at Epic that could be utilized by the Company.

With regards to synergies related to raw materials usage, the strategic alliance allowed the Company to purchase such raw materials from Epic, at the Epic acquisition cost, without markup. In all cases, the acquisition cost of Epic was lower than those costs available to the Company, mainly as a result of efficiencies of scale generated by significantly larger volumes purchased by Epic during the course of their normal operations. During the fiscal year ended 3/31/2011, an aggregate amount of \$232,305 in such materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma's acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC's acquisition cost.

F-50

With regards to synergies related to regulatory and operational resources, the strategic alliance allowed the Company to utilize Epic's substantial resources and technical competencies on an "as needed" basis at a cost equal to Epic's actual cost for only the resources utilized by the Company. Without such access to Epic's resources, the Company would have to invest significant amounts in human resources and fixed assets as well as incur substantial costs with third party providers to provide the same resources provided by Epic and necessary for the operations of the Company. During the fiscal year ended 3/31/2011, an aggregate amount of \$73,440 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company as well as \$140,000 in manufacturing equipment.

The Company also purchased an ANDA for Phentermine 37.5mg tablets from Epic Pharma LLC for a cost of \$450,000. Please refer to Exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010 for further details on this ANDA purchase.

Total purchases from Epic by the Company during the fiscal year ended March 31, 2011 were \$895,745.

During the fiscal year ended March 31, 2011, the Company also performed method development services for Epic Pharma LLC, for which it was paid \$25,000, sold retired equipment to Epic for \$30,000 and sold excess raw materials to Epic for a total of \$2,903.

#### **NOTE 27 - CONVERSIONS OF PREFERRED STOCK DERIVATIVES TO COMMON STOCK**

The Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series D Preferred Derivatives"), includes provisions entitling the holders of Series D Preferred Derivatives to convert shares of the Series D Preferred Derivatives into shares of Common Stock. The Series D Preferred Derivatives are classified as a liability to the Company, and the liability represented by those shares of Series D Preferred Derivatives being converted must be valued at the time of such conversion, with increases/(decreases) in the value of preferred share derivative liabilities being appropriately recorded and reflected in the Other Income section of the Company's Statement of Operations. The amount of equity recorded as a result of the conversion of Series D Preferred Derivatives is equal to the value of such Series D Preferred Derivatives being converted, at the time of the conversion, with such amount also representing the decrease in the Preferred Share Derivative Liability on the Company's Balance Sheet.

Conversions of Series D Preferred Derivatives during the year ended March 31, 2011 are summarized as follows:

# of Series D Preferred Derivative shares converted	4,945
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# of Common Shares issued pursuant to conversions of Series D Preferred Derivatives	70,649,154
Value of Series D Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions)	\$4,465,584
Change in value of preferred share derivative liability recorded at time of conversion	1,639,618
Par value of Common Shares issued	70,649
Additional paid in capital recorded as a result of the conversions	4,394,935

NOTE 28 - SUBSEQUENT EVENTS

The Company has evaluated subsequent events from the balance sheet date through June 29, 2011, the date the accompanying financial statements were issued. The following are material subsequent events:

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

Derivative interest expense related to the Preferred Share derivatives due and payable as of March 31, 2011 were paid during April 2011 through the issuance of 7,775,017 shares of common stock.

Conversion of Series D Convertible Preferred Stock to Common Stock

On May 24, 2011 the Company issued a press release announcing that all of the outstanding shares of its Series D 8% Convertible Preferred Stock (the "Series D") has been converted into the Company's common stock, pursuant to the Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010. The Series D conversion thereby eliminates the Company's obligations to pay \$720,000 in annual dividends and eliminates the administrative costs associated therewith.

A Current Report on Form 8-K was filed with the SEC on May 24, 2011, such filing being herein incorporated by this reference.

Reclassification of Supplement filed with the FDA

On May 31, 2011, the Company received a letter from the US Food and Drug Administration (FDA) responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 8 mg ANDA purchased from Mikah Pharma. The letter from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which will significantly delay the commercialization.

The reclassification of the Company's application as a prior approval supplemental application is expected to have a material and detrimental effect on the Company's future operations as well as its ability to operate in the future.

