ELITE PHARMACEUTICALS INC /NV/
Form POS AM
June 25, 2013

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

REGISTRATION NO. 333-188139

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE

AMENDMENT NO. 1 TO

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

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 JUNE 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 June 19, 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 seven 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")
- Phentermine 15mg capsules ("Phentermine 15mg")
- Phentermine 30mg capsules ("Phentermine 30mg")

We own the following product which has been approved for manufacture by the United States Food and Drug Administration ("FDA"), but for which commercial production has not yet begun:

- 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 15mg and Phentermine 30mg were launched in April 2013. Naltrexone Generic was approved by the 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.

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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 Company's Abuse Resistant Technology.

On April 23, 2013, the USPTO issued U.S. Patent No. 8,425,933, entitled "Abuse-Resistant Oral Dosage Forms and Method of User Thereof", with such patent providing further protection for the Company's Abuse Resistant Technology.

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.

Through June 19, 2013, we have sold to Lincoln Park an aggregate of 4,691,352 shares under the Purchase Agreement for aggregate gross proceeds of approximately $320,000. In addition, we have issued 3,022,847 Commitment Shares. Other than the foregoing, we do not have the right to commence any additional sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the post-effective amendment to 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, the date that we entered into the Purchase Agreement, there were 394,580,173 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 had 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) 3,022,847 shares that we have issued to Lincoln Park as a commitment fee (ii) 4,691,352 shares that we have issued to Lincoln Park pursuant to the Purchase Agreement; (iii) an additional 70,308,648 shares which may be issued to Lincoln Park in the future under the Purchase Agreement and (iii) 2,835,383 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 16% of the total number of shares of our common stock outstanding and 17% 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: · 3,022,847 commitment shares issued to Lincoln Park · 4,691,352 shares that we have issued to Lincoln Park under the Purchase Agreement and · 73,144,031 shares we may sell to Lincoln Park under the Purchase Agreement, including

	· 2,835,383 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 (exclusive of all shares previously issued to Lincoln Park)	386,865,974 shares
Common stock to be outstanding after giving effect to the issuance of 80,858,230 shares under the Purchase Agreement (inclusive of all shares previously issued to Lincoln Park)	467,724,204 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

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. We achieved a net income of $1.5 million during Fiscal 2013 and incurred a net loss $15.1 million during Fiscal 2012. However, please note that such net income and net loss amounts include other income and expense from preferred share and warrant derivatives totaling a net $3.5 million of other income in Fiscal 2013 and a net $12.7 million in other expenses for Fiscal 2012. We incurred losses from operations of $1.6 million and $2.0 million during Fiscal 2013 and Fiscal 2012, respectively. We expect to continue to incur operating 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, 2013, 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 March 31, 2013, we had cash reserves of approximately $0.4 million, a working capital deficit of approximately $2.8 million, and for Fiscal 2013, we had losses from operations totaling $1.6 million, net other income totaling $3.5 million and a net income of $1.5 million.

In addition, as discussed below in "Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight as evidenced by the FDA's removal from the market of our Lodrane® extended release product line", 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 assist in financing our short term working capital requirements, 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 (please see "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Purchase Agreement with Lincoln Park Capital"), 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. Through June 19, 2013, we have raised approximately $320,000 in gross proceeds from sales under the Purchase Agreement. Assuming a purchase price of $0.07 per share and the purchase by Lincoln Park of all of the shares registered herein, proceeds to us would only be $5,250,000 and not the full $10,000,000 allowed by the Purchase Agreement.

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, Phentermine capsule products and, the eventual launch of the generic naltrexone product and other opportunities in our pipeline, Elite eventually could be profitable. In addition, the commercialization of the Epic product 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 product 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.

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 protect 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.

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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 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, and, while we anticipate that some of the increase in API pricing could be offset with increase manufacturing efficiencies, the volumes and profits from these products will be impaired. 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. In this regard, as of May 24, 2013, Chris Dick, the Company's President, Chief Operating Officer and member of the Board of Directors, stepped down from his positions as President and Chief Operating Officer and a Director. However, Mr. Dick remains as a consultant with Elite to ensure a smooth transition while the Board of Directors conducts a search for a permanent replacement.

