ELITE PHARMACEUTICALS INC /NV/
Form 10-K
June 15, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED – MARCH 31, 2015

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 001 – 15697

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Nevada	22-3542636
(State or other jurisdiction of incorporation)	(IRS Employer Identification No.)

165 Ludlow Avenue, Northvale, New Jersey 07647

(Address of principal executive offices)

(201) 750 – 2646

(Registrant's telephone number, including area code)

Securities Registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
None	

Securities Registered pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act	Yes ¨	No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act	Yes ¨	No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days.	Yes x	No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).	Yes x	No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K.	Yes ¨	No x

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

Large Accelerated Filer	Accelerated Filer	Non-Accelerated Filer	Smaller Reporting Company
¨	x	¨	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ¨ No x

State the aggregate market value of the voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (for purposes of determining this amount, only directors, executive officers and, based on Schedule 13(d) filings as of September 30, 2013, 10% or greater stockholders, and their respective affiliates, have been deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes).

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock - $0.001 par value	$ 153,849,213	September 30, 2014

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practical date

Title of Class	Shares Outstanding	As of Close of Business on
Common Stock - $0.001 par value	658,419,047	June 8, 2014

DOCUMENTS INCORPORATED BY REFERENCE

None.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated herein contain "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 report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "anticipate," "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. All statements other than statements of historical fact included in this report regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note, without limitation, that statements regarding the preliminary nature of the clinical program results and the potential for further product development, that involve known and unknown risks, delays, uncertainties and other factors not under our control, the requirement of substantial future testing, clinical trials, regulatory reviews and approvals by the Food and Drug Administration and other regulatory authorities prior to the commercialization of products under development, and our ability to manufacture and sell any products, gain market acceptance earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature. These risks and other factors are discussed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I

ITEM 1 BUSINESS

General

Elite Pharmaceuticals, Inc., a Nevada corporation (the "Company", "Elite", "*Elite Pharmaceuticals*", the "registrant", "we", "u "our") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary, Elite Laboratories, Inc. (*"Elite Labs""*), was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada.

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 and occupy manufacturing, warehouse, laboratory and office space at 165 Ludlow Avenue and 135 Ludlow Avenue in Northvale, NJ (the "Northvale Facility"). 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.

Commercial Products

We own, license or contract manufacture the following products currently being sold commercially:

Product	Branded Product Equivalent	Therapeutic Category	Launch Date
Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)	Adipex-P®	Bariatric	April 2011
Lodrane D ® Immediate Release capsules (“Lodrane D”)	n/a	OTC Allergy	September 2011
Methadone HCl 10mg tablets (“Methadone 10mg”)	Dolophine®	Pain	January 2012
Hydromorphone HCl 8mg tablets (“Hydromorphone 8mg”)	Dilaudid®	Pain	March 2012
Phendimetrazine Tartrate 35mg tablets (“Phendimetrazine 35mg”)	Bontril®	Bariatric	November 2012
Phentermine HCl 15mg and 30mg capsules (“Phentermine 15mg” and “Phentermine 30mg”)	Adipex-P®	Bariatric	April 2013
Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)	Revia®	Pain	September 2013
Isradipine 2.5mg and 5mg capsules (“Isradipine 2.5mg” and “Isradipine 5mg”)	n/a	Cardiovascular	January 2015
Hydroxyzine HCl 10mg, 25mg and 50mg tablets (“Hydroxyzine 10mg” and “Hydroxyzine 25mg” and “Hydroxyzine 50mg”)	Atarax®, Vistaril®	Antihistamine	April 2015

Note: Phentermine 15mg and Phentermine 30mg are collectively and individually referred to as “Phentermine Capsules”. Isradipine 2.5mg and Isradipine 5mg are collectively and individually referred to as “Isradipine Capsules”. Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are collectively and individually referred to as “Hydroxyzine”.

Phentermine 37.5mg

The approved Abbreviated New Drug Application “ANDA” for Phentermine 37.5mg was acquired pursuant to an asset purchase agreement with Epic Pharma LLC (“Epic”) dated September 10, 2010 (the “Phentermine Purchase Agreement”). For further details on the Phentermine Purchase Agreement, please see exhibit 10.7 to the Quarterly Report on Form 10-Q, filed with the SEC on November 15, 2010, with such filing being herein incorporated by reference.