A Current Report on Form 8-K was filed with the SEC on June 7, 2011, such filing being herein incorporated by this reference.

Manufacturing and Supply Agreement with Mikah Pharma

On June 1, 2011, Elite Pharmaceuticals Inc. ("Elite") executed a Manufacturing and Supply Agreement (the "Agreement") with Mikah Pharma, LLC ("Mikah") to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg (the "Products"), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to

Elite's facility and the appropriate regulatory filing for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the United States of America, its territories, possessions, and commonwealths in accordance with the requirements of this Agreement; Elite shall perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing the Products for commercial sale by Mikah or its designees in accordance with the terms of this Agreement. During the term of this Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of the Products. For the Isradipine product, Elite will also receive a 10% royalty on net profits of the finished Product. The payment is to be calculated and paid quarterly. Elite will also receive a onetime milestone payment for each Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch.

The Manufacturing and Supply Agreement has a term of five (5) years and shall automatically renew for additional periods of one (1) year unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term.

A Current Report on Form 8-K was filed with the SEC on June 7, 2011, such filing being herein incorporated by this reference.

Manufacturing and Supply Agreement with ThePharmaNetwork

On June 29, 2011 the Company announced that it has entered into a commercial Manufacturing and Supply Agreement with ThePharmaNetwork, LLC, and its wholly owned subsidiary, Ascend Laboratories, LLC (together "TPN"). Under the terms of the agreement, Elite will perform manufacturing and packaging for TPN's Methadone Hydrochloride, 10 mg tablets.

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

A Current Report on Form 8-K was filed with the SEC on June 29, 2011, such filing being herein incorporated by this reference. Please also refer to exhibit 10.71 of the Company's annual report on Form 10-K for this fiscal year ended March 31, 2011.

F-53

## **PART II**

### **INFORMATION NOT REQUIRED IN PROSPECTUS**

#### **Item 13. Other Expenses of Issuance and Distribution**

We will pay all expenses in connection with the registration and sale of the common stock by the selling stockholder. The estimated expenses of issuance and distribution are set forth below.

SEC filing fee	\$773.75
Legal expenses	\$25,000.00*
Accounting expenses	\$5,000.00 *
Miscellaneous	\$5,000.00 *
Total	\$35,773.75

\* Estimate

#### **Item 14. Indemnification of Directors and Officers**

Our directors and officers are indemnified by our articles of incorporation and bylaws to the fullest extent legally permissible under the laws of Nevada against all expenses, liability and loss, reasonably incurred by them in connection with the defense of any action, suit or proceeding in which they are a party by reason of being or having been directors or officers of the Company. Unless our Board determines by a majority vote of a quorum of disinterested directors that, based upon the facts known, such person acted in bad faith and in a manner that such person did not believe to be in or not opposed to our best interest (or, with respect to any criminal proceeding, that such person believed or had reasonable cause to believe his conduct was unlawful), costs, charges and expenses (including attorneys' fees) incurred by such person in defending a civil or criminal proceeding shall be paid by the Company in advance upon receipt of an undertaking to repay all amounts advanced if it is ultimately determined that the person is not entitled to be indemnified by the Company as authorized by the bylaws, and upon satisfaction of other conditions required by current or future legislation. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to such directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore,



unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by us of expenses incurred or paid by such director, officer or controlling person in the successful defense of any action, suit or proceeding, is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

II-1

**Item 15. Recent Sales of Unregistered Securities****SUMMARY OF ISSUANCES OF COMMON STOCK, PREFERRED STOCK, WARRANTS AND OPTIONS**

