ELITE PHARMACEUTICALS INC /NV/
Form S-1
April 25, 2013

**AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON APRIL 25, 2013**

**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) | (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, 16th 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. **x**

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

x Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

| **Title of each class of securities to be registered** | **Amount to be Registered(1)** | **Proposed Maximum Offering Price Per Security (2)** | **Proposed Maximum Aggregate Offering Price** | **Amount Of Registration Fee** | |
|---|---|---|---|---|---|
| Common Stock, $0.001 par value per share | | $ 0.07 | $ 5,660,076.10 | $ 772.03 | |
| | | | | (772.03 | ) |
| Total | | | $ 5,660,076.10 | $ 0.00 | (3) |

(1) The shares being registered include 2,929,115 shares issued to Lincoln Park Capital Fund, LLC, shares issuable to Lincoln Park Capital Fund, LLC, and such indeterminate number of additional shares of common stock issuable for no additional consideration by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration, which results in an increase in the number of outstanding shares of our common stock. In the event of a stock split, stock dividend or similar transaction involving our common stock, in order to prevent dilution, the number of shares registered shall be automatically increased to cover the additional

shares in accordance with Rule 416(a) under the Securities Act of 1933.

(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, using the average of the high and low prices reported on the Over-the-Counter Bulletin Board on April 22, 2013, which was $0.07 per share.

(3) The Registrant previously filed Form S-1 (333-179834) on March 1, 2012, and paid a filing fee of $773.75. The Registrant did not sell any securities pursuant to that Form S-1, and that Form S-1 was terminated on June 20, 2012. Pursuant to Rule 457(p), the Registrant hereby applies $773.75 of the previously paid filing fee against amounts due herewith.

**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 April 25, 2013**

**ELITE PHARMACEUTICALS, INC.**

**80,858,230 Shares of Common Stock**

This prospectus relates to the offer and sale of up to 80,858,230 shares of common stock, par value $0.001, of Elite Pharmaceuticals, Inc., a Nevada corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park or the selling stockholder.

The shares of common stock being offered by the selling stockholder have been or may be issued pursuant to the purchase agreement dated April 19, 2013 that we entered into with Lincoln Park. See “The Lincoln Park Transaction” in “Selling Stockholder” for a description of that agreement and “Selling Stockholder” for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See “Plan of Distribution” for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

We will pay the expenses incurred in registering the shares, including legal and accounting fees. See “Plan of Distribution”.

Our common stock is currently quoted on the Over-the-Counter Bulletin Board, or the OTCBB, under the symbol "ELTP". On April 18, 2013, the last reported sale price of our common stock on the OTCBB was $0.07.

**Investment in the Common Stock involves a high degree of risk. You should consider carefully the risk factors beginning on page 4 of this prospectus before purchasing any of the shares offered by this prospectus.**

**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 _____, 2013.**

**ELITE PHARMACEUTICALS, INC.**

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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 own, license or contract manufacture five products currently being sold commercially, as follows:

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

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

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

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

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

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

In addition, Elite also has an undisclosed generic product filed with the FDA that is awaiting review and for which Elite retains all rights.

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

Additionally, the Company is developing abuse resistant opioid products, and once-daily opioid products.

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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**

On April 19, 2013, we entered into a purchase agreement with Lincoln Park, which we refer to in this prospectus as the Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from us up to $10,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also on April 19, 2013, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than 2,929,115 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, we do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to $80,000 on any single business day so long as at least two business days have passed since the most recent purchase. We can also accelerate the amount of our common stock to be purchased under certain circumstances to up to $500,000 per purchase. Except as described in this prospectus, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount; provided that in no event will such shares be sold to Lincoln Park when our closing sale price is less than $0.07 per share, subject to adjustment as provided in the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of April 19, 2013, there were 377,781,737 shares of our common stock outstanding, of which 342,365,495 shares were held by non-affiliates, including the 2,929,115 shares that we have already issued to Lincoln Park under the

Purchase Agreement. Although the Purchase Agreement provides that we may sell up to $10,000,000 of our common stock to Lincoln Park, only 80,858,230 shares of our common stock are being offered under this prospectus, which represents (i) 2,929,115 shares that we issued to Lincoln Park as a commitment fee (ii) an additional 75,000,000 shares which may be issued to Lincoln Park in the future under the Purchase Agreement and (iii) 2,929,115 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell shares to Lincoln Park under the Purchase Agreement. If all of the 80,858,230 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 17 % of the total number of shares of our common stock outstanding and 18 % of the total number of outstanding shares held by non-affiliates, in each case as of the date hereof. If we elect to issue and sell more than the 80,858,230 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

For more detailed information on the transaction with Lincoln Park, please see "The Lincoln Park Transaction" in "Selling Stockholder" below.

**Securities Offered**

Common stock to be offered by the selling stockholder 80,858,230 shares consisting of:

· 2,929,115 commitment shares issued to Lincoln Park and

· 75,000,000 shares we may sell to Lincoln Park under the Purchase Agreement, including

· 2,929,115 shares that we are required to issue proportionally in the future, as an additional commitment fee, if and when we sell additional shares to LPC under the Purchase Agreement

| | |
|---|---|
| Common stock outstanding prior to this offering | 377,781,737 shares |
| Common stock to be outstanding after giving effect to the issuance of 80,858,230 shares under the Purchase Agreement | 449,852,622 shares |
| Use of Proceeds | We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive up to $10,000,000 under the Purchase Agreement with Lincoln Park. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used to fund the production development and commercial activities of the Company, for general and administrative expenses, to pay down liabilities and for working capital. See "Use of Proceeds." |
| Risk factors | This investment involves a high degree of risk. See "Risk Factors" for a discussion of factors you should consider carefully before making an investment decision. |

| | |
|---|---|
| Symbol on OTCBB | ELTP |

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**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.

In addition to the other information contained in this prospectus, the following risk factors should be considered carefully in evaluating an investment in us and in analyzing our forward-looking statements.

**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. During the nine months ended December 31, 2012 and for the past two fiscal years, we incurred net losses of $109,023, $15,058,274 and $13,582,159, respectively and losses from operations of $1,275,243, $1,966,137 and $885,760, 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.***

The independent auditor's report for the year ended March 31, 2012, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and working capital deficiency raise substantial doubt about our ability to continue as a going concern. As of December 31, 2012, we had cash reserves of approximately $0.07 million and a working capital deficit of $3.7 million, and we had losses from operations totaling $1.2 million for the nine months ended December 31, 2012, net other income totaling $1.25 million for the nine months then ended and a net loss of $0.1 million for the nine months ended December 31, 2012. 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", in March 2011. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA's directive. The FDA 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.

To tide us over in the short term, our CEO, Jerry Treppel has provided Elite with a revolving bridge credit line of up to $1,000,000. The line is due and payable on the earlier of the date that Elite raises $2.0 million from the sale of its equity securities or July 31, 2013, whichever occurs first.

In addition, pursuant to the Purchase Agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $10,000,000 worth of shares of our common stock under our agreement over a 36 month period generally in amounts up to $80,000 worth of our shares of our common stock on any such business day. However, Lincoln Park shall not purchase any shares of our common stock on any business day that the closing sale price of our common stock is less than $0.07 per share, subject to adjustment as set forth in the Purchase Agreement. Assuming a purchase price of $0.07 per share (the closing sale price of the common stock on April 18, 2013) and the purchase by Lincoln Park of all of the 75,000,000 purchase shares registered herein under the Purchase Agreement, proceeds to us would only be $5,250,000.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $10,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans.

We are anticipating that, with the growth of the generic phentermine product, the contract manufacturing of methadone, Lodrane D® immediate release, Hydromorphone, Phendimetrazine and, the eventual launch of the generic naltrexone, generic phentermine capsule products and other opportunities in our pipeline, Elite eventually 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 that we will be able to timely raise additional funds on acceptable terms through the Purchase Agreement or otherwise, that the development of such Epic products will be successful or that such Epic products will be successfully commercialized or that other pipeline products of Elite will be successfully commercialized. There can also be no assurances of Elite becoming profitable. For more detailed information about the Epic Strategic Alliance Agreement please see “Business; Epic Strategic Alliance Agreement.”

To sustain operations and meet our business objectives we must be able to commercialize our products and other products or pipeline opportunities. If we are unable to timely obtain additional financing and we are unable to timely generate greater revenues from our operations, we will be required to reduce and, possibly, cease operations and liquidate our assets. No assurance can be given that we will be able to commercialize the new opportunities, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets.

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***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 March 31, 2013 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 Notices of Default from the Trustee in relation to the utilization of the debt service reserve fund for of semi-annual interest payments from March 2009 to the present and for the non-payment of principal amounts due on September 1, 2010, 2011 and 2012. While the Company has replenished all amounts withdrawn from the debt service reserve fund in accordance with the terms of the bond agreement, there can be no assurances of the Company being able to make future semi-annual interest payments without utilizing the debt service reserve fund, nor can there be assurances of the Company being able to replenish the debt service reserve fund in the future. In addition, there can be no assurances of the Company being able to pay the principal payments currently due as well as those which are due in the future

Resolution of our default under the NJED Bonds 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 dependent 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. The cessation of production of the Lodrane Extended Release Products has had a material adverse effect on Elite's revenues for all periods beginning after 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 six patents and we have eight 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 this regard, the launch of commercial production of Phentermine Capsules was delayed and the sale of the phentermine 37.5 mg tablets hampered as a result of the sole supplier of the API approved for both the Phentermine tablet product and the soon to be launched Phentermine capsule products restricting the amount of API available to us. While we have resolved this issue for the next year, the purchase orders now in place are at a substantially higher price than previously paid. This type of supply restriction could prevent us, and our sales and marketing partner, from meeting growing demand for the products and restrict sales of products utilizing the restricted API.

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, without limitation:

- 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 involve 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 less than 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 March 31, 2013, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.17 per share to a low of $0.07 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, without limitation:

- 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.

***The sale or issuance of our common stock to Lincoln Park or upon conversion of outstanding preferred stock or exercise of outstanding warrants may cause dilution and the sale of the shares of common stock acquired by Lincoln Park or the issuance of shares upon conversion or exercise of outstanding preferred stock and warrants,, or the perception that such sales and issuances may occur, could cause the price of our common stock to fall.***

On April 19, 2013, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $10,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement, we issued 2,929,115 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below $0.07 per share, subject to adjustment as set forth in the Purchase Agreement. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares.

In addition, as of April 19, 2013, there were outstanding shares of preferred stock convertible into approximately 93.6 million shares of Common Stock and warrants to purchase an aggregate of approximately 139.3 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 anti-dilution provisions in the outstanding preferred stock and warrants; and, dividends on outstanding preferred stock. 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.

As a result of the above discussed potential issuance of securities, such issuances by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park or pursuant to the conversion or exercise of outstanding shares of preferred stock and warrants, or the anticipation of such issuances, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

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

Any additional 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.***

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).

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 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 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 "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.