Sales and marketing rights for Phentermine 37.5mg are included in the licensing agreement between the Company and Precision Dose Inc. ("Precision Dose") dated September 10, 2010 (the "Precision Dose License Agreement"). Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipment of Phentermine 37.5mg was made to Precision Dose's wholly owned subsidiary, TAGI Pharmaceuticals Inc. ("TAGI"), pursuant to the Precision Dose License Agreement, with such initial shipment triggering a milestone payment under this agreement. Phentermine 37.5mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Lodrane D® Immediate Release capsules

On September 27, 2011, the Company, along with ECR Pharmaceuticals ("ECR"), launched Lodrane D®, an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl, an effective, low-sedating antihistamine combined with a decongestant.

ECR products have since been divested so that Lodrane D® is promoted and distributed in the U.S. now by Valeant Pharmaceuticals International Inc. Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is one of the only adult brompheniramine containing products available to the consumer at this time.

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

There have been several mergers relating to ECR and successor entities and transfer of brand name ownership since this product was originally launched. Lodrane D® is accordingly currently promoted and distributed in the U.S. by Valeant Pharmaceuticals International Inc. ("Valeant"). Lodrane D® is available over-the-counter but also has physician promotion. Lodrane D® is the one of the only adult brompheniramine containing products available to the consumer at this time.

Elite is manufacturing the product for Valeant and will receive revenues for the manufacturing, packaging and laboratory stability study services for the product, as well as royalties on sales.

Methadone 10mg tablets

Methadone 10mg is contract manufactured by Elite for Ascend Laboratories, LLC ("Ascend"), the owner of the approved ANDA.

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to Ascend pursuant to a commercial manufacturing and supply agreement dated June 23, 2011, as amended on September 24, 2012 and January 19, 2015, between Elite and Ascend (the "Methadone Manufacturing and Supply Agreement"). Under the terms of the Methadone Manufacturing and Supply Agreement, Elite performs manufacturing and packaging of Methadone 10mg for Ascend.

Hydromorphone 8mg tablets

The approved ANDA for Hydromorphone 8mg was acquired pursuant to an asset purchase agreement with Mikah Pharma LLC dated May 18, 2010 (the "Hydromorphone Purchase Agreement"). Transfer of the manufacturing process of Hydromorphone 8mg to the Northvale Facility, a prerequisite of the Company's commercial launch of the product, was approved by the FDA on January 23, 2012.

Sales and marketing rights for Hydromorphone 8mg are included in the Precision Dose License Agreement. Please see the section below titled “Precision Dose License Agreement” for further details of this agreement.

The first shipment of Hydromorphone 8mg was made to TAGI, pursuant to the Precision Dose License Agreement, in March 2012, with such initial shipment triggering a milestone payment under this agreement. Hydromorphone 8mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Phendimetrazine Tartrate 35mg tablets

The ANDA for Phendimetrazine 35mg was acquired by Elite as part of the asset purchase agreement between the Company and Mikah Pharma, dated August 1, 2013 (the “Mikah ANDA Purchase”). Please see “Elite’s Acquisition of 13 Abbreviated New Drug Applications (“ANDAs”)” below for more information on this agreement. The Northvale Facility was already an approved manufacturing site for this product as of the date of the Mikah ANDA Purchase. Prior to the acquisition of this ANDA, Elite had been manufacturing this product on a contract basis pursuant to a manufacturing and supply agreement with Mikah Pharma, dated June 1, 2011.

Phendimetrazine 35mg is currently a commercial product being manufactured by Elite and distributed by Epic Pharma LLC ("Epic") on a non-exclusive basis, and by Elite.

Phentermine 15mg and 30mg capsules

Phentermine 15mg capsules and Phentermine 30mg capsules were developed by the Company, with Elite receiving approval of the related ANDA in September 2012.

Sales and marketing rights for Phentermine 15mg and Phentermine 30mg are included in the Precision Dose License Agreement. Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipments of Phentermine 15mg and Phentermine 30mg were made to TAGI, pursuant to the Precision Dose License Agreement, in April 2013, with such initial shipments triggering a milestone payment under this agreement. Phentermine 15mg and Phentermine 30mg are currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Naltrexone 50mg

The approved ANDA for Naltrexone 50mg was acquired by the Company pursuant to an asset purchase agreement between the Company and Mikah Pharma dated August 27, 2010 (the "Naltrexone Acquisition Agreement") for aggregate consideration of $200,000.