	Year Ended March 31,			Mar 31, 2011 Through February 21, 2012
	2009	2010	2011	
<b>Common Stock Issuances</b>				
Common stock issued in lieu of cash in payment of dividends due and owing on Series B, Series C and Series D Preferred Stock	13,901,178	18,647,826	21,241,590	8,410,374
Common stock issued pursuant to conversions of Series B, Series C, Series D and Series E Preferred Stock	23,682,161	5,973,360	70,649,154	132,871,245
Common stock issued in payment of the Chairman's fee in accordance with the Company's policy regarding payment of Chairman's fees	—	—	587,834	—
Common stock issued in payment of the Directors' fees in accordance with the Company's policy regarding payment of Directors' fees	—	—	1,905,755	—
Common stock issued in payment of employee salaries pursuant to applicable employment contracts	—	—	930,231	—
Common stock issued to Richardson and Patel LLP in December 2009, in payment of legal expenses owed by the Company in the amount of \$100,000	—	909,091	—	—
Common stock issued in February 2010 to Brockington Securities Inc. for consulting fees pursuant to an agreement dated April 2009	—	204,000	—	—
Common stock issued to Mikah Pharma LLC in November 2010, in payment of \$75,000 due and owing by the Company pursuant to an asset purchase agreement dated May 18, 2010.	—	937,500	—	—
Common stock issued to Harmon Aronson in February 2011, in payment of consulting fees owed by the Company in the amount of \$13,737	—	343,425	—	—
<b>Total Common Stock Issuances</b>	<b>37,708,339</b>	<b>25,734,277</b>	<b>96,595,489</b>	<b>141,281,619</b>
<b>Preferred Stock Issuances</b>				
Series D Preferred Stock	13,814	(1) —	—	—
Series E Preferred Stock	—	2,000	(2) 1063	(3) 250 (4)

Total Preferred Stock Issuances	13,814	2,000	1,063	250
Total Warrants Issued	30,386,462 <sup>(5)</sup>	80,000,000 <sup>(6)</sup>	40,000,000 <sup>(7)</sup>	—
Total Options Issued	258,000	<sup>(8)</sup> 1,000,000	<sup>(9)</sup> —	—

(1) A total of 13,814 shares of Series D Preferred Stock was issued in September 2008, with 1,777 of such Series D Shares being issued for cash payments of \$1,000 per share and 7,139 of such Series D Shares being issued in exchange for an equivalent number of Series B Shares and 4,898 of such Series D Shares being issued in exchange for an equivalent number of Series C Shares.

II-2

(2) Represents the following issuances of Series E Preferred Stock:

- 1,000 shares of Series E Preferred stock issued in June 2009 at a price of \$1,000 per share.
- 1,000 shares of Series E Preferred stock issued in September 2009 at a price of \$1,000 per share

(3) Represents the following issuances of Series E Preferred Stock:

- 62.5 shares of Series E Preferred stock issued in September 2010 at a price of \$1,000 per share.
- 1,000 shares of Series E Preferred stock issued in March 2011 at a price of \$1,000 per share

(4) Represents the following issuances of Series E Preferred Stock:

- 125 shares of Series E Preferred Stock issued in July 2011 at a price of \$1,000 per share.
- 125 shares of Series E Preferred Stock issued in February 2012 at a price of \$1,000 per share.

(5) Represents warrants to purchase 355,400 shares of common stock issued pursuant to placement agent agreements related to the private placement of Series D Preferred Stock, and warrants to purchase 17,770,000 shares of common stock pursuant to the private placement of Series D Preferred Stock, and warrants to purchase 12,261,062 shares of common stock issued in exchange for previously issued warrants and pursuant to the private placement of Series D Preferred Stock. All such warrants were issued in September 2008, carry a term of five years and include an exercise price of \$0.25 per share upon their issuance.

(6) Represents warrants to purchase 40,000,000 shares of common stock issued in relation to the issuance of 1,000 shares of Series E Preferred stock in June 2009 and warrants to purchase 40,000,000 shares of common stock issued in relation to the issuance of Series E Preferred Stock in September 2009. All such warrants carry a term of seven years and include an exercise price of \$0.0625 per share.

(7) Represents warrants to purchase 40,000,000 shares of common stock issued in relation to the issuance of 1,000 shares of Series E Preferred stock in March 2011. The warrants carry a term of seven years and include an exercise price of \$0.0625 per share.

(8) Represents options to purchase common stock issued to employees and members of the Board of Directors in December 2008. Such options carry an exercise price of \$0.06 per share and expire on the earlier of ten years from their issuance or thirty days after an employee's end of employment with the Company or the Director's end of membership on the Company's Board.

