ELITE PHARMACEUTICALS INC /NV/
Form S-1/A
April 28, 2014

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON APRIL 28, 2014

REGISTRATION NO. 333-195265

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

FORM S-3
ON 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)

Nasrat Hakim

Chief Executive Officer

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

917-720-0863 (fax)

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

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

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

(COVER CONTINUES ON FOLLOWING PAGE)

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

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

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

¨ Large accelerated filer

¨ Accelerated filer

¨ Non-accelerated filer

x Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Security	Proposed Maximum Aggregate Offering Price	Amount Of Registration Fee(2)
Common Stock, $0.001 par value per share	108,000,000		$ 41,600,000	$ 5,358
Total				$ 5,358

(1) The registrant is registering for resale, from time to time, up to 108,000,000 shares of its common stock, par value $0.001, that the registrant has issued and may sell and issue to Lincoln Park Capital Fund, LLC (“Lincoln Park”) pursuant to a Purchase Agreement (the “Purchase Agreement”), dated as of April 10, 2014, by and between Lincoln Park and the registrant. In the event of stock splits, stock dividends, or similar transactions involving the common stock, the number of shares of common stock registered shall, unless otherwise expressly provided, automatically be deemed to cover the additional securities to be offered or issued pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended (the “Securities Act”).

(2) The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

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

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

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED APRIL 28, 2014

PROSPECTUS

ELITE PHARMACEUTICALS, INC.

108,000,000 Shares of

Common Stock

This prospectus relates to the offer and sale of up to 108,000,000 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 shareholder.

The shares of common stock being offered by the selling shareholder have been or may be issued pursuant to the purchase agreement dated April 10, 2014 that we entered into with Lincoln Park. See “The Lincoln Park Transaction” in “Selling Shareholder” for a description of that agreement and “Selling Shareholder” 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 shareholder.

The selling shareholder 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 shareholder may sell the shares of common stock being registered pursuant to this prospectus. The selling shareholder is an “underwriter” within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended.

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

Our common stock is currently quoted on the Over-the-Counter Bulletin Board, or the OTCBB, under the symbol “ELTP”. On April 22, 2014, the last reported sale price of our common stock on the OTCBB was $0.39.

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 as well as in any prospectus supplement related to these specific offerings 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 _____, 2014.

ELITE PHARMACEUTICALS, INC.

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ABOUT THIS PROSPECTUS

You may only rely on the information contained in this prospectus and any prospectus supplement. We have not authorized anyone to provide you with different information. The selling shareholder is not making an offer of these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of that document. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

PROSPECTUS SUMMARY

This prospectus summary highlights certain information about our company and other information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, any prospectus supplement, including the section entitled “Risk Factors”, before making an investment decision.

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 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 eight 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
- Phentermine 15mg capsules (“Phentermine 15mg”)
- Phentermine 30mg capsules (“Phentermine 30mg”)
- Naltrexone HCl 50mg tablets (“Naltrexon 50mg”)

In October 2013, we acquired approved Abbreviated New Drug Applications (“ANDAs”) for 12 products and one ANDA that is under active review with the FDA from Mikah Pharma, and we executed a Manufacturing and License

Agreement with Epic Pharma LLC to manufacture, market and sell in the United States and Puerto Rico 12 generic products owned by Elite.

Elite has a license agreement with Precision Dose, Inc. (the "Precision Dose License Agreement") and a manufacturing agreement with The PharmaNetwork LLC (now Ascend Laboratories LLC) (the "TPN Agreement").

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 50mg was launched in September 2013.

The TPN Agreement 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.

On April 22, 2014, the USPTO issued U.S. Patent No. 8,703,186, entitled "Abuse-Resistant Oral Dosage Forms and Method of Use Thereof", with such patent providing further protection for the Company's Abuse Resistant Technology.

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

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 operates under Good Manufacturing Practice ("GMP") and is a United States DEA registered facility for research, development and manufacturing.