Sales and marketing rights for Hydromorphone 8mg are included in the Precision Dose License Agreement. Please see the section below titled "Precision Dose License Agreement" for further details of this agreement.

The first shipment of Naltrexone 50mg was made to TAGI, pursuant to the Precision Dose License Agreement, in September 2013, with such initial shipment triggering a milestone payment under this agreement. Naltrexone 50mg is currently being manufactured by Elite and distributed by TAGI under the Precision Dose License Agreement.

Isradipine 2.5mg and Isradipine 5mg

The approved ANDAs for Isradipine 2.5mg and Isradipine 5mg were acquired by Elite as part of the Mikah ANDA Purchase

Sales and marketing rights for Isradipine 2.5mg and Isradipine 5mg are included in the manufacturing and license agreement between the Company and Epic Pharma LLC, dated October 2, 2013 (the "Epic Manufacturing and License Agreement"). Please see the section below titled "Epic Manufacturing and License Agreement" for further details of this agreement.

The first shipment of Isradipine 2.5mg and Isradipine 5mg were made to Epic, pursuant to the Epic Manufacturing and License Agreement, in January 2015. Isradipine 2.5mg and Isradipine 5mg are currently being manufactured by Elite and distributed by Epic under the Epic Manufacturing and License Agreement.

Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

The approved ANDAs for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were acquired by Elite as part of the Mikah ANDA Purchase.

Sales and marketing rights for Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are included in the Epic Manufacturing and License Agreement.

The first shipment of Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg were made by Epic, pursuant to the Epic Manufacturing and License Agreement, in April 2015. Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg are currently being manufactured and distributed by Epic under the Epic Manufacturing and License Agreement.

Approved products not yet commercialized

The Company currently owns seven different approved ANDA's, all of which were acquired as part of the Mikah ANDA Purchase. Each of these approved ANDA's require manufacturing site transfers as a prerequisite to commencement of commercial manufacturing and distribution. The products are relating to each of these approved ANDA's are included in the Epic Manufacturing and License Agreement, with Elite granting ANDA specific, exclusive or non-exclusive market rights (depending on the ANDA) to Epic. Commercial manufacturing of these products is expected to be transferred to either Epic or the Northvale Facility, with the required supplements to be filed with FDA in the manner and time frame that is economically beneficial to the Company.

Asset Acquisition Agreements

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

This product is currently being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which 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 Acquisition Agreement"). Pursuant to the Naltrexone Acquisition 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.

This product is currently being marketed and distributed by Precision Dose and its wholly owned subsidiary, TAGI, pursuant to the Precision Dose License Agreement, a description of which is set forth below.

Elite's Acquisition of 13 Abbreviated New Drug Applications

On August 1, 2013, Elite executed an asset purchase agreement (the "Mikah ANDA Purchase") with Mikah and acquired from Mikah a total of 13 ANDAs, consisting of 12 ANDAs approved by the FDA and one 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 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 the date filing of this Annual Report on Form 10-K, the following products included in the Mikah Purchase Agreement have successfully achieved manufacturing site transfers:

- Phendimetrazine 35mg
- Isradipine 2.5mg and Isradipine 5mg
- Hydroxyzine 10mg, Hydroxyzine 25mg and Hydroxyzine 50mg

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.

Licensing, Manufacturing and Development Agreements

Sales and Distribution Licensing Agreement with Epic for Abuse-Deterrent ELI-200

On June 4, 2015, Elite Pharmaceuticals Inc. and its wholly-owned subsidiary Elite Laboratories, Inc. (collectively, "Elite") executed an exclusive License Agreement (the "Agreement") with Epic Pharma LLC. ("Epic"), to market and sell in the United States, ELI-200, an undisclosed opioid with sequestered naltrexone capsules, owned by Elite. Epic will have the exclusive right to market ELI-200 and its various dosage forms as listed in Schedule A of the Agreement (the "Products"). Epic is responsible for all regulatory and pharmacovigilance matters related to the products. Pursuant to the Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of net sales of the Products as defined in the Agreement by Epic. Elite will manufacture the product for sale by Epic on a cost plus basis and both parties agree to execute a separate Manufacturing and Supply Agreement. The license fee is payable quarterly for the term of the Agreement. Epic shall pay to Elite certain milestone payments as defined by the Agreement. The first milestone payment was due and was received upon signing the agreement. Subsequent milestone payments are due upon the filing of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for the Products and upon receipt of the approval letter for the NDA from the FDA. The term of the License Agreement is five years and may be extended for an additional five years upon mutual agreement of the parties. Elite can terminate the Agreement on 90 days' written notice in the Event that Epic does not pay to Elite certain minimum annual license fees over the initial five year term of the Agreement. Either party may terminate this Agreement upon a material breach and failure to cure that breach by the other party within a specified period.