(9) Represents options to purchase common stock issued to employees in January 2010. Such options vest in equal annual increments on the anniversary dates of each of the immediately subsequent years from the date of issuance, carry an exercise price of \$0.10 per share and expire on the earlier of ten years from their issuance or thirty days after an employee's end of employment with the Company.

In connection with the foregoing, the Company relied upon the exemption from securities registration afforded by Rule 506 of Regulation D as promulgated by the United States Securities and Exchange Commission under the

Securities Act of 1933, as amended (the “Securities Act”) and/or Section 4(2) of the Securities Act.

II-3

**Item 16. Exhibits**

Exhibit

No. Description

- 2.1 Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation (“Elite-Delaware”) and Elite Pharmaceuticals, Inc., a Nevada corporation (“Elite-Nevada”), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
- 3.1(a) Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
- 3.1(b) Certificate of Incorporation of the Company, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the “Form S-4”), (b) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.\*
- 3.1(c) Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.\*
- 3.1(d) Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.\*
- 3.1(e) Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.\*
- 3.1(f) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(g) Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(h) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(i)

Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*

3.1(j) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*

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

II-4

- 3.1(l) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 3.1(m) Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*
- 3.1(n) Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*
- 3.2(a) By-Laws of Elite-Nevada, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.
- 3.2(b) By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").\*
- 4.1 Socius Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 4.2 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.\*
- 4.3 Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*
- 4.4 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.5 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.6 Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.\*
- 4.7 Warrant to purchase 50,000 shares of Common Stock issued to Jason Lyons incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.\*
- 4.8 Form of Warrant to purchase shares of Common Stock issued to designees of lender with respect to financing of an equipment loan incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.\*
- 4.9



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Form of Short Term Warrant to purchase shares of Common Stock issued to purchasers in the private placement which initially closed on October 6, 2004 (the "Series A Financing"), incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

- 4.10 Form of Long Term Warrant to purchase shares of Common Stock issued to purchasers in the Series A Financing, incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

II-5

4.11 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series A Financing, incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

4.12 Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*

4.13 Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.\*

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

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

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

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

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

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

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

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

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

4.23

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

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

II-6

- 4.25 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.26 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 5.1 Opinion of Richard Feiner, Esq.\*\*
- 10.1 2004 Employee Stock Option Plan approved by stockholders on June 22, 2004, incorporated by reference to Exhibit A to the Proxy Statement filed on Schedule 14A with respect to the Annual Meeting of Stockholders held on June 22, 2004.
- 10.2 Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
- 10.3 Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
- 10.4 Amended and Restated Employment Agreement dated as of September 2, 2005 between Bernard Berk and the Company, incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.5 Option Agreement between Bernard Berk and the Company dated as of July 23, 2003 incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q for three months ended June 30, 2003 (the "June 30, 2003 10Q Report").
- 10.6 Option Agreement between Bernard Berk and the Company dated as of July 23, 2003, incorporated by reference to Exhibit 10.8 to the June 30, 2003 10Q Report.
- 10.7 Amendment, dated as of September 2, 2005, by and between, the Company and Bernard Berk, to the Stock Option Agreement, dated as of July 23, 2003, incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.8 Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.9 Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.10 Engagement letter dated February 26, 1998, between Gittelman & Co. P.C. and the Company incorporated by reference to Exhibit 10.10 to the Form 10-K for the period ended March 31, 2004 filed with the SEC on June 29, 2004.
- 10.11 Product Development and Commercialization Agreement, dated as of June 21, 2005, between the Company and IntelliPharmaceutics, Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K,

dated June 21, 2005 and originally filed with the SEC on June 27, 2005, as amended on the Current Report on Form 8-K/A filed September 7, 2005, as further amended by the Current Report on Form 8-K/A filed December 7, 2005 (Confidential Treatment granted with respect to portions of the Agreement).

10.12 Agreement, dated December 12, 2005, by and among the Company, Elite Labs, and IntelliPharmaCeutics Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated December 12, 2005, and originally filed with the SEC on December 16, 2005, as amended by the Current Report on Form 8-K/A filed March 7, 2006 (Confidential Treatment granted with respect to portions of the Agreement).