About This Offering

On April 10, 2014, 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 $40,000,000 of our common stock (subject to certain limitations) from time to time over a 36-month period. Also, on April 10, 2014, we entered into a Registration Rights Agreement, or the Registration Rights Agreement, with Lincoln Park, pursuant to which we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Act, the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Other than 1,928,641 shares of our common stock that we have already issued to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, we do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until the SEC has declared effective the registration statement of which this prospectus forms a part. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase up to 500,000 shares of our common stock on any business day, provided that at least one business day has passed since the most recent purchase. However, in no event shall Lincoln Park purchase more than $760,000 worth of our common stock on any single business day, plus an additional "accelerated amount" under certain circumstances. 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 up to 500,000 shares that may be sold to Lincoln Park under the Purchase Agreement on any business day 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 $0.10 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's notice. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of April 22, 2014, there were 560,354,843 shares of our common stock outstanding, of which 451,791,002 shares were held by non-affiliates, excluding the 1,928,641 shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to $40,000,000 of our common stock to Lincoln Park, only 108,000,000 shares of our common stock are being offered under this prospectus, which represents (i) 1,928,641 shares that we issued to Lincoln Park as a commitment fee and (ii) an additional 106,071,359 shares which may be issued to Lincoln Park in the future under the Purchase Agreement. If all of the 108,000,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 15.9% of the total number of shares of our common stock outstanding and 19.0% 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 108,000,000 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 shareholders, except that the economic and voting interests of each of our existing shareholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing shareholders own will not decrease, the shares owned by our existing shareholders 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 Shareholder” below.

Securities Offered

Common stock to be offered by the selling shareholder	108,000,000 shares
Common stock outstanding prior to this offering	562,283,484 shares
Common stock to be outstanding after giving effect to the issuance of 106,071,359 additional shares under the Purchase Agreement	668,354,843 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 $40,000,000 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 our company involves a high degree of risk. In addition to the other information included in this prospectus, you should carefully consider the following risk factors described in this prospectus and the risk factors that may be described in any applicable prospectus supplement. You should consider these matters in conjunction with the other information included in this prospectus. The risks and uncertainties described in this prospectus and any applicable prospectus supplement are not the only ones facing us. Additional risks and uncertainties that we do not presently know about or that we currently believe are not material may also adversely affect our business. Our business, results of operations or financial condition could be seriously harmed, and the trading price of our common stock may decline due to any of these or other risks.

This prospectus contains statements that constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements appear in a number of places in this prospectus and include statements regarding the intent, belief or current expectations of our management, directors or officers primarily with respect to our future operating performance. Prospective purchasers of our securities are cautioned that these forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those in the forward-looking statements due to various factors. The accompanying information contained in this prospectus, including the information set forth below, identifies important factors that could cause these differences. See “Forward-Looking Statements” below.

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 from operations in each year since our incorporation in 1990. During the nine months ended December 31, 2013 and for the past two fiscal years, we incurred net losses from operations of $2,899,322, $1,563,133 and $1,966,138, respectively We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

We may require additional financing 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 December 31, 2013, we had cash reserves of approximately $1.1 million and a working capital deficit of $8.6 million, and we had losses from operations totaling $2.9 million for the nine months ended December 31, 2013, net other expenses totaling $6.9 million for the nine months then ended and a net loss of $ 9.8 million for the nine months ended December 31, 2013. 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.

Over the past year, we raised approximately $10 million from the sale of shares to Lincoln Park pursuant to a prior April 19, 2013 purchase agreement. That agreement terminated in March 2014 with the sale of all shares covered by that agreement. In addition, both Nasrat Hakim, our CEO, and Jerry Treppel, our Chairman, have each provided Elite with a revolving bridge credit line of up to $1,000,000.