Licensing Agreement with Precision Dose Inc.

On September 10, 2010, Elite executed a License Agreement with Precision Dose (the "Precision Dose License Agreement") to market and distribute Phentermine 37.5mg, Phentermine 15mg, Phentermine 30mg, Hydromorphone 8mg, Naltrexone 50mg, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada (the "Precision Dose License Agreement"). Phentermine 37.5mg was 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. Precision Dose will have the exclusive right to market these products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada.

Pursuant to the Precision Dose License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Precision Dose License Agreement, earned by Precision Dose as a result of sales of the products. The license fee is payable monthly for the term of the Precision Dose License Agreement. The milestone payments will be paid in six installments. The first installment was paid upon execution of the License Agreement. The remaining installments are to be paid upon FDA approval and initial shipment of the products to Precision Dose. The term of the License Agreement is 15 years and may be extended for 3 successive terms, each of 5 years. Please see Item 3. Legal Proceedings below for details of an arbitration proceeding commenced by Precision Dose related to certain terms and conditions of the Precision Dose License Agreement.

Manufacturing and License Agreement with Epic Pharma LLC

On October 2, 2013, Elite executed the Epic Pharma Manufacturing and License Agreement. This agreement granted Epic Pharma certain rights to manufacture, market and sell in the United States and Puerto Rico the 12 approved ANDAs acquired by Elite pursuant to the Mikah Purchase Agreement. Of the 12 approved ANDAs, Epic Pharma will have the exclusive right to market six products as listed in Schedule A of the Epic Pharma Manufacturing and License Agreement, and a non-exclusive right to market six products as listed in Schedule D of the Epic Pharma Manufacturing and License Agreement. Epic Pharma 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 Pharma Manufacturing and License Agreement, Elite will receive a license fee and milestone payments. The license fee will be computed as a percentage of the gross profit, as defined in the Epic Pharma Manufacturing and License Agreement, earned by Epic Pharma 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 Pharma, then Epic Pharma shall pay to Elite 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 Pharma Manufacturing and License Agreement. Epic Pharma shall pay to Elite certain milestone payments as defined by the Epic Pharma Manufacturing and License Agreement. To date, milestones totaling $1,000,000 have been earned and received in relation to the signing of the Epic Pharma Manufacturing and License Agreement and the filing and approval by the FDA of supplements relating to the transfer of manufacturing site for Isradipine 2.5mg and Isradipine 5mg. The term of the Epic Pharma Manufacturing and License 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 Pharma Manufacturing and License Agreement, Elite may terminate the marketing rights for any product if the license fee paid by Epic Pharma falls

below a designated amount for a six month period of that product. Elite may also terminate the exclusive marketing rights if Epic Pharma is unable to meet the annual unit volume forecast for a designated product group for any year, subject to the ability of Epic Pharma, during the succeeding six month period, to achieve at least one-half of the prior year's minimum annual unit forecast. The Epic Pharma Manufacturing and License Agreement may be terminated by mutual agreement of Elite and Epic Pharma, 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 Pharma becoming a party to a bankruptcy, reorganization or other insolvency proceeding that continues for a period of 30 days or more.

Methadone Manufacturing and Supply Agreement

On June 23, 2011 and as amended on September 24, 2012 and January 19, 2015, Elite entered into an agreement to manufacture and supply Methadone 10mg to ThePharmaNetwork LLC (the "Methadone Manufacturing and Supply Agreement"). ThePharmaNetworkLLC was subsequently acquired by Alkem Laboratories Ltd ("Alkem") and now goes by the name Ascend Laboratories LLC ("Ascend") and is a wholly owned subsidiary of Alkem.

Ascend in the owner of the approved ANDA for Methadone 10mg, and the Northvale Facility is an approved manufacturing site for this ANDA. The Methadone Manufacturing and Supply Agreement provides for the manufacture and packaging by the Company of Ascend's methadone hydrochloride 10mg tablets.