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 product 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 May 9, 2013, the date that the SEC 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 June 19, 2013, there were outstanding shares of preferred stock convertible into up to approximately 81.4 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 a product developed by Epic under the Epic Strategic Alliance Agreement, we may issue to Epic up to an aggregate of 3,000,000 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 a certain immediate-release product 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.

Pursuant to the Epic Strategic Alliance Agreement, at present two of our directors are appointees of Epic. In addition, the terms of the Series E Preferred Stock provide 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. Except as provided by law or by the other provisions of the Series E Preferred Stock, 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 terms of the Series E Preferred Stock, 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 terms of the Series E Preferred Stock, we must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein. Accordingly, 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 post-effective amendment no. 1 to 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 June 19, 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 394,580,173 shares of

our common stock actually outstanding as of June 19, 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	*

*** 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 prior to the commencement of this offering 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 394,580,173 outstanding shares of our common stock as of June 19, 2013, which includes 3,022,847 shares of our common stock issued to Lincoln Park 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.

Through June 19, 2013, we have sold to Lincoln Park an aggregate of 4,691,352 shares under the Purchase Agreement for aggregate gross proceeds of approximately $320,000. In addition, we have issued 3,022,847 Commitment Shares as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. Other than the foregoing, we do not have the right to commence any additional sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the post-effective amendment to 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 May 9, 2013, the date that the registration statement including this prospectus became 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)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (2)	Proceeds from the Sale of Shares to Lincoln Park Under the Purchase Agreement
$0.07(4)(5)	76,331,272	16.15%	$5,343,189
$0.15	66,666,667	14.36%	$10,000,000
$0.25	42,929,115	9.14%	$10,000,000
$0.35	31,500,544	6.71%	$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. However, the number of registered shares to be issued excludes the commitment shares because no proceeds will be attributable to such commitment shares.

(2) The denominator is based on (i) 394,580,173 shares outstanding as of June 19, 2013, (ii) additional shares issueable to Lincoln Park as commitment shares pro rata as up to $10,000,000 of our common stock is purchased by Lincoln Park and (iii) the shares listed in column 2 at the applicable assumed purchase price per share set forth in column 1. The numerator does not include the total number of shares issued or issuable to Lincoln Park as commitment shares in connection with this offering.

(3) 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.

(4) The closing sale price of our shares on June 19, 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 seven 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")
- Phentermine 15mg capsules ("Phentermine 15mg")
- Phentermine 30mg capsules ("Phentermine 30mg")

We own the following product which has been approved for manufacture by the FDA, but for which commercial production has not yet begun:

- 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 15mg and Phentermine 30mg were launched in April 2013. Naltrexone Generic was approved by the 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 Company's Abuse Resistant Technology.

On April 23, 2013, the USPTO issued U.S. Patent No. 8,425,933, entitled “Abuse-Resistant Oral Dosage Forms and Method of User Thereof”, with such patent providing further protection for the Company’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 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 each of the last two fiscal years, the Company has conducted research and development activities. We incurred total costs of $975,250 during the fiscal year ended March 31, 2013 (“Fiscal 2013”) and $1,735,689 during the fiscal year ended March 31, 2012 (“Fiscal 2012”) in relation to 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

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 15mg and Phentermine 30mg were launched in April 2013. Phentermine 37.5mg tablets and Phentermine 15mg and 30mg capsules are 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”) launched 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 FDA for Phentermine 15mg and Phentermine 30mg. These products were developed by Elite. The commercial launch of Phentermine 15mg and Phentermine 30mg had been delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. We resolved this issue and the Phentermine 15mg and Phentermine 30mg products were launched in April 2013. The resolution of this issue related to the supply of API, however, required us to pay substantially higher prices than previously paid for the Phentermine API. Elite anticipates that some of the increase in API pricing could be offset with increase manufacturing efficiencies, but also that volumes and profits from these products will be impaired.