Pursuant to the Purchase Agreement with Lincoln Park, we may direct Lincoln Park to purchase up to $40,000,000 worth of shares of our common stock under our agreement over a 36 month period generally in amounts up to 500,000 shares on any such business day. However, Lincoln Park shall not be required to purchase more than $760,000 worth of stock on any business day and cannot purchase any shares of our common stock on any business day that the closing sale price of our common stock is less than $0.10 per share, subject to adjustment as set forth in the Purchase Agreement. Assuming a purchase price of $0.39 per share (the closing sale price of the common stock on April 22, 2014) and only 104,142,718 shares available for purchase, we would only receive $40 million in gross proceeds from purchases under the Purchase Agreement by Lincoln Park of shares registered herein.

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 $40,000,000

under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans.

Our ability to raise additional funds from the sale of equity securities to Lincoln Park or others is limited. In this regard, we only have approximately 108,139,572 shares authorized but unissued and unreserved. At our upcoming annual shareholders' meeting scheduled to be held on May 21, 2014 we are seeking to amend our Articles of Incorporation to increase the number of authorized shares of Common Stock. If we are unable to obtain approval for this increase, the amount of proceeds we may receive from the sale of our remaining Common Stock is limited.

We are anticipating that, with the growth of the current generic product line consisting of generic phentermine tablets and capsules, hydromorphone, naltrexone, methadone, phendimetrazine and immediate release Lodrane D®, combined with the successful transfer of manufacturing site and commercial launch of the 12 approved generic products licensed to Epic Pharma LLC and other opportunities in our pipeline, Elite eventually could be profitable. 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 sales of the current generic product line will continue, that the 12 approved generic products licensed to Epic Pharma LLC will be successfully commercialization and generate future revenues or that the other opportunities in our pipeline will be successfully commercialized. There can also be no assurances of Elite becoming profitable

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, 2014 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, 2012 and 2013. 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. 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".

Elite's pipeline consists of products in various stages of development, including products in early development.

Elite's product pipeline, including its abuse deterrent opioid products, are in various stages of development. Prior to commercialization, product development must be completed that could include scale-up, clinical studies, regulatory filing, regulatory review, approval by the FDA, and/or other development steps. Additionally, Elite has 12 approved generic products for which a site transfer must be completed prior to product launches. For these generic products, Elite must complete site transfer studies, file a changes being effective in 30 days (CBE 30) and await FDA review and approval. Development is subject to risks. We cannot assure you that development will be successful, or that during development unexpected delays might occur or additional costs might be incurred.

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; and

- 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.

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 eight patents and we have five 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 or obtained by other entities or become known, obtained or independently developed by our competitors or, if patents are not issued with respect to products arising from research, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights can be costly, time-consuming and/or ultimately unsuccessful.

Litigation is common in the 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 routinely bring litigation against applicants and allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant. Elite develops, owns and/or manufactures generic and branded pharmaceutical products and such drug products may be subject to such litigation. Litigation often involves significant expense and can delay or prevent introduction or sale of our products.

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

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

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

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

- obtaining new patents on drugs whose original patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay approval from the FDA;
- filing citizens’ petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues; developing controlled-release or other “next-generation” products, which often reduce demand for the

generic version of the existing product for which we may be seeking approval;

- changing product claims and product labeling;
- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

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

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

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

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

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

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

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved.

In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers and there is a risk of a sole approved supplier significantly raising prices. Please note that such an occurrence has taken place recently, wherein significant price increases from a sole supplier greatly reduced profit margins, sales and delayed product launches. These occurrences were ultimately resolved by the successful FDA approval of an alternate supplier, with such approval process being lengthy and costly.

Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including, without limitation:

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

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

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR COMMON STOCK

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

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2014, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.9379 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; and
- Fluctuations in our operating results.