The initial shipment of Methadone 10mg pursuant to the Methadone Manufacturing and Supply Agreement occurred in January 2012.

Development and License Agreement with Hong Kong based company

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

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

The Hong Kong-based Customer shall own and market the Prescription Product under its own Trademark. The term of this D&L Agreement shall be effective from the date consummated and shall continue for a five (5) year term after the commercial launch of the Prescription Product. Upon the expiration of the initial term or any renewal term, this

D&L Agreement will automatically renew for an additional one (1) year term, unless one Party gives at least six (6) months notice in writing in advance of its intent not to renew.

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As of the date of filing of this annual report on Form 10-K, there has been minimal to no development activity being conducted pursuant to the D&L Agreement, and there can be no assurances that development activities will resume or that the resumption of development activities will result in the successful development of the product identified.

Development agreement with Akorn Pharmaceuticals

On January 10, 2011, Elite and Hi-Tech Pharmacal Co, Inc. (subsequently acquired by Akorn Pharmaceuticals), entered into an agreement for Elite to develop an intermediate product for a generic version of a prescription product for Akorn Pharmaceuticals ("Akorn"). Under the terms of the agreement, Elite will undertake a development program for an intermediate product that Akorn shall then incorporate into a final product. Akorn or its designees, shall be responsible for the filing of the ANDA for the finished product and the ANDA will be filed under the Akorn name. Upon approval of the ANDA, Elite will manufacture the intermediate product. Akorn will manufacture the final product and will be responsible for the marketing and sales of the final product. Akorn will pay Elite milestone payments for the development work. Upon commercialization, Elite will receive payment for the manufacturing of the intermediate product and a percentage of the profits generated from the sale of the product.

Please note that there can be no assurances that the development program will result in an intermediate product that can be incorporated into a final product. There can be no assurances that an ANDA will be filed by Akorn or its designees or that any such ANDA filed will receive marketing approval by the FDA. Furthermore, there can be no assurances of the commercialization of a final product containing the intermediate relating to this agreement or that such commercialization will result in profits being generated from the sale of the product.

For further details, please refer to the Current Report on Form 8-K filed with the SEC on January 10, 2011, such filing being herein incorporated by reference.

Research and Development

Elite is actively involved in research and development activities, particularly in relation to the development of a line of abuse deterrent opioid products. We incurred total costs of approximately $14.8 million during the fiscal year ended March 31, 2015 ("Fiscal 2015") and approximately $4.0 million during the fiscal year ended March 31, 2014 ("Fiscal 2014") in relation to research and development activities. It is, however, our general policy, for competitive reasons, and because disclosure of certain information might suggest the occurrence of future matters or events that may not occur, not to disclose specific products in our development pipeline or the status of such product development activities until a product reaches a stage that we determine, in our discretion, to be appropriate for disclosure.

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

Products Under Development

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

Abuse-Deterrent and Sustained Release Opioids

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

Elite has developed, and retains the rights to these abuse resistant and sustained release opioid products. Elite may license these products at a later date to a third party who could provide funding for the remaining clinical studies and who could provide sales and distribution for the product.

Elite also developed controlled release technology for oxycodone under a joint venture with Elan which terminated in 2002. According to the Elan Termination Agreement, Elite acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including the sustained release opioid products. Upon licensing or commercialization of an oral controlled release formulation of oxycodone for the treatment of pain, Elite will pay a royalty to Elan pursuant to the Termination Agreement. If Elite were to sell the product itself, Elite will pay a 1% royalty to Elan based on the product's net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite's net revenues from this product. (Elite's net product revenues would include license fees, royalties, manufacturing profits and milestones) Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Patents

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

PATENT	EXPIRATION DATE
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 2018
U.S. patent 6,620,439	October 2020
U.S. patent 6,635,284 (assigned to Celgene Corporation)	March 2018
U.S. patent 6,926,909	April 2023
U.S. patent 8,182,836	April 2024

U.S. patent 8,425,933	April 2024
U.S. patent 8,703,186	April 2024
Canadian patent 2,521,655	April 2024
Canadian patent 2,541,371	September 2024
U.S. patent 9,056,054	June 2030

We also have pending applications for two additional U.S. patents and three foreign patents. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade ("GATT"), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured from the date of grant. Under GATT, the term of any U.S. Patent granted on an application filed subsequent to June 8, 1995 terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

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

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

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

Trademarks

We currently plan to license at least some of our products to other entities in the marketing of pharmaceuticals, but may also sell products under our own brand name in which case we may register trademarks for those products.