***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 G Preferred Stock and Series E Preferred Stock 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 si 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**

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. However, we may receive gross proceeds of up to $10,000,000 under the Purchase Agreement. See “Plan of Distribution” elsewhere in this prospectus for more information.

We expect to use any proceeds that we receive under the Purchase Agreement to fund the product development and commercial activities of the Company, for general and administrative expenses, to pay down liabilities and for working capital.

**SELLING STOCKHOLDER**

This prospectus relates to the possible resale by the selling stockholder, Lincoln Park, of shares of common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on April 19, 2013 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to sales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement.

Lincoln Park, as the selling stockholder, may, from time to time, offer and sell pursuant to this prospectus any or all of the shares that we have sold or may sell to Lincoln Park under the Purchase Agreement. The selling stockholder may sell some, all or none of its shares. 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 following table presents information regarding the selling stockholder and the shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling stockholder, and reflects its holdings as of April 22, 2013. Neither Lincoln Park nor any of its affiliates has held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. As used in this prospectus, the term “selling stockholder” includes Lincoln Park and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from Lincoln Park as a gift, pledge or other non-sale related transfer. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the Securities and Exchange Commission (the “SEC”) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The percentage of shares beneficially owned prior to the offering is based on 377,781,737 shares of our common stock actually outstanding as of April 22, 2013.

| Selling Stockholder | Shares Beneficially Owned Before this Offering | | Percentage of Outstanding Shares Beneficially Owned Before this Offering | | Shares to be Sold in this Offering Assuming The Company issues the Maximum Number of Shares Under the Purchase Agreement | | Percentage of Outstanding Shares Beneficially Owned After this Offering |
|---|---|---|---|---|---|---|---|
| Lincoln Park Capital Fund, LLC (1) | 2,929,115 | (2) | * | (3) | 80,858,230 | (4) | * |

*** Less than 1%**

(1) Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, are deemed to be beneficial owners of all of the shares of common stock owned by Lincoln Park Capital Fund, LLC. Messrs. Cope and Scheinfeld have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Lincoln Park Capital, LLC is not a licensed broker dealer or an affiliate of a licensed broker dealer.

(2) Represents 2,929,115 shares of our common stock issued to Lincoln Park on April 19, 2013 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement, all of which shares are covered by the registration statement that includes this prospectus. See the description under the heading "The Lincoln Park Transaction" for more information about the Purchase Agreement.

(3) Based on 377,781,737 outstanding shares of our common stock as of April 22, 2013, which includes 2,929,115 shares of our common stock issued to Lincoln Park on April 19, 2013 as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement. Although we may at our discretion elect to issue to Lincoln Park up to an aggregate amount of $10,000,000 of our common stock under the Purchase Agreement, other than the shares described in the immediately preceding sentence, such shares are not included in determining the percentage of shares beneficially owned before this offering.

**The Lincoln Park Transaction**

**General**

On April 19, 2013, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to $10,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes

this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement on April 19, 2013, we issued to Lincoln Park 2,929,115 shares of our common stock as a fee for its commitment to purchase additional shares of our common stock under the Purchase Agreement. Other than the shares of our common stock that we have already issued to Lincoln Park as described above, we do not have the right to commence any further sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter and upon satisfaction of the other conditions set forth in the Purchase Agreement, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase shares of our common stock in amounts up to $80,000 on any single business day so long as at least two business days have passed since the most recent purchase. We can also accelerate the amount of our common stock to be purchased under certain circumstances to up to $500,000 per purchase. The purchase price per share is based on the market price of our common stock immediately preceding the time of sale as computed under the Purchase Agreement without any fixed discount.

**Purchase of Shares Under the Purchase Agreement**

Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to $80,000 worth of our common stock on any such business day so long as two business days have passed since the last purchase. On any day that the closing sale price of our common stock is not below $.12 the purchase amount may be increased, at our sole discretion, to up to $150,000 per purchase, on any day that the closing sale price of our common stock is not below $.175 the purchase amount may be increased, at our sole discretion, to up to $250,000 per purchase, on any day that the closing sale price of our common stock is not below $.25 the purchase amount may be increased, at our sole discretion, to up to $350,000 per purchase and on any day that the closing sale price of our common stock is not below $.40 the purchase amount may be increased, at our sole discretion, to up to $500,000 per purchase. The purchase price per share for each such purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

**Minimum Purchase Price**

Under the Purchase Agreement, we have set a floor price of $0.07 per share. Lincoln Park shall not purchase any shares of our common stock on any day that the closing sale price of our common stock is below the floor price. The floor price will be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction and, effective upon the consummation of any such event, the floor price will be the lower of (i) the adjusted price and (ii) $1.00.

**Events of Default**

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of three consecutive business days;

- the de-listing of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, The NASDAQ Global Market, The NASDAQ Global Select Market, The NASDAQ Capital Market, the NYSE MKT, the NYSE Arca or the OTC Bulletin Board (or nationally recognized successor thereto);

- the transfer agent's failure for five business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the Purchase Agreement;

- any breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreement which has or which could have a material adverse effect on us subject to a cure period of five business days;

- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or

- if at any time we are not eligible to transfer our common stock electronically or a material adverse change in our business, financial condition, operations or prospects has occurred.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park's control, shares of our common stock cannot be sold by us or purchased by Lincoln Park under the Purchase Agreement.

**Our Termination Rights**

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

**No Short-Selling or Hedging by Lincoln Park**

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

**Effect of Performance of the Purchase Agreement on Our Stockholders**

All 80,858,230 shares registered in this offering which have or may be sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could

cause the market price of our common stock to decline and to be highly volatile. Lincoln Park may ultimately purchase all, some or none of the 77,929,115 shares of common stock registered in this offering and issuable to Lincoln Park. If we sell these shares to Lincoln Park, Lincoln Park may sell all, some or none of such shares. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to $10,000,000 of our common stock. Depending on the price per share at which we sell our common stock to Lincoln Park, we may be authorized to issue and sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

| Assumed Average Purchase Price Per Share | | Number of Registered Shares to be Issued if Full Purchase (1)(2) | Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (3) | Proceeds from the Sale of Shares to Lincoln Park Under the Purchase Agreement |
|---|---|---|---|---|
| $ 0.07 | (4)(5) | 76,537,785 | 16.85 % | $ 5,250,000 |
| $ 0.15 | | 69,595,782 | 15.56 % | $ 10,000,000 |
| $ 0.25 | | 42,929,115 | 10.20 % | $ 10,000,000 |
| $ 0.35 | | 31,500,544 | 7.70 % | $ 10,000,000 |

(1) Although the Purchase Agreement provides that we may sell up to $10,000,000 of our common stock to Lincoln Park, we are only registering 80,858,230 shares under this prospectus, which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering including the applicable additional commitment shares issuable to Lincoln Park.

(2) The number of registered shares to be issued excludes the 2,929,115 commitment shares because no proceeds will be attributable to such commitment shares.

(3) The denominator is based on 377,781,737 shares outstanding as of April 22 2013, adjusted to include the 2,929,115 shares issued to Lincoln Park as commitment shares in connection with this offering and the number of shares set forth in the adjacent column which we would have sold to Lincoln Park at the applicable assumed average purchase price per share. The numerator does not include the 2,929,115 shares issued to Lincoln Park as commitment shares in connection with this offering, and is based on the number of shares registered in this offering to be issued under the Purchase Agreement which includes the additional commitment shares issued pro rata as up to $10,000,000 of our common stock is purchased by Lincoln Park at the applicable assumed purchase price per share set forth in the adjacent column. The number of shares in such column does not include shares that may be issued to Lincoln Park under the Purchase Agreement which are not registered in this offering.

(4) Under the Purchase Agreement, we may not sell and Lincoln Park may not purchase any shares on a day in which the closing sale price of our common stock is below $0.07, as may be adjusted in accordance with the Purchase Agreement.

(5) The closing sale price of our shares on April 22, 2013.

**Plan of Distribution**

The common stock offered by this prospectus is being offered by the selling stockholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus could be effected in one or more of the following methods:

· ordinary brokers' transactions;

- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made 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. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions. In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the expenses incident to the registration, offering, and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has Lincoln Park or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park or may be sold by Lincoln Park without restriction under Rule 144(b)(1)(i) under the Securities Act.

Our common stock is quoted on the OTCBB under the symbol “ELTP”.

**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 know-how and technology, particularly as it relates to abuse resistant products. Our strategy includes improving off-patent drug products for life cycle management and developing generic versions of controlled-release drug products with high barriers to entry.

We own, license or contract manufacture five products currently being sold commercially, as follows:

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

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

- Phentermine 15mg capsules (“Phentermine 15mg”)
- Phentermine 30mg capsules (“Phentermine 30mg”)

· Naltrexone HCl (“Naltrexone Generic”)

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

The Precision Dose License Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg, Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA. Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine Capsules were approved by the US-FDA on September 28, 2012, but not yet launched. Naltrexone Generic was approved by the US-FDA in January 2013, but not yet launched.

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

In addition, Elite also has an undisclosed generic product filed with the FDA that is awaiting review and for which Elite retains all rights.

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

Additionally, the Company is developing abuse resistant opioid products, and once-daily opioid products.

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

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

**Strategy**

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

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

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

**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 Pharma, LLC 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 below.

**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 8mg") 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.

**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 recorded 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.

**Licensing Agreement with Precision Dose Inc.**

On September 10, 2010, Elite executed a License Agreement with Precision Dose to market and distribute Phentermine 37.5mg ("Phentermine 37.5mg"), Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada (the "Precision Dose License Agreement"). Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine Capsules were launched in April 2013. Naltrexone Generic has been approved by the US-FDA for manufacture by Elite but not yet launched. Precision Dose will have 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 Precision Dose 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 the nine months ended December 31, 2012 and each of the last two fiscal years, we have focused on research and development activities, spending, respectively, $663,625, $1,735,689 and $1,385,211on 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**

**Phentermine 37.5mg tablets**

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

**Lodrane D® Immediate Release capsules**

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

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

Lodrane D® is marketed under the Over-the-Counter Monograph (the “OTC Monograph”) and accordingly, under the Code of Federal Regulations can be lawfully marketed in the US without prior approval. Under the Federal Food Drug and Cosmetic Act (“FDCA”), FDA regulations and statements of FDA policy, certain drug products are permitted to be marketed in the U.S. without prior approval. Within the past few years, the FDA has revised its enforcement policies,

significantly limiting the circumstances under which these unapproved products may be marketed. If the FDA determines that a company is distributing an unapproved product that requires approval, the FDA may take enforcement action in a variety of ways, including, without limitation, product seizures and seeking a judicial injunction against distribution.

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

**Methadone 10mg tablets**

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend Laboratories, LLC. ( “Ascend”) pursuant to a commercial manufacturing and supply agreement dated June 23, 2011 between Elite and Ascend (the “Methadone Manufacturing and Supply Agreement”). Under the terms of the Methadone Manufacturing and Supply Agreement, Elite performs manufacturing and packaging of Methadone 10mg for Ascend.