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 10, 2014, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $40,000,000 of our common stock. Concurrently with the execution of the Purchase Agreement, we issued 1,928,641 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The purchase shares that may be sold pursuant to the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park, except that, pursuant to the terms of our agreements with Lincoln Park, we would be unable to sell shares to Lincoln Park if and when the closing sale price of our common stock is below $0.10 per share, subject to adjustment as set forth in the Purchase Agreement, and in no event would Lincoln Park purchase more than $760,000 worth of our common stock on any single business day, plus an additional “accelerated amount” under certain circumstances. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all, some or none of the shares of our common stock that may be sold pursuant to the Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares.

In addition, as of April 22, 2014, there were outstanding shares of preferred stock convertible into approximately 148.9 million shares of Common Stock and warrants to purchase an aggregate of approximately 102.0 million shares of Common Stock at exercise prices that range from $0.625 per share to $0.25 per share. Additional shares of Common Stock may be issuable as a result of anti-dilution provisions in the outstanding preferred stock and warrants

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 shareholders. 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.

Provisions of our Articles of Incorporation and By-Laws could defer a change of our Management which could discourage or delay offers to acquire us.

Provisions of our Articles of Incorporation and By-Laws law may make it more difficult for someone to acquire control of us or for our shareholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our shareholders. For example, as discussed above, our Articles of Incorporation allows us to issue shares of preferred stock without any vote or further action by our shareholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further shareholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, on November 15, 2013, we entered into a Shareholder Rights Plan and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of our common stock and one right for each share of Common Stock into which any of our outstanding Preferred Stock is convertible, to shareholders of record at the close of business on that date. Each Right entitles the registered holder to purchase from us one “Unit” consisting of one one-millionth (1/1,000,000) of a share of Series H Junior Participating preferred stock, at a purchase price of $2.10 per Unit, subject to adjustment, and may be redeemed prior to November 15, 2023, the expiration date, at $0.000001 per Right, unless earlier redeemed by the Company. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Mr. Hakim, our Chief Executive Officer, the Rights Plan’s the 15% threshold excludes shares beneficially owned by him as of November 15, 2013 and all shares issuable to him pursuant to his employment agreement and the Mikah Note. Our By-Laws provide for the classification of our Board of Directors into three classes.

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.

Our Common Stock is 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 identified under “Risk Factors” and from time to time in our other 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 $40,000,000 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.

DETERMINATION OF OFFERING PRICE

The selling shareholder may offer and sell the shares of common stock covered by this prospectus at prevailing market prices or privately negotiated prices. See “Plan of Distribution.”

SELLING SHAREHOLDER

This prospectus relates to the possible resale by the selling shareholder, Lincoln Park, of shares of common stock that have been or may be issued to Lincoln Park pursuant to the Purchase Agreement. We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on April 10, 2014 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 shareholder, 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 shareholder may sell some, all or none of its shares. We do not know how long the selling shareholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling shareholder regarding the sale of any of the shares.

The following table presents information regarding the selling shareholder 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 shareholder, and reflects its holdings as of April 22, 2014. 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 shareholder" 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 562,283,484 shares of our common stock actually outstanding as of April 22, 2014.

Selling Shareholder	Shares Beneficially Owned Before this Offering		Percentage of Outstanding Shares Beneficially Owned Before this Offering		No. of Shares to be Sold in this Offering		Percentage of Outstanding Shares Beneficially Owned After this Offering
Lincoln Park Capital Fund, LLC (1)	1,928,641	(2)	*	(3)	108,000,000	(4)	*

*** Less than 1%**

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

(2) Represents 1,928,641 shares of our common stock issued to Lincoln Park on or about April 11, 2014 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 562,283,484 outstanding shares of our common stock as of April 22, 2014, with the above mentioned commitment shares deemed issued as of that date.

(4) Although the Purchase Agreement provides that we may sell up to $40,000,000 of our common stock to Lincoln Park, we have reserved approximately 108,000,000 shares for sale to Lincoln Park under the Purchase Agreement. See “We may require additional financing to meet our business objectives and to continue as a going concern” in “Risk Factors”.

The Lincoln Park Transaction

General

On April 10, 2014, 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 $40,000,000 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.