Discontinued Products, Terminated Agreements, Prior Investments

Discontinued Products - Lodrane 24® and Lodrane 24D®

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

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

The Lodrane® Extended Release Products were co-developed with our partner, ECR, and the Company was receiving revenues from the manufacture of the Lodrane® Products and laboratory stability study services, as well as royalties on in-market sales. Contracts relating to the manufacture and sale of the Lodrane® Extended Release Products were formally terminated on April 26, 2013.

During the three months ended June 30, 2011, Elite made its final shipments of the Lodrane® Extended Release Products. In addition, the Company sold to ECR, at cost without markup, all raw materials related to the manufacture of the Lodrane® Extended Release Products which remained in stock subsequent to the final shipment of the Lodrane® Extended Release Products. As manufacturing of the Lodrane® Extended Release Products has ceased, there will be no further manufacturing revenues derived from the Lodrane® Extended Release Products unless and until such products receive the necessary approvals from the FDA.

Please note that there can be no assurances that such approvals will be granted or that future manufacturing revenues will be earned by the Company from the manufacture of the Lodrane® Extended Release Products, should such approvals be granted by the FDA. Furthermore, the Company has been advised that ECR has decided not to proceed with the development of the extended release formulations marketed under the Lodrane® brand. The Company also has no plans currently to proceed with the development of an extended release brompheniramine/pseudoephedrine product. Notwithstanding the foregoing, Elite may proceed with the development of these formulations and may seek partners in conjunction with such activities, but there can be no assurances that the Company will pursue the development of these formulations, or that such development activities, if pursued, will result in approvals from the FDA. Please also note that the Company does not have ownership of the Lodrane® brand name, and that if any products containing the formulations associated with the Lodrane® brand name are approved and marketed, such would be done under a different brand name.

While Elite’s manufacturing of the Lodrane® Extended Release Products has ceased, the sale of such products in the US market was still permitted by the FDA until August 30, 2011. The Company earned royalties on any in-market sales that occurred up to that date.

Terminated Agreement - Contract Manufacturing of Isradipine and Phendimetrazine

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

On November 13, 2012, the Company made the initial shipment of Phendimetrazine tartrate 35mg tablets, the generic equivalent of Bontril PDM® 35mg tablets under a previously announced manufacturing and supply agreement with Mikah Pharma ("Mikah").

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

On August 1, 2013, Elite executed the Mikah Purchase Agreement in relation to the Mikah 13 ANDA Acquisition, with such transaction including the transfer of ANDAs for Phendimetrazine 35mg and Isradipine 2.5mg and 5mg. In addition, the principal owner of Mikah, Mr. Nasrat Hakim, assumed the position of Elite's Chief Executive Officer and President on August 2, 2013. Accordingly, the Isradipine/Phendimetrazine Agreement has been terminated by mutual consent of the parties thereto.

Terminated Agreement – Mikah Development Agreement

On January 28, 2015, The Development and License Agreement dated August 27, 2010 and between the Company and Mikah Pharma LLC (the "Mikah Development Agreement") was terminated by mutual agreement of the Company and Mikah Pharma LLC.

Pursuant to the Mikah Development Agreement, Mikah Pharma LLC ("Mikah") made advance consideration payments to the Company totaling $200,000 in exchange for product development services to be provided at a future date. Subsequent to the execution of the Mikah Development Agreement, and before any development milestones were achieved, the sole owner of Mikah, Mr. Nasrat Hakim, became the President and Chief Executive Officer of the Company. Mikah has accordingly ceased operating and is in the process of winding down and liquidating its assets.

Any further development of the product related to this agreement will belong to the Company, although there can be no assurances that such development will occur or be successful.

The Mikah Development Agreement requires that the consideration paid in advance to the Company be refunded in the event of no milestones being achieved. Mr. Hakim, as owner of Mikah, has directed that the $200,000 refund due to Mikah not be paid currently, but rather be added to the amounts due under the Hakim Credit Line.

For further details on the Mikah Development Agreement, please see Exhibit 10.6 of the Quarterly Report on Form 10-Q filed with the SEC on November 14, 2010, with such filing being herein incorporated by reference.