**Hydromorphone 8mg tablets**

On March 13, 2012, Elite commenced shipping Hydromorphone 8mg to TAGI Pharma. This triggered a milestone payment under the License, Manufacturing and Supply Agreement with Precision Dose. Hydromorphone 8mg is now a commercial product being distributed by our partner, TAGI Pharma.

**Phendimetrazine Tartrate 35 mg tablets**

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

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

**Approved Products**

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

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

Phentermine HCl 37.5mg tablets

The ANDA for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC ("Epic") dated September 10, 2010 (the "Phentermine Purchase Agreement").

Hydromorphone HCl 8mg tablets

The ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (the "Hydromorphone Purchase Agreement").

Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company's commercial launch of the product, was approved by the FDA on January 23, 2012. However, please note that the completion of such transfer had been significantly delayed as a result of the FDA's reclassification of the Company's CBE-30 supplement filing to a prior approval supplement filing. As a result of the delays caused by this reclassification, the Company recorded an impairment of the Hydromorphone 8mg ANDA in an amount equal to the entire purchase price of the acquisition. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011.

Naltrexone HCl 50mg tablets

The ANDA for Naltrexone 50mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC (the "Naltrexone Purchase Agreement").

Transfer of the manufacturing process of Naltrexone 50mg to the Northvale Facility is a prerequisite of the Company's commercial launch of the product. The completion of such transfer had been significantly delayed as a result of the FDA's reclassification of the Company's CBE-30 supplement filing to a prior approval supplement filing. However, on January 31, 2013, the FDA approved the Company's supplemental application for the manufacturing and packaging of naltrexone hydrochloride 50mg tablets. This approval will allow the Company to commence the commercial manufacturing and packaging of this product for its sales and marketing partner, which will distribute the product as part of a multi-product distribution agreement. As a result of the prior delays caused by this reclassification, the Company has recorded an impairment of the Naltrexone 50mg ANDA in an amount equal to the entire purchase price of the acquisition. This impairment was recorded and is included in the Company's audited financial statements as of March 31, 2011.

Phentermine 15mg and Phentermine 30mg

Elite received approval as of September 28, 2012 from the US-FDA for Phentermine 15mg and Phentermine 30mg. These products were developed by Elite. The commercial launch of Phentermine 15mg and Phentermine 30mg has been delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. We have resolved this issue for the next year. The purchase orders now in place will allow us to obtain adequate amounts of API, although at a substantially higher price than previously paid, to supply both the Phentermine tablet product and the soon to be launched Phentermine capsule products. Elite anticipates that some of the increase in API pricing could be offset with increase manufacturing efficiencies.

**Contract Manufacturing of Isradipine and Phendimetrazine**

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

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

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

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

On March 16, 2012, Elite executed a Development and License Agreement ("D&L Agreement") with a private Hong Kong-based company (the "Hong Kong-based Customer") for Elite to develop for the Hong Kong-based Customer a branded prescription pharmaceutical product in the United States. The Hong Kong-based Customer has informed us that it has been in business for more than five years and it has multiple FDA approved manufacturing sites outside of

the United States.

Pursuant to the D&L Agreement, the Hong Kong-based Customer has engaged Elite to develop and manufacture a prescription pharmaceutical product (the "Prescription Product"). Elite agrees to be the Preferred Manufacturer and supplier of the Prescription Product pursuant to the D&L Agreement and perform maintenance activities such as stability or annual report filings for the Prescription Product. The Hong Kong-based Customer, or its designees, shall prepare all applications necessary to obtain any Prescription Product registration and permits required to file the Prescription Product in the Territories required to market the Prescription Product. All Registrations shall be solely owned by the Hong Kong-based Customer including any NDA filed with the FDA for the Prescription Product. Elite shall provide the Hong Kong-based Customer with all pharmaceutical, technical, and clinical data and information in support of the NDA application by the Hong Kong-based Customer for the approval of the Prescription Product. In consideration of Elite's performance in accordance with the terms and conditions of the D&L Agreement, the Hong Kong-based Customer shall pay Elite milestone for the Development Program and shall pay Elite for the manufacturing of the Prescription Product. Maintenance activities will be paid separately on a quarterly basis.

The Hong Kong-based Customer shall own and market the Prescription Product under its own Trademark. The term of this D&L Agreement shall be effective from the date consummated and shall continue for a five (5) year term after the commercial launch of the Prescription Product. Upon the expiration of the initial term or any renewal term, this D&L Agreement will automatically renew for an additional one (1) year term, unless one Party gives at least six (6) months notice in writing in advance of its intent not to renew.

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

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

ECR (the owner and marketer of the Lodrane® Extended Release Products) initiated a formal approval process with the FDA in 2010 regarding the Lodrane® Extended Release Products and issued a press release on March 3, 2011 stating that they will continue to actively pursue approval for the Lodrane® Extended Release Products. In addition, on April 29, 2011, ECR filed a Petition for Review with the United States Court of Appeals for the District of Columbia, petitioning such court to review and set aside the final order of the FDA with relation to the Lodrane® Extended Release Products. The Company has received no further information from ECR with regards to the status of the Petition filed.

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

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane® Extended Release Products. Elite's revenues for the manufacturing these products for the three months ended June 30, 2012 and 2011 were zero and $252k, respectively. In addition, the Company sold to ECR, at cost without markup, all raw materials related to the manufacture of the Lodrane® Extended Release Products which remained in stock subsequent to the final shipment of the Lodrane® Extended Release Products. Revenues from the sale of these raw materials totaled approximately $221k. As manufacturing of the Lodrane® Extended Release Products has ceased, there will be no further manufacturing revenues derived from the Lodrane® Extended Release Products unless and until such products receive the necessary approvals from the FDA.

Please note that there can be no assurances that such approvals will be granted or that future manufacturing revenues will be earned by the Company from the manufacture of the Lodrane® Extended Release Products, should such approvals be granted by the FDA.

Royalties on in-market sales of the Lodrane® Extended Release Products earned during the three months ended June 30, 2012 and 2011 were zero and $150k, respectively. While Elite's manufacturing of the Lodrane® Extended Release Products has ceased, the sale of such products in the US market was still permitted by the FDA until August 30, 2011. The Company earned royalties on any in-market sales that occurred up to that date.

Contract laboratory services for the Lodrane® Extended Products will continue, on a residual basis, as such services consist of stability studies that must be performed over certain defined time periods. These revenues are expected to be significantly less than laboratory service revenues earned in periods prior to the removal of the Extended Release Lodrane products from the market.

**Discontinued Development – Isradipine**

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

**Products Under Development**

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

**Abuse Resistant and Sustained Release Opioids**

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

The abuse resistant opioid products utilize our patented abuse-deterrent technology that is based on a pharmacological approach. These products are combinations of a narcotic agonist, in a sustained-release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, formulated to deter abuse of the drug. Both, agonist and antagonist, have been on the market for a number of years and sold separately in various dose strengths. Elite has filed an IND for the product and has tested the product in a series of pharmacokinetic studies. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by King Pharmaceuticals, have been approved by the FDA and are being marketed in the United States.

Elite has developed, and retains the rights to these abuse resistant and sustained release opioid products. Elite may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product. The drug delivery technology development underlying the sustained release products was initiated under a joint venture with Elan which terminated in 2002.

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

**Epic Strategic Alliance Agreement**

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a subsidiary of Epic Pharma LLC (collectively, "Epic") entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009). 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"). Although the Term has expired, cooperation under the Epic Strategic Alliance Agreement is ongoing. 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(a)(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 terms of the Series E Convertible Preferred Stock in Epic's Articles of Incorporation, 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 exercisable until the date that is the seventh anniversary of the Second Closing Date and has 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, in accordance with the Strategic Alliance Agreement, Epic has paid to Elite a total of twelve payments of $62,500 each, for an aggregate purchase price of $750,000, in exchange for an additional 62.5 shares of Series E Preferred Stock for each payment, and 750 shares of Series E Preferred Stock, in aggregate.

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. In this regard, Ram Potti resigned as a director in December, 2012 and Epic has yet to replace him. 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.

For additional information regarding the Epic Strategic Alliance Agreement, please see the disclosure in “Directors and Executive Officers”.

**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 less than 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 six 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 5,837,284 (assigned to Celgene Corporation) | November 2018 |

| | |
|---|---|
| U.S. patent 6,620,439 | October 2020 |
| U.S. patent 6,635,284 (assigned to Celgene Corporation) | March 2018 |
| U.S. patent 6,926,909 | April 2023 |
| U.S. patent 6,984,402 | April 2023 |
| U.S. patent 8,425,933 | April 2024 |

We have pending applications for eight additional U.S. patents and four foreign patents. The pending patent applications are for an opioid agonist and antagonist products that we are developing to be used with controlled-release oxycodone and other opioids to minimize the abuse potential for 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. This cancellation of outstanding orders and the cessation of manufacturing of Lodrane Products has had a material adverse effect on revenues for periods beginning subsequent to March 31, 2011.

Lodrane D® which is an immediate release product that is different from the Lodrane Products that were included in the list of products removed from the market by the FDA, 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”.

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.

In this regard, the commercial launch of Phentermine 15mg and Phentermine 30mg was delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. We have resolved this issue for the next year. Please see “Approved Products; Phentermine 15mg and Phentermine 30mg “ above.

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, Precision Dose and TPN 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 26 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.

**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**

**Market Information**

Our Common Stock is 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 by OTC Bulletin Board. 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, 2013 | | |
| March 31, 2013 | $0.10 | 0.06 |
| December 31, 2012 | $0.12 | 0.05 |
| September 30, 2012 | $0.14 | 0.10 |
| June 30, 2012 | $0.17 | 0.08 |
| | | |
| Fiscal Year Ending March 31, 2012 | | |
| March 31, 2012 | $0.13 | $0.09 |
| December 31, 2012 | $0.10 | $0.07 |
| September 30, 2012 | $0.14 | $0.07 |
| June 30, 2011 | $0.24 | $0.07 |

As of April 22, 2013, the last reported sale price of our Common Stock, as reported by the OTCBB, was $.07.

**Holders**

As of April 22, 2013, there were, respectively, approximately 130, 1, 1 and 5 holders of record of our Common Stock, Series C Preferred Stock, Series E Preferred Stock and Series G 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.

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

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 "*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 of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe 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, 2012, the Company had a working capital deficit of $3.7 million, losses from operations totaling $1.2 million for the nine months ended December 31, 2012, net other income totaling $1.25 million for the nine months then ended and a net loss of $0.1 million for the nine months ended December 31, 2012. Please note that the Company's other income/(expenses) are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that such fair values strongly correlate to and vary inversely with the market share price of the Company's Common Stock.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2013.

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

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

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

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

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

We have successfully completed the initial, second and third closings of the Epic Strategic Alliance Agreement and the twelve quarterly payments, with each such quarterly payment being equal to the Epic Quarterly Payment Amount and have accordingly received the full investment from Epic, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under “Epic Strategic Alliance Agreement”.