Pursuant to the Purchase Agreement we have issued 1,928,641 shares of our common stock to Lincoln Park pursuant to the terms of the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under the Purchase Agreement and we are obligated to issue up to an additional 1,928,641 commitment shares to Lincoln Park pro rata as up to $40,000,000 of our common stock is purchased by Lincoln Park.

We may, from time to time and at our sole discretion but no more frequently than every other business day, direct Lincoln Park to purchase up to 500,000 shares of our common stock on any such business day, provided that in no event shall Lincoln Park purchase more than $760,000 worth of our common stock on any single business day, plus an additional "accelerated amount" under certain circumstances, at a purchase price per share 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 500,000 shares of our common stock on any such business day. On any day that the closing sale price of our common stock is not below $.65 the purchase amount may be increased, at our sole discretion, to up to 600,000 shares per purchase, on any day that the closing sale price of our common stock is not below $.80 the purchase amount may be increased, at our sole discretion, to up to 700,000 shares per purchase, on any day that the closing sale price of our common stock is not below $.95 the purchase amount may be increased, at our sole discretion, to up to 800,000 shares per purchase. Notwithstanding the foregoing, in no event shall Lincoln Park purchase more than $760,000 worth of our common stock on any single business day. Such purchases are hereinafter referred to as "Regular Purchases". The purchase price per share for each such Regular 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 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and the closing sale price is not below $0.15, to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, not to exceed the lesser of:

- three times the number of purchase shares purchased pursuant to the corresponding Regular Purchase; and

- 30% of the aggregate shares of our common stock traded during normal trading hours on the purchase date.

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price during (i) the entire trading day on the purchase date, if the volume of shares of our common stock traded on the purchase date has not exceeded a volume maximum calculated in accordance with the Purchase Agreement, or (ii) the portion of the trading day of the purchase date (calculated starting at the beginning of normal trading hours) until such time at which the volume of shares of our common stock traded has exceeded such volume maximum; or

- the closing sale price of our common stock on the purchase date.

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In the case of both Regular Purchases and Accelerated Purchases, 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 $0.10 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 Shareholders

All of the shares of our common stock registered in this offering which may be sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Lincoln Park may sell all, some or none of the shares it has purchased or will purchase under the Purchase Agreement. 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 $40,000,000 of our common stock exclusive of the shares issued to Lincoln Park as a commitment fee. 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 shareholders. 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		Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (1)		Proceeds from the Sale of Shares to Lincoln Park Under the Purchase Agreement (2)
$ 0.10	(2)	108,000,000	(4)	19.2	%	$ 10,556,238
$ 0.39	(3)	106,421,385	(4)	15.9	%	$ 40,000,000
$ 0.45		92,746,171	(4)	16.5	%	$ 40,000,000
$ 0.55		76,584,555	(4)	13.6	%	$ 40,000,000
$ 0.65		65,395,744	(4)	11.6	%	$ 40,000,000

(1) The denominator is based on the number of shares outstanding as of April 22, 2014, inclusive of 1,928,641 commitment shares issued as of that date.

(2) 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 $0.10, as may be adjusted in accordance with the Purchase Agreement.

(3) The closing sale price of our shares on April 22, 2014.

(4) Although the Purchase Agreement provides that we may sell up to $40,000,000 of our common stock to Lincoln Park, we have initially reserved approximately 108,000,000 shares for sale to Lincoln Park under the Purchase Agreement. See “We may require additional financing to meet our business objectives and to continue as a going concern.” in “Risk Factors”.

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling shareholder, Lincoln Park. The common stock may be sold or distributed from time to time by the selling shareholder 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 shareholder 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 shareholder, 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 shareholder, 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 shareholder, 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.