II-7

- 10.13 Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority (“NJEDA”) and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.14 Series A Note in the aggregate principal amount of \$3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.15 Series B Note in the aggregate principal amount of \$495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.16 Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.17 Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.18 Form of Warrant Exercise Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 14, 2005 and filed with the SEC on December 20, 2005.
- 10.19 Form of Registration Rights Agreement, between the Registrant and signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated December 14, 2005 and filed with the SEC on December 20, 2005.
- 10.20 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.21 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.22 Form of Placement Agent Agreement, between the Registrant and Indigo Securities, LLC, incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated March 15, 2006, and filed with the SEC on March 16, 2006.
- 10.23 Financial Advisory Agreement between the Registrant and Indigo Ventures LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated July 12, 2006 and filed with the SEC on July 18, 2006.
- 10.24 Seconded Amended and Restated Employment Agreement between the Registrant and Bernard Berk, incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.
- 10.25 Employment Agreement between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on

November 14, 2006.

Employment Agreement between the Registrant and Chris Dick, incorporated by reference as Exhibit 10.3 to 10.26 the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.

II-8

10.27 Product Collaboration Agreement between the Registrant and ThePharmaNetwork LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated November 10, 2006 and filed with the SEC on November 15, 2006. (Confidential Treatment granted with respect to portions of the Agreement).

10.28 Strategic Alliance Agreement among the Registrant, VGS Pharma (“VGS”) and Veerappan S. Subramanian (“VS”), incorporated by reference as Exhibit 10(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.29 Advisory Agreement, between the Registrant and VS, incorporated by reference as Exhibit 10(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.30 Registration Rights Agreement between the Registrant, VGS and VS, incorporated by reference as Exhibit 10(c) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.31 Employment Agreement between Novel Laboratories Inc. (“Novel”) and VS, incorporated by reference as Exhibit 10(d) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.32 Stockholders’ Agreement between Registrant, VGS, VS and Novel, incorporated by reference as Exhibit 10(e) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.33 Amended and Restated Employment Agreement, between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated February 9, 2007 and filed with the SEC on February 14, 2007.

10.34 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.35 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.36 Form of Placement Agent Agreement, between the Company and Oppenheimer & Company, Inc., incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.37 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.38 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.39 Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending



September 30, 2007 and filed with the SEC on November 14, 2007.

10.40 Consulting Agreement, dated as of September 4, 2007, between the Registrant, Bridge Ventures, Inc. and Saggi Capital, Inc., incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.

10.41 Employment Agreement, dated as of January 3, 2008, by and between the Registrant and Dr. Stuart Apfel, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated January 3, 2008 and filed with the SEC on January 9, 2008.

II-9

10.42 Form of Securities Purchase Agreement, between the Company and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.43 Form of Placement Agent Agreement, between the Company, ROTH Capital Partners, LLC and Boenning & Scattergood, Inc., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.44 Separation Agreement and General Release of Claims, dated as of October 20, 2008, by and between the Company and Stuart Apfel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

10.45 Consulting Agreement, dated as of October 20, 2008, by and between the Company and Paralex Clinical Research, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

10.46 Separation Agreement and General Release of Claims, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.

10.47 Consulting Agreement, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.

10.48 Separation Agreement and General Release of Claims, dated as of November 5, 2008, by and between the Company and Bernard J. Berk, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 6, 2008 and filed with the SEC on November 6, 2008.

10.49 Amendment to Employment Agreement, dated as of November 10, 2008, by and between the Company and Chris Dick, incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ended September 30, 2008 and filed with the SEC on November 14, 2008.

10.50 Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.

10.51 Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.

10.52 Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.

10.53 Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.

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10.54 Employment Agreement, dated as of July 1, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K dated July 1, 2009 and filed with the SEC on July 8, 2009.

10.55 Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.