Despite having received the full investment from Epic Investments LLC, exclusive of warrant exercise, as provided for in the Epic Strategic Alliance Agreement, we still will most likely be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50mg were experienced as a result of the a notification received from the FDA reclassifying to a Prior Approval Supplement, the Company's Changes Being Effected in 30 Days Supplement ("CBE-30") related to a change the manufacturing and packaging site of Naltrexone 50mg. The Supplemental Application for Naltrexone 50mg was approved by the FDA on January 31, 2013.

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

For the nine months ended December 31, 2012, we sustained a negative cash flow from operations of approximately $1.5 million, compared with a negative cash flow from operations of approximately $0.8 million being achieved during the comparable period in the prior year. Our working capital deficit at December 31, 2012 was approximately $3.7 million compared with working capital deficit of approximately $3.1 million at December 31, 2011. Please note that the working capital deficits include the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling $3.4 million is classified as a current liability due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please see "NJEDA Bonds" below.

Cash and cash equivalents at December 31, 2012, were approximately $0.1 million, a decrease of approximately $0.5 million from the approximately $0.6 million balance of cash and cash equivalents at December 31, 2011.

As of December 31, 2012, our principal source of liquidity was approximately $0.1 million of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. We also hope to generate funds pursuant to the sale of shares to Lincoln Park pursuant to the Purchase Agreement. There can be no assurance that the sale of shares to Lincoln Park and/or the exercise of outstanding warrants or options will generate or provide sufficient cash.

**NJEDA Bonds**

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

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

Bond issue costs of $354,453 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,178 for the fiscal year March 31, 2012.

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

The interest payments due on March 1st and September 1st of 2009, 2010 and 2011, as well as the interest payments due on March 1st 2012 and September 1st 2012, totaling $920,000 for all eight payments, were paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient funds to make such payments when they were due.

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

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling $225,000 and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling $225,000 was not made.

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

The Company did not have sufficient funds available to make the principal payments due on September 1, 2012, with such amounts due inclusive of amounts due on September 1, 2011 and not paid. There were not sufficient funds available in the debt service reserve and accordingly, the principal payment totaling $730,000 was not made.

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011, September 1, 2011 and March 1, 2012.

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

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

**Off-Balance Sheet Arrangements**

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

**Effects of Inflation**

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

**Results of Consolidated Operations**

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

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

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

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

Depreciation and amortization for the nine months ended December 31, 2012 was $108k, a decrease of $228k, or approximately 68%, from $336k for the comparable period of the prior year. The decrease was primarily due to manufacturing fixed assets being utilized at higher levels during the current year as a result of the current year's operations being comprised of a broader line of commercial products, as compared to operations of comparable period of the prior year which consisted of a limited commercial product that was undergoing an almost complete shutdown due to the discontinuance of the Lodrane® Extended Release Products.

Non-cash compensation through the issuance of stock options and warrants for the nine months ended December 31, 2012 was $36k, an increase of $18k, or approximately 98% from $18k for the comparable period of the prior year. The increase is due to the issuance of employee stock options in June of 2012. For further details on such employee stock options, please see Note 11 of the unaudited financial statements as of and for the nine months ended December 31, 2012.

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

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

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

**Material Changes in Financial Condition**

Our working capital (total current assets less total current liabilities), decreased to a deficit of $3.7 million as of December 31, 2012 from a working capital deficit of $3.1 million as of March 31, 2012, primarily due to our net loss from operations, exclusive of non-cash charges. In addition, it should be noted that current liabilities includes the entire principal amount due on the Company's NJEDA Bonds Payable. This amount, totaling $3.4 million has been classified as a current liability as a result of the Company receiving a notice of default from the Trustee of the NJ-EDA Bonds. Please refer to Note 6 to our unaudited financial statements as and for the nine months ended December 31, 2012.

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

**Year Ended March 31, 2012 as compared to the Year Ended March 31, 2011**

Our revenues for the year ended March 31, 2012 were $2,424,118 a decrease of $1,841,845 or approximately 43% from revenues for the comparable period of the prior year, and consisted of $1,120,050 in manufacturing fees, $655,857 in lab and product development fees and $648,211 in royalties and license fees. Revenues for the year ended March 31, 2011, consisted of $3,086,183 in manufacturing fees, $348,242 in lab and product development fees, and $831,538 in royalties and license fees. Manufacturing fees decreased by approximately 64% 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 88% due to product development fees earned from the Hi-Tech Development Agreement and the Mikah Development Agreement, and fees earned from Elite's Development and License Agreement with a private Hong Kong-based company, offset by decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees decreased by 22% 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 License Agreement and related to the April 2011 launch of Phentermine 37.5 mg tablets and the March 2012 launch of Hydromorphone 8mg tablets. In-market sales of the Lodrane® Extended Release Products were only permitted for five of the twelve months in the year ended March 31, as compared to a full year of sales occurring during the comparable period of the prior year.

Research and development costs for the year ended March 31, 2012 were $1,735,689, an increase of $350,478 or approximately 25% from $1,385,211 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 year ended March 31, 2012, were $1,410,192, an increase of $534,178, or approximately 61% from $876,014 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 the preparation of the preliminary and final proxy statements which were filed during Fiscal 2012.

Depreciation and amortization for the year ended March 31, 2012 was $206,248, an increase of $32,884, or approximately 19%, from $173,364 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 year ended March 31, 2012 was $24,453, a decrease of $17,563, or approximately 42% from $42,016 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 year ended March 31, 2012 was $1,966,138, compared to a loss from operations of $885,760 for the year ended March 31, 2011.

Other expenses for the year ended March 31, 2012 were a net expense of $13,576,088, an increase in other net expenses of $578,277 from the net other expense of $12,997,812 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 year ended March 31, 2012 totaling $12,672,032, as compared to a net derivative expense of $11,714,374 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 March 31, 2012 was $0.090, as compared to a closing price of $0.078 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 $0.24 during the year ended March 31, 2012. 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 year ended March 31, 2012.

As a result of the foregoing, our net loss for the year ended March 31, 2012 was $15,058,274, compared to a net loss of $13,582,159 for the year ended March 31, 2011.

**Material Changes in Financial Condition – Year Ended March 31, 2012**

Our working capital (total current assets less total current liabilities), decreased to a working capital deficiency of $3,051,269 as of March 31, 2012 from a working capital deficiency of $1,521,956 as of March 31, 2011, primarily due to the loss from operations sustained during Fiscal 2012.

We experienced negative cash flows from operations of $394,082 for the year ended March 31, 2012, primarily due to our net loss of $15,058,274, offset by non-cash expenses totaling $14,292,415, included in the net loss, combined with decreases in accounts receivable and inventory of $174,820 and $311,480, respectively and an increase in accounts payable and accrued expenses of 133,749.

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

None

**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[1] | 59 | Chairman and Chief Executive Officer | November 2008 |
| Barry Dash, Ph. D. | 81 | Director | April 2005 |
| Chris Dick[2] | 58 | President, Chief Operating Officer and Director | October 2009[3] |
| Ashok G. Nigalaye, Ph.D. | 61 | Chief Scientific Officer and Director | June 2009[4] |
| Jeenarine Narine | 62 | Director | June 2009 |
| Jeffrey Whitnell | 57 | Director | October 2009 |
| Carter J. Ward | 48 | 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.

Ram Potti, one of the Epic appointed directors resigned as a director of the Company in December 2012.

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 Wheaten 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. (NASDQ: 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.

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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 Metalology 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.

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 September 2010, Mr. Whitnell has been the Chief Financial Officer of 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.

Each director holds office until the next annual meeting of stockholders or until such director's death, resignation or removal.

There are no family relationships between any of our directors and executive officers.

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, 2012, 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.

**Named Executive Officers and Key Employees**

The named executive officers and key employees for the fiscal year ending March 31, 2012 are:

- Jerry Treppel, Chief Executive Officer for the full year

- Chris C. Dick, President and Chief Operating Officer for the full year
- Carter J. Ward, Chief Financial Officer, Secretary and Treasurer for the full year.

These individuals are referred to collectively in this prospectus as the “Named Executive Officers”.

**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 no 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.

***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 Employment Agreement"). The Dick Employment 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 Employment 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 November 12, 2009, the Company entered into an employment agreement (the "Ward Employment *Agreement*"). Pursuant to the terms of the Ward Employment 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.

**Hedging Policy**

We do not permit the Named Executive Officers to “hedge” ownership by engaging in short sales or trading in any options contracts involving securities.

**Options Exercises and Stock Vested**

No options have been exercised by our Named Executive Officers during the 2012 Fiscal Year.

**Pension Benefits**

We do not provide pension benefits to the Named Executive Officers

**Nonqualified Deferred Compensation**

We do not have any defined contribution or other plan that provides for the deferral of compensation on a basis that is not tax-qualified.

**Potential Payments Upon Termination or Change of Control**

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.

**Compensation of named executive officers**

Summary Compensation Table

| Name And Principal Position | Fiscal Year | Salary ($) | Bonus ($) | Option Awards ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|
| Jerry Treppel | | | | | | |
| Chairman of the Board and | 2012 (1) | — | — | — | 30,000 (2) | 30,000 |
| Chief Executive Officer | 2011 (1) | — | — | — | 30,000 (2) | 30,000 |
| Chris Dick | | | | | | |
| President and | 2012 (1) | 200,000 (3) | — | — | 8,400 (4) | 208,400 |
| Chief Operating Officer | 2011 (1) | 200,000 (3) | — | — | 8,400 (4) | 208,400 |
| Carter J. Ward | | | | | | |
| Chief Financial Officer | 2012 (1) | 150,000 (5) | — | — | — | 150,000 |
| Secretary and Treasurer | 2011 (1) | 150,000 (5) | 600 (6) | — | — | 150,600 |

(1) Represents the fiscal years ended March 31, 2012 and 2011, respectively.

(2) 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.

A total of 503,332 shares of Common Stock were issued to Mr. Treppel in payment of compensation due to him for Fiscal 2011. A total of 210,601 shares of Common Stock were issued to, and 73,927 shares of Common Stock are due and owing to, Mr. Treppel in payment of compensation due to him for Fiscal 2012.

(3) Represents total salaries due to Mr. Dick pursuant to the Dick Employment. 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. A total of 419,443 shares of Common Stock were issued to Mr. Dick in payment of salaries due to him for Fiscal 2011. A total of 175,501 shares of Common Stock were issued to, and 61,606 shares of Common Stock are due and owing to, Mr. Dick in payment of salaries due to him for Fiscal 2012.

(4) Represents amounts paid for auto allowance

(5) Represents total salaries due to Mr. Ward pursuant to the Ward Employment. 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. A total of 419,443 shares of Common Stock were issued to Mr. Ward in payment of salaries due to him for Fiscal 2011. A total of 175,501 shares of Common Stock were issued to, and 61,606 shares of Common Stock are due and owing to, Mr. Ward in payment of salaries due to him for Fiscal 2012.