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 eight 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”)
· Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)

We also recently acquired approved Abbreviated New Drug Applications (“ANDAs”) for 12 products (the “Mikah Approved ANDAs”) and one ANDA that is under active review with the FDA (the “Mikah ANDA Application Product”) that were acquired pursuant to the asset purchase agreement with Mikah Pharma dated August 1, 2013 (the “Mikah Asset Purchase Agreement”). On October 2, 2013, we executed a Manufacturing and License Agreement (the “Epic Agreement”) with Epic Pharma LLC. (“Epic”), to manufacture, market and sell in the United States and Puerto Rico 12 generic products owned by Elite. Of the 12 products, Epic will have the exclusive right to market six products as listed in Schedule A of the Epic Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Epic Agreement. Epic is responsible for all regulatory and pharmacovigilance matters related to the products and for all costs related to the site transfer for all products. Pursuant to the Epic 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 Epic Agreement, earned by Epic as a result of sales of the products. The manufacturing cost used for the calculation of the license fee is a predetermined amount per unit plus the cost of the drug substance (API) and the sales cost for the calculation is predetermined based on net sales. If Elite manufactures any product for sale by Epic, then Epic shall pay that same predetermined manufacturing cost per unit plus the cost of the API. The license fee is payable monthly for the term of the Epic Agreement. Epic shall pay to Elite certain milestone payments as defined by the Epic Agreement. We received the first milestone payment in November 2013. Subsequent milestone payments are due upon the filing of each product’s supplement with the FDA and the FDA approval of site transfer for each product as specifically itemized in the Epic Agreement. The term of the Epic Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Twelve months following the launch of a product covered by the Epic Agreement, Elite may terminate the marketing rights for any product if the license fee paid by Epic falls below a designated amount for a six month period of that product. Elite may also terminate the exclusive marketing rights if Epic is unable to meet the annual unit volume forecast for a designated Product group for any year, subject to the ability of Epic, during the succeeding six month period, to achieve at least one-half of the prior year’s minimum annual unit volume forecast. The Epic Agreement may be terminated by mutual agreement of Elite and Epic, as a result of a breach by either party that is not cured within 60 days’ notice of the breach or by Elite as a result of Epic becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

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 50mg was launched in September 2013.

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.

On April 22, 2014, the USPTO issued U.S. Patent No. 8,703,186, entitled "Abuse-Resistant Oral Dosage Forms and Method of Use 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 (“Epic Pharma”) 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.

This product is being marketed and distributed by Precision Dose and its wholly owned subsidiary, 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 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 received approval from the FDA of its application for transfer of manufacturing site and made its initial shipment in September 2013.

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.

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 Acquisition of a 13 Abbreviated New Drug Applications ("ANDAs")

As disclosed above, o n August 1, 2013, Elite executed an asset purchase agreement (the "Mikah Purchase Agreement") with Mikah and acquired from Mikah a total of 13 ANDAs, consisting of 12 ANDAs approved by the FDA and on ANDA under active review with the FDA, and all amendments thereto (the "Mikah 13 ANDA Acquisition") for aggregate consideration of $10,000,000, payable pursuant to a secured convertible note due in August 2016.

Each of the products referenced in the 12 approved ANDAs require manufacturing site approval with the FDA. Elite will submit filings to the FDA for each of the products for the manufacturing site transfer. Elite believes that the site transfers qualify for CBE 30 review, with one exception, which would allow for the product manufacturing transfer on an expedited basis. However, Elite can give no assurances that all will qualify for CBE 30 review, or on the timing of these transfers of manufacturing site, or on the approval by the FDA of the transfers of manufacturing site.

As of April 22, 2014 (the latest practicable date), Elite has been approved to manufacture, Phendimetrazine 35mg tablets at the Northvale Facility. A CBE 30 application has been filed with the FDA and is pending for the manufacture of Isradipine 2.5mg 5mg capsules at the Northvale Facility.

Elite has executed a Manufacturing and License Agreement with Epic Pharma dated October 2, 2013 (the "Epic Pharma Manufacturing and License Agreement"), relating to the manufacturing, marketing and sale of these 12 ANDAs. Please see below for further details on the Epic Pharma Manufacturing and License Agreement.