II-10

- 10.56 Employment Agreement, dated as of November 13, 2009, by and between the Company and Chris Dick, , incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.57 Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.58 Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
- 10.59 Stipulation of Settlement and Release, dated as of June 25, 2010, by and among the Company, Midsummer Investment, Ltd., Bushido Capital Master Fund, LP, BCMF Trustees, LLC, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010
- 10.60 Amendment Agreement, dated as of June 25, 2010, by and among the Company, and the investors signatory thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010
- 10.61 Amendment Agreement, dated as of June 2010, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010
- 10.62 Asset Purchase Agreement dated as of May 18, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010.
- 10.63 Asset Purchase Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.64 Master Development and License Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.65 Purchase Agreement, dated as of September 10, 2010, by and among Epic Pharma LLC and the Company, incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

- 10.66 License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.67 Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.68 Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.69 Settlement Agreement between the Company and ThePharmaNetwork, LLC, dated as of March 11, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 11, 2011 and filed with the SEC on March 17, 2011.
- 10.70 Manufacturing & Supply Agreement between the Company and Mikah Pharma LLC, dated as of June 1, 2011, incorporated by reference to Exhibit 10.70 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.71 Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.72 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount Mikah Pharma LLC and the Company (Confidential Treatment granted with respect to portions of the Agreement), incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for three and nine months ended December 31, 2011.
- 10.73 Securities Purchase Agreement with Socius dated December 30, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 10.74 Amendment to Agreement with Socius dated February 28, 2012, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K/A filed with the SEC February 29, 2012.
- 10.75 Form of Lock-Up Agreement (included as Exhibit D to the Securities Purchase Agreement with Socius mentioned in 10.2 above), incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 21 Subsidiaries of the Company.\*\*
- 23.1 Consent of Demetrius & Company LLC, Independent Registered Public Accounting Firm\*\*

II-12

23.2 Consent of Richard Feiner, Esq. (included in Exhibit 5.1)

101 The following materials from Elite Pharmaceuticals' Registration Statement on Form S-1, related to the audited financial statements as and for the fiscal years ended March 31, 2011 and 2010 and the unaudited financial statements as of and for the nine months ended December 31, 2011 and 2010, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

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

\*\*

Filed herewith.

**Item 17. Undertakings**

1. The undersigned registrant hereby undertakes to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (B)(1)(i) and (B)(1)(ii) of this section do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

2. The undersigned registrant hereby undertakes that, for the purpose of determining any liability under the Securities Act of 1933, as amended, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. The undersigned registrant hereby undertakes to remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of the offering.



4. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

5. The undersigned registrant hereby undertakes that, for the purposes of determining liability to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) For purposes of determining liability under the Securities Act of 1933, each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

6. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the undersigned registrant according the foregoing provisions, or otherwise, the undersigned registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933, as amended, and will be governed by the final adjudication of such issue.

**SIGNATURES**

In accordance with the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Northvale, State of New Jersey, on March 1, 2012.

ELITE PHARMACEUTICALS, INC.  
(Registrant)

By: /s/ Jerry Treppel  
Jerry Treppel,  
Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jerry Treppel his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933 and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement on Form S-1 has been signed by the following persons in the capacities indicated on the dates indicated.

Signature	Title	Date
/s/ Jerry Treppel Jerry Treppel	Chairman of the Board, Chief Executive Officer (Principal Executive) and Director	March 1, 2012

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/s/ Carter Ward Carter Ward	Chief Financial Officer (Principal Financial Officer), Treasurer, Secretary and Chief Accounting Officer	March 1, 2012
/s/ Chris Dick Chris Dick	President, Chief Operating Officer, Director	March 1, 2012
/s/ Barry Dash Barry Dash	Director	March 1, 2012
/s/ Jeenarine Narine Jeenarine Narine	Director	March 1, 2012
/s/ Ashok Nigalaye Ashok Nigalaye	Director	March 1, 2012
/s/ Ram Potti Ram Potti	Director	March 1, 2012
/s/ Jeffrey Whitnell Jeffrey Whitnell	Director	March 1, 2012

II-16

Elite Pharmaceuticals, Inc.

Form S-1

Index to Exhibits

Exhibit No. Description

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|------|--|
| 5.1  | Opinion of Richard Feiner, Esq.  |
| 21.1 | Subsidiaries   |
| 23.1 | Consent of Demetrius & Company LLC, independent registered public accounting firm. |

II-17