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

**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, 2012:

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

| | (#) | | (#) | (#) | | | |
|---|---|---|---|---|---|---|---|
| Chris Dick | | | | | | | |
| | 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 | 6/13/2013 |
| | 10,000 | (2) | — | — | | 2.21 | 6/13/2013 |
| | 10,000 | (2) | — | — | | 2.21 | 6/13/2013 |
| | 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 | (5) | 2.25 | 11/13/2016 |
| | — | | — | 200,000 | (7) | 2.25 | 11/13/2016 |
| | 133,333 | (8) | — | 66,667 | (8) | 0.10 | 1/17/2020 |
| Jerry Treppel | | | | | | | |
| | 60,000 | (9) | — | — | | 0.06 | 12/1/2018 |
| | 60,000 | (10) | — | — | | 0.06 | 12/1/2018 |
| | 60,000 | (11) | — | — | | 0.06 | 12/1/2018 |
| Carter J. Ward | | | | | | | |
| | 133,333 | (8) | — | 66,667 | (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.

(5) These options vest upon the closing of an exclusive product license for the first of the United States national 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.

(6) Reserved

(7) These options vest as follows: upon the commencement of the first Phase III clinical trial relating to the first "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, 2012:

| Name | Fees Earned or Paid In Cash ($) | Stock Awards ($) | Option Awards ($) | Non-Equity Incentive Plan Compensation ($) | Non-qualified Deferred Compensation ($) | All Other Compensation ($) | Total ($) |
|---|---|---|---|---|---|---|---|
| Barry Dash | — | 15,000 (1) | — | — | — | 5,000 (2) | 20,000 |
| Ashok Nigalaye | — | 15,000 (1) | — | — | — | 5,000 (2) | 20,000 |
| Jeenarine Narine | — | 15,000 (1) | — | — | — | 5,000 (2) | 20,000 |
| Ram Potti* | — | 15,000 (1) | — | — | — | 5,000 (2) | 20,000 |
| Jeffrey Whitnell | — | 15,000 (1) | — | — | — | 5,000 (2) | 20,000 |

(1) Represents directors fees earned during the quarters ended June 30, 2011, September 30, 2011 and December 31, 2011. Each Director received 140,401 shares of Common Stock in payment of these director fees, pursuant to the Company's policy regarding payment of Directors' fees.

(2) Represents directors fees earned during the quarter ended March 31, 2012 for which 49,285 shares of Common Stock is due and owing to each Director.

* Mr. Potti resigned as a director in December 2012.

**Director Fee Compensation**

The Company's policy regarding director fees is 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**

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, 2012 and March 31, 2011 did not receive any options or equity compensation for serving as directors other than shares of Common Stock earned in lieu of cash in relation to Director and Chairman fees due.

**Other**

The Company's Articles of Incorporation provide for the indemnification of each of the Company's directors to the fullest extent permitted under Nevada General Corporation Law.

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

The following table sets forth certain information, as of April 22, 2013 (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 April 22, 2013, we had 377,781,737 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 1,800 shares of Series E Preferred Stock outstanding as of April 22, 2013 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). As of April 22, 2013 there were 24 shares of Series C Preferred Stock outstanding and 1,351 shares of Series G Preferred Stock outstanding, with all such shares of Series C and Series G Preferred Stock being nonvoting.

As of April 22, 2013, none of the individuals listed below beneficially owned any shares of Series G Preferred Stock or Series E Preferred Stock, except for the following (as further described in the footnotes to the table): (a) 1,800 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 prospectus, 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 April 22, 2013. 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 | 1,491,423 | (1) | *** |

| | | | | |
|---|---|---|---|---|
| Barry Dash, Director | 925,839 | (2) | *** | |
| Jerry Treppel, Chairman of the Board and Chief Executive Officer | 3,436,399 | (3) | *** | |
| Ashok G. Nigalaye, Chief Scientific Officer and Director * | 186,402,618 | (4) | 30 | % |
| Jeenarine Narine, Director * | 177,305,057 | (4) | 29 | % |
| Ram Potti, Director * ** | 177,907,949 | (4) | 29 | % |
| Jeffrey Whitnell | 757,293 | (5) | *** | |
| Carter J. Ward, Chief Financial Officer | 2,767,104 | (6) | *** | |
| Epic Investments LLC<br>227-15 North Conduit Ave.<br>Laurelton, NY 11413 | 175,469,929 | (4) | 29 | % |
| Epic Pharma LLC<br>227-15 North Conduit Ave.<br>Laurelton, NY 11413 | 175,469,929 | (4) | 29 | % |
| All Directors and Officers as a group | 200,053,824 | (7) | 33 | % |

*The address is c/o Epic Investments LLC, 227-15 North Conduit Ave., Laurelton, NY 11413.
**Mr. Potti resigned as a director in December 2012.
***Less than 1%
****As of April 22, 2013

(1) Includes vested options to purchase 520,000 shares of Common Stock and 971,423 shares of Common Stock.

(2) Includes vested options to purchase 120,000 shares of Common Stock, warrants to purchase 12,434 shares of Common Stock and 793,405 shares of Common Stock.

(3) Includes 2,131,399 shares of Common Stock, warrants to purchase up to 1,125,000 shares of Common Stock and options to purchase up to 180,000 shares of Common Stock.

(4) Includes 1,800 shares of Series E Preferred Stock convertible into 73,954,598 shares of Common Stock, 15,060,666 shares of Common Stock and warrants to purchase up to 86,454,665 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 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. Please note that the number of shares of Common Stock held by Epic Investments, LLC was compiled from Statements of Changes in Beneficial Ownership on Form 4 that were filed by Epic Investments LLC since June of 2009.

In addition to beneficial interests related to Epic Investments, Dr. Nigalaye owns 7,599,356 shares of common stock and warrants to purchase up to 3,333,333 shares of common stock.

In addition to beneficial interests related to Epic Investments, Mr. Narine owns 1,501,795 shares of common stock and warrants to purchase up to 333,333 shares of common stock.

In addition to beneficial interests related to Epic Investments, Mr. Potti owns 1,771,353 shares of common stock and warrants to purchase up to 666,667 shares of common stock.

(5) Includes 757,293 shares of Common Stock.

(6) Includes vested options to purchase 200,000 shares of Common Stock, warrants to purchase 666,667 shares of Common Stock and 1,900,437 shares of Common Stock.

(7) Includes 1,800 shares of Series E Preferred Stock convertible into 73,954,598 shares of Common Stock, warrants to purchase up to 92,592,099 shares of Common Stock, and vested options to purchase up to 1,020,000 shares of

Common Stock

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**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 June 29, 2012, Epic held a beneficial interest in an aggregate of 204,322,588 shares of Common Stock, as further described in footnote 4 of the above table listing the amount and nature of beneficial ownership. Further, the 1,750 shares of Series E Preferred Stock in which Epic has a beneficial interest as of June 29, 2012 are entitled to vote 71,688,118 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 36,000,000 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.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTION

**Certain Related Person Transactions**

*Transactions with Epic Pharma LLC, Epic Investments LLC and Jerry Treppel*

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 “Business: Epic Strategic Alliance Agreement”. 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. Potti resigned as a director in December, 2012. 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, equipment purchases, contract manufacturing/packaging 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 years ended 3/31/2012 and 3/31/2011, an aggregate amount of $15,552 and $232,305, respectively, 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 3/31/2012, an aggregate amount of $133,003 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by 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.

During the fiscal year ended March 31, 2012, the Company incurred a total of $275,768 in contract manufacturing and/or packaging costs for the Company's Phentermine, Hydromorphone, Methadone and Immediate Release Lodrane products.

During the fiscal years ended March 31, 2012 and 2011, equipment purchases from Epic totaled $52,000 and $140,000, respectively.

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

Total purchases from Epic by the Company during the fiscal years ended March 31, 2012 and 2011 were $476,323 and $895,745, respectively.

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.

On June 12, 2012, we entered into a bridge loan agreement with Jerry Treppel, our Chairman and CEO, pursuant to which, as subsequently amended, we have the right, in our sole discretion, to a line of credit in the maximum principal amount of up to $1,000,000 at any one time. For more information, please see “Treppel $1,000,000 Bridge Revolving Credit Line” in “Management’s Discussion and Analysis of Financial Condition and Results Of Operation; Liquidity and Capital Resources”.

**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, 2012 and 2011 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, 2012, included in this registration statement on Form S-1, have been audited by Demetrius Berkower 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 Berkower LLC given upon their authority as experts in accounting and auditing.

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED MARCH 31, 2012 AND 2011**

**CONTENTS**

**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, 2012 and 2011 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, 2012. 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, 2012 and 2011 and the results of their operations and their cash flows for each of the years in the two year period ended March 31, 2012 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

June 29, 2012

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

**MARCH 31, 2012 and 2011**

| | 2012 | 2011 |
|---|---|---|
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $668,407 | $1,825,858 |
| Accounts receivable (net of allowance for doubtful accounts of -0-) | 396,847 | 571,667 |
| Inventories (net of reserve of $93,338 and $1,047,456, respectively) | 304,882 | 616,362 |
| Prepaid expenses and other current assets | 127,704 | 133,472 |
| Total Current Assets | 1,497,840 | 3,147,359 |
| PROPERTY AND EQUIPMENT - net of accumulated depreciation of $4,659,670 and $4,189,618, respectively | 4,284,786 | 4,118,274 |
| INTANGIBLE ASSETS – net of accumulated amortization of $-0- and $-0-, respectively | 642,848 | 597,556 |
| OTHER ASSETS | | |
| Investment in Novel Laboratories, Inc. | 3,329,322 | 3,329,322 |
| Security deposits | 14,913 | 28,377 |
| Restricted cash – debt service for EDA bonds | 280,585 | 291,420 |
| EDA bond offering costs, net of accumulated amortization of $93,030 and $78,898, respectively | 261,423 | 275,554 |
| Total Other Assets | 3,886,243 | 3,924,673 |
| TOTAL ASSETS | $10,311,717 | $11,787,862 |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

**MARCH 31, 2012 and 2011**

| | 2012 | 2011 |
|---|---|---|
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| CURRENT LIABILITIES | | |
| EDA bonds payable | $3,385,000 | $3,385,000 |
| Short term loans and current portion of long-term debt | 13,316 | 13,105 |
| Accounts payable and accrued expenses | 1,066,494 | 935,797 |
| Customer Deposits | — | 39,400 |
| Deferred revenues – current | 13,333 | 13,333 |
| Preferred share derivative interest payable | 70,966 | 282,680 |
| Total Current Liabilities | 4,549,109 | 4,669,315 |
| LONG TERM LIABILITIES | | |
| Deferred revenues | 165,558 | 178,890 |
| Other long term liabilities | 87,404 | 75,463 |
| Derivative liability – preferred shares | 8,506,106 | 14,192,329 |
| Derivative liability – warrants | 11,987,222 | 10,543,145 |
| Total Long Term Liabilities | 20,746,290 | 24,989,827 |
| TOTAL LIABILITIES | 25,295,399 | 29,659,142 |
| STOCKHOLDERS' DEFICIT | | |
| Common stock – par value $0.001, Authorized 690,000,000 shares Issued and outstanding – 331,649,728 shares and 180,545,657 shares, respectively | 331,650 | 180,546 |
| Additional paid-in-capital | 114,910,812 | 97,116,044 |
| Accumulated deficit | (129,919,303) | (114,861,029) |
| Treasury stock at cost (100,000 common shares) | (306,841) | (306,841) |
| TOTAL STOCKHOLDERS' DEFICIT | (14,983,682) | (17,871,280) |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT | $10,311,717 | $11,787,862 |