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”

Development and License Agreement with Hong Kong based company

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. Contracts relating to the manufacture and sale of the Lodrane® Extended Release Products were formally terminated on April 26, 2013.

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane® Extended Release Products. 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. 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. Furthermore, the Company has been advised that ECR has decided not to proceed with the development of the extended release formulations marketed under the Lodrane® brand. The Company has received FDA feedback on clinical protocols for the extended release brompheniramine product, the active ingredient in Lodrane24®. It also has filed a Citizen Petition with the FDA related to the extended release brompheniramine/pseudoephedrine product, the active ingredients in Lodrane24D®. The Company believes a successful resolution of the Citizen Petition would put this product in a position to move forward with clinical trials and eventually secure the requisite approvals for introduction of the product to the market. The Company may proceed with the development of these formulations and may seek partners in conjunction with such activities, but there can be no assurances that the Company will pursue the development of these formulations, or that such development activities, if pursued, will result in approvals from the FDA. Please also note that the Company does not have ownership of the Lodrane® brand name, and that if any products containing the formulations associated with the Lodrane® brand name are approved and marketed, such would be done under a different brand name.

On June 10, 2013, the Company submitted a Citizen Petition to the FDA requesting that the FDA make a determination that (a) it is suitable to use the currently approved and marketed ANDA product (ANDA 078648, generic to Drixoral brand) as the Reference Listed Drug ("RLD") since the current RLD Drixoral brand is no longer available in the marketplace, and (b) that this currently approved and marketed ANDA product is suitable to use as a RLD for an equivalent active ingredient comprised of a different salt.

The filing of the Citizen Petition represents another step forward in the Company's continuing efforts to reintroduce its extended release brompheniramine maleate and pseudoephedrine hydrochloride to the marketplace.

Citizen petitions are filed to ask that the FDA take, or refrain from taking, a particular action. Any person may file a citizen petition, and any person may comment on a petition that has been filed. Petitions are governed by and must comply with FDA regulations, specifically 21 C.F.R §10.30, as well as the Federal Food, Drug and Cosmetic Act, specifically §355(q), when applicable.

The Company cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition.

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. The Company expects their first commercially scaled-up, abuse-resistant opioid product to enter human pilot studies later this year. Work has also been conducted on another abuse-resistant opioid product. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by Pfizer, Inc., 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). The Epic Strategic Alliance Agreement expired on June 4, 2012.

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 "Term"). Although the Term has expired, cooperation between the Company and Epic continued. In addition to the use of the Facility, Epic used 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.

During the Term, Epic was permitted to 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 were agreed upon by Epic and Elite.

Pursuant to the Epic Strategic Alliance Agreement, Epic also was permitted to 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 could 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 was permitted to 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 was to 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 was to 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 was to 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 was to 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 has 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. During the Term and through June 19, 2013, a total of 4,000,000 Milestone Warrants were issued to Epic pursuant to the Epic Strategic Alliance Agreement.

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.

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 the Company's 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, 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. Epic neither made such an additional investment nor made such a loan and the Term has expired.

Board of Directors Composition and Voting Rights

As of the Initial Closing Date, except as otherwise set forth in the Epic Strategic Alliance Agreement, Elite and its Board of Directors was required to take any and all action necessary so that (i) the size of the Board of Directors would be set and remain at seven directors, (ii) three individuals designated by Epic (the “Epic Directors”) would be appointed to the Board of Directors and (iii) the Epic Directors would be nominated at each annual or special meeting of stockholders at which an election of directors was held. The foregoing obligations terminated pursuant to the terms of the Epic Strategic Alliance Agreement in April, 2013 when Epic’s ownership of Company securities dropped below a certain defined level.

The terms of the Series E Preferred Stock provide 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 Preferred Stock, 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 terms of the Series E Preferred Stock, 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, if ever, 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 terms of the Series E Preferred Stock, 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 8,182,836	April 2024
U.S. patent 8,425,933	April 2024

We have pending applications for three 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 U.S. 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.

cGMP

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