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years Ended March 31, 2012 | 2011 |
|---|---|---|
| REVENUES | | |
| Manufacturing Fees | $1,120,050 | $3,086,183 |
| Royalties and Profit Splits | 648,211 | 831,538 |
| Lab Fee Revenues | 655,857 | 348,242 |
| Total Revenues | 2,424,118 | 4,265,963 |
| COSTS OF REVENUES | 1,013,674 | 2,675,118 |
| Gross Profit | 1,410,444 | 1,590,845 |
| OPERATING EXPENSES | | |
| Research and Development | 1,735,689 | 1,385,211 |
| General and Administrative | 1,410,192 | 876,014 |
| Non-cash compensation through issuance of stock options | 24,453 | 42,016 |
| Depreciation and Amortization | 206,248 | 173,364 |
| Total Operating Expenses | 3,376,582 | 2,476,605 |
| (LOSS) FROM OPERATIONS | (1,966,138) | (885,760) |
| OTHER INCOME / (EXPENSES) | | |
| Interest expense, net | (229,592) | (231,745) |
| Change in fair value of warrant derivatives | (1,444,075) | (1,297,998) |
| Change in fair value of preferred share derivatives | (11,227,957) | (10,416,376) |
| Interest expense attributable to preferred share derivatives | (424,465) | (1,259,480) |
| Discount in Series E issuance attributable to beneficial conversion features | (250,000) | (292,213) |
| Proceeds from litigation settlement | — | 500,000 |
| Total Other Income / (Expense) | (13,576,088) | (12,997,812) |
| (LOSS) BEFORE PROVISION FOR INCOME TAXES | (15,542,226) | (13,883,572) |
| CREDIT FOR INCOME TAXES | 483,952 | 301,413 |
| NET (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS | $(15,058,274) | $(13,582,159) |
| BASIC AND DILUTED LOSS PER COMMON SHARE | $(0.06) | $(0.14) |

| | | |
|---|---|---|
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 259,163,279 | 100,020,520 |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY**

**FOR THE YEAR ENDED MARCH 31, 2011**

| | Common Stock | | Additional Paid-In | Treasury Stock | | Accumulated | Stockholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | 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 Director's Fees | 2,493,589 | 2,494 | 97,249 | | | | 99,743 |
| 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 STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY**

**FOR THE YEAR ENDED MARCH 31, 2012**

| | Common Stock | | Additional Paid-In | Treasury Stock | | Accumulated | Stockholders' |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Shares | Amount | Deficit | Deficit |
| Balance at Mar 31, 2011 | 180,545,657 | $180,546 | $97,116,044 | 100,000 | $(306,841) | $(114,861,029) | $(17,871,280) |
| Net Income | | | | | | (15,058,274) | (15,058,274) |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expense | 8,410,374 | 8,410 | 627,769 | | | | 636,179 |
| Common shares issued pursuant to the conversion of Series B, Series C, Series D and Series E Convertible Preferred Derivatives | 140,493,195 | 140,493 | 17,023,687 | | | | 17,164,181 |
| Non-cash compensation through the issuance of stock options | | | 24,452 | | | | 24,452 |
| Costs associated with raising capital | | | (342,169) | | | | (342,169) |
| Common shares issued in payment of Director's Fees | 1,505,613 | 1,506 | 144,388 | | | | 145,894 |
| Common shares issued in payment of employee salaries | 694,889 | 695 | 66,641 | | | | 67,336 |
| Proceeds received in exchange for beneficial conversion features embedded in Series E Preferred Shares | | | 250,000 | | | | 250,000 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Balance at Mar 31, 2012 | 331,649,738 | $331,650 | $114,910,812 | 100,000 | $(306,841) | $(129,919,303) | $(14,983,682) |

*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, | |
|---|---|---|
| | 2012 | 2011 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Loss from continuing operations | $(15,058,274) | $(13,582,159) |
| Adjustments to reconcile net loss to cash used in operating activities: | | |
| Depreciation and amortization | 484,151 | 483,473 |
| Change in fair value of warrant derivative liability | 1,444,075 | 1,297,997 |
| Change in fair value of preferred shares derivative liability | 11,227,957 | 10,416,375 |
| Discount in Series E issuance attributable to embedded beneficial ownership feature | 250,000 | 292,213 |
| Preferred shares derivative interest satisfied by the issuance of common stock | 636,179 | 1,283,240 |
| Legal and consulting expenses satisfied by the issuance of common stock | — | 13,737 |
| Salaries and Directors Fees satisfied by the issuance of common stock | 213,230 | 136,953 |
| Non-cash compensation satisfied by the issuance of common stock, options and warrants | 24,452 | 42,017 |
| Non-cash rent expense | 11,090 | 48,064 |
| Impairment of Intangible Assets | — | 440,000 |
| Non-cash lease accretion | 1,276 | 20,682 |
| Changes in assets and liabilities: | | |
| Accounts and interest receivable | 174,820 | (166,706) |
| Inventories | 311,480 | 754,931 |
| Prepaid expenses and other current assets | 5,767 | (1,962) |
| Security deposit | 13,464 | (13,725) |
| Accounts payable, accrued expenses and other current liabilities | (133,749) | 87,686 |
| NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES | (394,082) | 1,552,815 |
| | | |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchases of property and equipment | (201,777) | (178,169) |
| Cost of leasehold improvements | (421,556) | (343,631) |
| Proceeds from sale of retired equipment | — | 30,000 |
| Costs incurred for intellectual property assets | (45,292) | (866,150) |
| Withdrawals from restricted cash, net | 10,835 | 3,416 |
| | | |
| NET CASH (USED IN ) INVESTING ACTIVITIES | (657,790) | (1,354,533) |
| | | |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Other loan payments | (13,411) | (13,106) |
| Costs associated with raising capital | (342,169) | — |
| Proceeds from issuance of Series E Convertible Preferred Stock and Warrants | 250,000 | 1,062,500 |
| | | |
| NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES | (105,580) | 1,049,394 |
| | | |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | (1,157,451) | 1,247,676 |

| | | |
|---|---|---|
| CASH AND CASH EQUIVALENTS – beginning of period | 1,825,858 | 578,187 |
| CASH AND CASH EQUIVALENTS – end of period | $668,407 | $1,825,858 |

**Schedule continues on next page**

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(page 2 of 2)**

| | Years Ended March 31, | |
|---|---|---|
| | 2012 | 2011 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION | | |
| Cash paid for interest | $228,317 | $226,150 |
| Cash paid for income taxes | 2,849 | 7,822 |
| SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES | | |
| Common stock issued for purchase of intangible assets | — | 75,000 |
| Loan to purchase equipment | 13,200 | — |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**MARCH 31, 2012 AND 2011**

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 wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs") (collectively the "Company") for the years ended March 31, 2012 ("Fiscal Year 2012") and 2011 ("Fiscal Year 2011"). Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2012, 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, 2012 are $668,407. 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 2011 and Fiscal 2012 the Company generated all its revenues from four companies. The termination of the contracts with either of such four 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, 2012 and March 31, 2011.

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, 2012 and March 31, 2011.

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, 2012, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2008 and forward, and State, 2004 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 and profit splits are recognized when such are reasonably estimable and collectible. Revenues from royalties and profit splits 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

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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, 2012 and 2011 was $24,453 and $42,016, respectively.

FAIR VALUE MEASUREMENTS

The Company adopted Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures, for financial and non-financial assets and liabilities.

ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). The Company utilizes the market approach. The statement utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

| | |
|---|---|
| Level 1: | Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities. |
| Level 2: | Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active. |
| Level 3: | Unobservable inputs that reflect the reporting entity's own assumptions. |

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 June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* (ASU 2011-05). Under the amended

guidance, all changes in the components of net income and the components of other comprehensive income are to be presented either in a single continuous statement of comprehensive income, or in two separate but consecutive financial statements.

In December 2011, the FASB issued Accounting Standards Update No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). ASU 2011-12 defers the effective date of the requirement in ASU 2011-05 to disclose on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income. All other requirements of ASU 2011-05 are not affected by ASU 2011-12. The changes are effective April 1, 2012, with early adoption permitted. This change is not expected to have an impact to the consolidated financial results as it is a change in presentation only.

In April 2011, the FAS issued ASU No. 2011-04, *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, which amends the current fair value measurement and disclosure guidance. These changes will be effective April 1, 2012, on a prospective basis. Early application is not permitted. This change is not expected to have a material impact to the consolidated financial results.

NOTE 2 MANAGEMENT'S LIQUIDITY PLANS

The Company reported net losses of $15,058,274 and $13,582,159 for the fiscal years ended March 31, 2012 and 2011, respectively. At March 31, 2012, the Company had a working capital deficiency of approximately $3.1 million and an accumulated deficit of approximately $129.8 million, consolidated assets of approximately $10.2 million, and negative stockholders' equity of approximately $15.1 million. The Company has not generated any significant profits to date. During the fiscal year ended March 31, 2012, the Company raised $250,000 of net proceeds from the sale of Series E Preferred Stock.

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 four products currently being sold commercially. In addition, the Company has a generic product which was purchased and for which the Company is in the process of transferring the manufacture of such product to its facility in Northvale, New Jersey, and a pipeline of products under development.

As of March 31, 2012, the Company's principal source of liquidity was approximately $0.7 million of cash and cash equivalents. The Company may also receive funds through the exercise of outstanding stock options and warrants and $0.4375 million from the issuance of the Company's Series E Convertible Preferred Stock pursuant to the Strategic Alliance Agreement with Epic Pharma. The Company also is exploring raising additional funds through the sale of its equity or debt securities or otherwise. 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, the raising of funds pursuant to any new funding arrangements, or that any cash received from such sources will be material to contribute sufficient amounts to continue operating activities. Even if the Company were to receive the remaining amounts due pursuant to the Epic Strategic Alliance Agreement, it still most likely would be required to seek additional capital in the future and there can be no assurances that the Company will be able to obtain such additional capital on favorable terms, if at all.

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.

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NOTE 3 INVENTORIES

Inventories are recorded at the lower of cost or market. Inventories at March 31, 2012 and 2011 consist of the following:

| | 2012 | 2011 |
|---|---|---|
| Finished Goods | $— | $156,399 |
| Work-in-Process | 25,200 | — |
| Raw Materials | 373,020 | 1,507,419 |
| | 398,220 | 1,663,818 |
| Less: Inventory Valuation Reserve | (93,338 ) | (1,047,456) |
| | $304,882 | $616,362 |

The Inventory Valuation Reserve as of March 31, 2012, consists of raw materials with an aggregate cost of $93,338 being expired materials with no commercial value

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.

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment at March 31, 2012 and 2011 consists of the following:

| | 2012 | 2011 |
|---|---|---|
| Laboratory manufacturing, and warehouse equipment | $5,448,732 | $5,285,888 |
| Office equipment | 64,927 | 56,961 |
| Furniture and fixtures | 49,804 | 62,406 |

| | | |
|---|---|---|
| Transportation equipment | 66,855 | 66,855 |
| Land, building and improvements | 3,314,138 | 2,835,783 |
| | 8,944,456 | 8,307,893 |
| Less: Accumulated depreciation and amortization | (4,659,670) | (4,189,619) |
| | $4,284,786 | $4,118,274 |

Depreciation and amortization expense amounted to $484,156 and $483,473 for the years ended March 31, 2012 and 2011, 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, 2012 and 2011, the following costs were recorded as intangible assets on the Company’s balance sheet:

| | 2012 | 2011 |
|---|---|---|
| Intangible assets at beginning of fiscal year | | |
| Patent application costs | 597,556 | 172,841 |
| Trademarks | — | — |
| ANDA acquisitions | — | — |
| Less: Accumulated Amortization | — | (76,434 ) |
| Net Intangible Assets at beginning of fiscal year | 597,556 | 96,407 |
| | | |
| Intangible asset costs capitalized during the fiscal year | | |
| Patent application costs | 45,292 | 51,152 |
| Trademarks | | — |
| ANDA acquisition costs | — | 890,000 |
| Total cost of intangible assets capitalized | 45,291 | 941,152 |
| | | |
| Amortization of intangible assets during fiscal year | | |
| Patent application costs | — | — |
| Trademarks | — | — |
| ANDA acquisition costs | — | — |
| Total amortization of intangible assets | — | — |
| | | |
| Impairment of intangible assets during the fiscal year | | |
| Patent application costs | — | 76,434 |
| Trademarks | — | — |
| ANDA acquisition costs | — | (440,000) |
| Accumulated amortization of impaired assets | — | (76,434 ) |
| Net impairment of intangible assets | — | (440,000) |

| | | |
|---|---|---|
| Intangible assets at end of fiscal year | | |
| Patent application costs | 192,848 | 147,556 |
| Trademarks | — | — |
| ANDA acquisition costs | 450,000 | 450,000 |
| Less: Accumulated Amortization | — | — |
| Net Intangible Assets | $642,848 | $597,556 |

The costs incurred in patent applications totaling $45,292 and $51,152 for the 2012 and 2011 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.

Please also note that on May 22, 2012, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,182,836, entitled "Abuse-Resistant Oral Dosage Forms and Method of Use Thereof. A Current Report on Form 8-K was filed with the SEC on May 22, 2012, with such filing being herein incorporated by reference.

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 was a significant detrimental factor to the value of the Hydromorphone AND. In accordance with GAAP, the Company recorded an impairment equal to the full historical cost, with such impairment being included in the financial statements issued for Fiscal 2011.

On January 23, 2012, the Company received a letter from the FDA approving the prior approval supplement application. Please refer to the Current Report on Form 8-K filed with the SEC on January 27, 2012 for further details, with such filing being herein incorporated by reference.

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. Formal notification of the FDA's reclassification of the Company's CBE 30 application to a prior approval supplement was received by the company on December 14, 2011.

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.

As of June 2012, the US-FDA website lists 16 products approved in the name of Novel and an additional 7 products approved in the name of the Novel's marketing arm, Gavis Pharmaceuticals ("Gavis"). IMS data also list three additional products being marketed by Gavis. There are accordingly a total of 26 products currently identified as being approved/marketed by Novel and Gavis, with such total representing an increase of 7 products as compared to a comparable point in the prior year.

Furthermore, IMS data for the three products listed, indicate growing revenues over the last 3 years. Such revenues, as reported by the IMS were $7.3 million, 13.1 million and $24.9 million for the years ended March, 2010, March 2011 and March 2012, respectively.

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

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- 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, 2012. The valuation of the Company's investment in Novel remains at $3,329,322, an amount equal to the valuation as of March 31, 2011 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. 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 $14,132 for the fiscal year March 31, 2012.

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

The interest payments due on March 1st and September 1st of 2009, 2010 and 2011, as well as the interest payment due on March 1st 2012, totaling $806,925 for all seven payments, were paid from the debt service reserved held in the restricted cash account, due to the Company not having sufficient funds to make such payments when they were due.

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

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling $225,000 and requested that the Trustee withdraw such funds from the debt service reserve. The Company's request was denied and accordingly the principal payment due on September 1, 2010, totaling $225,000 was not made.

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

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011, September 1, 2011 and March 1, 2012.

The Company 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.

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

| | 2012 | 2011 |
|---|---|---|
| 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 |
|---|---|
| 2013 | $730,000 |
| 2014 | 185,000 |
| 2015 | 195,000 |
| 2016 | 210,000 |
| 2017 | 220,000 |
| Thereafter | 1,845,000 |
| | $3,385,000 |

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

Loans payable and long term debt consisted of the following:

| | March 31, 2012 | | March 31, 2011 | |
|---|---|---|---|---|
| | 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 | $6,923 | $— | $13,105 | $6,717 |
| Capital lease payable to Shimadzu Financial Services; 24 payments of $594; Final payment due in March 2014 | 6,393 | 6,295 | | |
| TOTAL | $13,316 | $6,295 | $13,105 | $6,717 |

**NOTE 9** - LEASES OF RENTAL PROPERTIES

The following leases for rental properties were operative during the year ended March 31, 2012:

| | 135 Ludlow Ave (see note 10) |
|---|---|
| Effective Date | July 1, 2010 |
| Termination Date | December 31, 2015 |
| Lease term | 5 years with 2 tenant renewal options for 5 years each |
| Rent expense for the 2011 Fiscal Year | $67,753 |
| Rent expense for the 2012 Fiscal Year | $90,338 |
| Minimum 5 Year Lease Payments* | |
| Fiscal year ended March 31, 2013 | 81,228 |
| Fiscal year ended March 31, 2014 | 83,259 |
| Fiscal year ended March 31, 2015 | 85,344 |
| Fiscal year ended March 31, 2016 | 87,363 |
| Fiscal year ended March 31, 2017 | 89,112 |
| | $426,306 |

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

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, 2012 | Fiscal Year Ended March 31, 2011 |
|---|---|---|
| Rent Expense | $ 90,338 | $ 67,753 |
| Actual lease payments | 79,248 | 19,689 |
| Increase in deferred rent liability | 11,090 | 48,064 |

| | | |
|---|---|---|
| Balance of deferred rent liability | 59,154 | 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.

**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** - EFERRED REVENUES

Deferred revenues in the aggregate amount of $178,891, consisting of a current component of $13,333 and a long term component of $165,558 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, 2012 consisted of $70,965 in derivative interest accrued as of March 31, 2012. The full amount of derivative interest payable as of March 31, 2012 was paid via the issuance of 802,789 shares of Common Stock, in lieu of cash, in April 2012.

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.

**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.

The Preferred Stock Derivative Liabilities are measured at fair market value, using the market approach and a level 1 fair value hierarchy, on a recurring basis as of March 31, 2011 and March 31, 2011, in accordance with the valuation techniques discussed in ASC 820.

**Preferred Stock Derivative Liabilities – Fiscal Year 2012**

| | Series B | Series C | Series D | Series E | Total |
|---|---|---|---|---|---|
| Preferred shares Outstanding as of March 31, 2012 | 797 | 2,666 | — | 1,750 | 5,213 |
| Underlying common shares into which Preferred may convert | 5,310,393 | 17,773,333 | — | 71,428,571 | 94,512,297 |
| Closing price on valuation date | $0.09 | $0.09 | $0.09 | $0.09 | $ 0.09 |
| Preferred stock derivative liability at March 31, 2012 | $477,935 | $1,599,600 | $— | $6,428,571 | $ 8,506,106 |

| | |
|---|---|
| Change in preferred stock derivative liability for the 2012 Fiscal Year | $ 11,227,957 |

The change of $11,227,957 in value of the preferred stock derivative liability occurring during the 2012 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 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 | | | | | $10,416,376 |

The change of $10,416,376 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 $3.00 per warrant. The warrants expire at various times through April 25, 2018.

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

| | Fiscal Year 2012 | | Fiscal Year 2011 | |
|---|---|---|---|---|
| | Warrant Shares | Weighted Average Exercise Price | Warrant Shares | Weighted Average Exercise Price |
| Balance at beginning of year | 155,325,048 | $ 0.15 | 125,299,740 | $ 0.25 |
| Warrants issued | 4,000,000 | $ 0.06 | 40,000,000 | $ 0.06 |
| Warrant Adjustments | 3,379,551 | — | — | — |
| Warrant exercises, forfeited or expired | 1,225,620 | $ 3.00 | 9,974,692 | $ 0.69 |
| Ending Balance | 161,478,979 | $ 0.09 | 155,325,048 | $ 0.15 |

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 Warrant Derivative Liabilities are measured at fair market value, using the market approach and a level 3 fair value hierarchy, on a recurring basis as of March 31, 2012 and March 31, 2011, in accordance with the valuation techniques discussed in ASC 820.

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The portion of derivative liabilities related to outstanding warrants was valued using the Black-Scholes option valuation model, a level 3 fair value hierarchy using the following assumptions:

| | March 31 2012 | March 31 2011 |
|---|---|---|
| Risk-Free interest rate | .05% - 1.3% | .09% - 2.9% |
| Expected volatility | 57% - 181% | 138% - 194% |
| Expected life (in years) | 0.1 – 6.1 | 0.3 – 7.0 |
| Expected dividend yield | — | — |
| Number of warrants | 161,478,979 | 155,325,048 |
| Fair value – Warrant Derivative Liability | $11,987,222 | $10,543,145 |
| Change in warrant derivative liability for the twelve months ended | $1,444,075 | $1,297,998 |

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 $1,444,075 and $ 1,297,998 in value of the warrant derivative liability occurring during the years ended March 31, 2012 and 2011, 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.

The following table summarizes, as of March 31, 2012, the warrant activity subject to Level 3 inputs which are measured on a recurring basis:

**Fair value measurements of warrants using significant unobservable inputs**
(Level 3)

| | Fiscal 2012 | Fiscal 2011 |
|---|---|---|
| Balance at March 31, 2011 | $ 10,543,145 | $ 8,499,423 |
| Warrants Issued | 815,761 | 2,951,297 |
| Warrants Exercised | — | — |
| Change in fair value of warrant liability | 628,316 | (907,575) |
| Balance at March 31, 2012 | $ 11,987,222 | $ 10,543,145 |

**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 2012, the Company issued a total of 250 shares of Series E Preferred Stock which included a conversion option at a price that was less than the market price of the Company's Common Stock on the date of issuance of the Series E Preferred Stock.

The valuation of the beneficial conversion feature, and detachable warrants, where applicable, for Series E Preferred Share issuances during Fiscal Year 2012 and Fiscal Year 2011 is summarized as follows:

| | Fiscal Year 2012 | Fiscal Year 2011 |
|---|---|---|
| Series E Shares Issued | 250 | 1,062.5 |
| Detachable Warrants Issued (March 2011 only) | — | 40,000,000 |
| Gross Proceeds Received | $ 250,000 | $ 1,062,500 |
| | | |
| Gross Valuation of Warrants Issued | — | $ 2,951,297 |
| Gross Valuation of Beneficial Conversion | $ 763,619 | $ 2,067,416 |
| | | |
| Proceeds Allocated to Warrants | — | $ 746,919 |
| Proceeds Allocated to Beneficial Conversion Feature | $ 250,000 | $ 315,581 |
| Total Allocation of Proceeds | $ 250,000 | $ 1,062,500 |

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**NOTE 17** - COMMON STOCK

During Fiscal Years 2012 and 2011, the Company issued a total of 151,104,071 shares and 96,595,489 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

| Description | Fiscal Year 2012 | Fiscal Year 2011 |
|---|---|---|
| Common Shares issued in lieu of cash payment in payment of preferred share derivative interest expenses totaling $636,179 and $1,283,240 for Fiscal Year 2012 and Fiscal Year 2011, respectively | 8,410,374 | 21,241,590 |
| Common Shares issued pursuant to the conversion of Series B, Series C, Series D and Series E Convertible Preferred Share derivatives, with such derivative liabilities totaling $17,164,181 and $4,465,584, for Fiscal Year 2012 and Fiscal Year 2011, respectively, at the time of their conversion. | 140,439,195 | 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 $145,894 and $99,743 for Fiscal Year 2012 and Fiscal Year 2011, respectively | 1,505,613 | 2,493,589 |
| Common shares issued in payment of employee salaries totaling $67,336 and $37,210 for Fiscal Year 2012 and Fiscal Year 2011, respectively. | 694,889 | 930,231 |
| Total Common Shares issued during Fiscal Years 2012 and 2011 | 151,104,071 | 96,595,489 |
| Common Shares outstanding at March 31, | 331,649,728 | 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 2012 and Fiscal Year 2011, Diluted EPS is not presented as the effect of the Company's common stock equivalents and convertible securities is anti-dilutive.

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Basic EPS is calculated as follows:

| | Fiscal Year 2012 | Fiscal Year 2011 |
|---|---|---|
| Numerator | | |
| Net (Loss) attributable to common shareholders | $(15,167,289 ) | $(13,582,159 ) |
| Denominator | | |
| Weighted average shares of common stock outstanding | 259,163,279 | 100,020,520 |
| Net (Loss) per Share – Basic and Diluted | $(0.06 ) | $(0.14 ) |
| Potentially dilutive securities excluded from the calculation of diluted loss per share ( in accordance with GAAP) | | |
| Stock Options | 2,999,000 | 3,057,000 |
| Convertible Preferred Stock | 94,512,298 | 180,881,120 |
| Warrants | 161,478,979 | 155,325,048 |

**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 2012, the Company issued 1,505,613 shares of Common Stock to its Directors in payment of Director’s fees in the aggregate amount of $130,000 and related to the period beginning on January 1, 2011 and ending on December 31, 2011. On the date of their issuance, the Common Shares had a value of $145,894, based upon the closing price of the Company’s Common Stock on such date. Please note that the shares issued during Fiscal Year 2012, include those shares owed and not yet issued at the end of Fiscal Year 2011.

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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 $182,167 and related to the period beginning on October 1, 2009 and ending on December 31, 2010. On the date of their issuance, the Common Shares had a value of $99,743, based upon the closing price of the Company's Common Stock on such date. 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, 2012, the Company owes its Directors a total of 320,350 shares of Common Stock in payment of Directors Fees totaling $32,500 for the three months ended March 31, 2012. The Company anticipates that these shares of Common Stock will be issued during the fiscal year ended March 31, 2013.

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 2012, the Company issued a total of 694,889 shares of Common Stock to its President, Chief Financial Officer and certain other employees in payment of salaries in the aggregate amount of $60,000 and related to the period beginning on January 1, 2011 and ending on December 31, 2011. On the date of their issuance, the Common Shares had a value of $67,336, based upon the closing price of the Company's Common Stock on such date. Please note that the shares issued during Fiscal Year 2012, include those shares owed and not yet issued at the end of Fiscal Year 2011.

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 $66,667 and related to the period beginning on October 1, 2009 and ending on December 31, 2010. On the date of their issuance, the Common Shares had a value of $37,210, based upon the closing price of the Company's Common Stock on such date. 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 President, Chief Financial Officer and certain other employees a total of 147,854 shares of Common Stock in payment of salaries totaling $15,000 for the three months ended March 31, 2012, 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, 2013.

Stock option based Employee Compensation

The Company did not issue options to purchase Common Stock to employees during the years ended March 31, 2012 and March 31, 2011.

During the year ended March 31, 2010 (“Fiscal 2010”) the Company issued 1,000,000 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 2012 | Fiscal Year 2011 |
|---|---|---|
| Non-cash compensation expense related to stock options granted prior to Fiscal Year 2010 | — | $ 17,056 |
| Non-cash compensation expense related to stock options granted during Fiscal Year 2010 | 24,453 | 24,960 |
| Total non-cash compensation through the issuance of stock options | $ 24,453 | $ 42,016 |

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 the years indicated were as follows:

| | Fiscal Year 2012 | | Fiscal Year 2011 | |
|---|---|---|---|---|
| | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| Outstanding at beginning of year | 3,057,000 | $ 1.51 | 3,287,000 | $ 1.41 |
| Options Granted | — | — | — | — |
| Options Exercised | — | — | | |
| Options Expired/Forfeited | (58,000 ) | $ 0.10 | (230,000 ) | $ 0.10 |

| | | | | |
|---|---|---|---|---|
| Options Vested | | | | |
| Outstanding at end of year | 2,999,000 | $ 1.53 | 3,057,000 | $ 1.51 |

The following table summarizes information about stock options outstanding at March 31, 2012:

| Range | Options Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Options Exercisable | Weighted Average Exercise Price |
|---|---|---|---|---|---|
| $ 0.01 – 1.00 | 920,000 | 7.2 | $ 0.09 | 673,334 | $ 0.08 |
| 1.01 – 2.00 | 99,000 | 5.8 | $ 1.08 | 99,000 | $ 1.08 |
| 2.01 – 3.00 | 1,980,000 | 4.5 | $ 2.22 | 1,480,000 | $ 2.21 |
| $ 0.01 – 3.00 | | 5.4 | $ 1.53 | | $ 1.53 |

As of March 31, 2012, there were 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, | |
|---|---|---|
| | 2012 | 2011 |
| Federal: | | |
| Current | $— | $— |
| Deferred | — | — |
| State | | |
| Current | $(2,849) | $(10,422) |
| Deferred | — | — |
| Sale of New Jersey Net Operating Losses | $486,801 | $311,835 |
| Net Credit for Income Taxes | $483,952 | $301,413 |

The Major components of deferred tax assets and liabilities at March 31, 2012 and 2011 are as follows:

| | March 31, | |
|---|---|---|
| | 2012 | 2011 |
| Federal | | |
| Net Operating Loss Carry forward | $16,995,825 | $17,789,382 |
| Less: Deferred Tax Liability | (169,208) | (305,716) |
| Subtotal | 16,826,617 | 17,483,666 |
| Valuation Allowance | (16,826,617) | (17,483,666) |
| | $— | $— |
| State | | |
| Net Operating Loss Carryforwards | $932,426 | $2,223,278 |
| Less: Deferred Tax Liability | (34,837) | (68,786) |
| Subtotal | 897,589 | 2,154,492 |
| Valuation Allowance | (897,589) | (2,154,492) |
| | $— | $— |

At March 31, 2012 and 2011, 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.

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NOTE 22 - REMOVAL OF LODRANE PRODUCTS FROM THE US MARKET

On March 3, 2011, the U.S. Food and Drug Administration ("US-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 US-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 US-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 US-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 US-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 US-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 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

Three customers accounted for approximately 90 percent of revenues for the year ended March 31, 2012, with such group of customers including a single customer that accounted for approximately 97 percent of revenues for the year ended March 31, 2011.

Please note that this major customer in the year ended March 31, 2011, was the purchaser of the Lodrane® products, which have been discontinued pursuant to an announcement by the US-FDA.

Shortly after the announcement by the US-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 US-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 US-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 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.

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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.

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.

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.

In addition, under the Series E Amendment Agreement, the third closing date is scheduled to occur on or before December 31, 2010, subject to certain conditions set forth in the Epic SAA (as amended by the Series E Amendment Agreement).

Under each of the Series D Amendment Agreement and the Series E Amendment Agreement, the Company agreed that at its next meeting of shareholders it will seek shareholder approval to amend its certificate of incorporation to increase the number of authorized but unissued shares of Common Stock to at least 760,000,000.

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' Releases.

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.

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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.

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 this Annual Report Form 10-K under Item 7 of Part II of this Annual Report on Form 10-K, under the heading "Epic Strategic Alliance Agreement," Item 9B and Item 10, under the heading "Directors and Executive Officers," and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which disclosures are incorporated herein by reference. 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, equipment purchases, contract manufacturing/packaging 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 years ended 3/31/2012 and 3/31/2011, an aggregate amount of 15,552 and $232,305, respectively, 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 3/31/2012, an aggregate amount of $133,003 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by 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.

During the fiscal year ended March 31, 2012, the Company incurred a total of $275,768 in contract manufacturing and/or packaging costs for the Company's Phentermine, Hydromorphone, Methadone and Immediate Release Lodrane products.

During the fiscal years ended March 31, 2012 and 2011, equipment purchases from Epic totaled $52,000 and $140,000, respectively.

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 years ended March 31, 2012 and 20111 were $476,323 and $895,745, respectively.

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 B 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series B Preferred Derivatives"), the Series C 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series C Preferred Derivatives"), the Series D 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series D Preferred Derivatives") and the Series E Convertible Preferred Stock Derivatives (the "Series E Preferred Derivatives", and together with the Series B Preferred Derivatives, the Series C Preferred Derivatives and the Series D Preferred Derivatives, the "Preferred Derivatives") include provisions entitling the holders of these Preferred Derivatives to convert shares of the Preferred Derivatives into shares of Common Stock. The Preferred Derivatives are classified as a liability to the Company, and the liability represented by those shares of 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 Preferred Derivatives is equal to the value of such 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 Preferred Derivatives during the years ended March 31, 2012 and March 31, 2011, are summarized as follows:

| | Fiscal 2012 | Fiscal 2011 |
|---|---|---|
| Series B Derivatives | | |
| Number of Derivative Shares Converted | 99 | — |
| Number of Common Shares issued pursuant to conversion | 660,001 | — |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | $72,600 | — |
| Change in value of preferred share derivative liability recorded at time of conversion | $(39,600) | — |
| Par value of Common Shares issued | $660 | — |
| Additional paid in capital recorded as a result of the conversions | $71,940 | — |
| | | |
| Series C Preferred Derivatives | | |
| Number of Derivative Shares Converted | 2,752 | — |
| Number of Common Shares issued pursuant to conversion | 18,346,673 | — |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | $1,712,667 | — |
| Change in value of preferred share derivative liability recorded at time of conversion | | |