For further details on the termination of the Mikah Development Agreement, please see Exhibit 10.84 of the Quarterly Report on Form 10-Q, filed with the SEC on February 17, 2015, with such filing being herein incorporated by reference.

Novel Labs Investment

At the end of 2006, Elite entered into a joint venture with VGS Pharma, LLC ("VGS") and created Novel Laboratories, Inc. ("Novel"), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite owned less than 10% of the outstanding shares of Class A Voting Common Stock of Novel.

Elite commenced an action against VGS, Novel and related parties (collectively, the "VGS Parties") related to the Novel transactions. The action was settled and, pursuant to that settlement, in June 2014, Elite received $5,000,000 from the VGS Parties in exchange for 9,800 shares of Novel Class A common stock owned by Elite. This resolved all disputes and claims between the Company and the VGS Parties and ended the Company's ownership in Novel.

Other Business Factors and Details

Government Regulation and Approval

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

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

Please note that, as discussed in “Discontinued Products” above, in March 2011, the FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with such list of 500 products including the Lodrane Extended Release Products. After this announcement by the FDA, the Company’s customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products has ceased. This cancellation of outstanding orders and the cessation of manufacturing of Lodrane Products has had a material adverse effect on revenues for periods beginning subsequent to March 31, 2011.

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

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

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

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

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

ANDAs

The FDA approval procedure for an ANDA differs from the procedure for a NDA in that the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. "Bioavailability" indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration

of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

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

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

Controlled Substances

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

cGMP

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

Compliance with Environmental Laws

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices of corporations as to which we are the legal successor or in possession. We do not expect that compliance with such environmental laws will have a material effect on our capital expenditures, earnings or competitive position in the

foreseeable future. There can be no assurance, however, that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on our capital expenditures, earnings or competitive position.

Competition

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

An increasing number of pharmaceutical companies have become interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many of these companies have greater financial and other resources as well as more experience than we do in commercializing pharmaceutical products. Certain companies have a track record of success in developing controlled-release drugs. Significant among these are, without limitation, Pfizer, Sandoz (a Novartis company), Durect Corporation, Mylan Laboratories, Inc., Par Pharmaceuticals, Inc., Alkermes, Inc., Teva Pharmaceuticals Industries Ltd., Impax Laboratories, Inc., and Actavis. Each of these companies has developed expertise in certain types of drug delivery systems, although such expertise does not carry over to developing a controlled-release version of all drugs. Such companies may develop new drug formulations and products or may improve existing drug formulations and products more efficiently than we can. In addition, almost all of our competitors have vastly greater resources than we do. While our product development capabilities and, if obtained, patent protection may help us to maintain our market position in the field of advanced drug delivery, there can be no assurance that others will not be able to develop such capabilities or alternative technologies outside the scope of our patents, if any, or that even if patent protection is obtained, such patents will not be successfully challenged in the future.

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

We also face competition in the generic pharmaceutical market. The principal competitive factors in the generic pharmaceutical market include: (i) introduction of other generic drug manufacturers’ products in direct competition with our products under development, (ii) introduction of authorized generic products in direct competition with any of our products under development, particularly if such products are approved and sold during exclusivity periods, (iii) consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups, (iv) ability of generic competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits, (v) the willingness of generic drug customers, including wholesale and retail customers, to switch among pharmaceutical manufacturers, (vi) pricing pressures and product deletions by competitors, (vii) a company’s reputation as a manufacturer and distributor of quality products, (viii) a company’s level of service (including maintaining sufficient inventory levels for timely deliveries), (ix) product appearance and labeling and (x) a company’s breadth of product offerings.

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Sources and Availability of Raw Materials; Manufacturing

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

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

Please see the Risk Factor in Part I, Item 1A entitled “We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products”.

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

In this regard, the commercial launch of Phentermine 15mg and Phentermine 30mg was delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. The API supplier required us to pay substantially higher prices than previously paid for the Phentermine API while we sought approval from the FDA of an alternate supplier of the API. Such approval was recently received, resulting in lower prices and a sufficient supply of materials. Please see “Approved Products; Phentermine 15mg and Phentermine 30mg”above.

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

Dependence on One or a Few Major Customers

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

Employees

As of June 15, 2015, we had 36 full time employees. Full-time employees are engaged in operations, administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

Available Information

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at http://www.Elitepharma.com under the Investor Relations tab for SEC Filings or by contacting the Investor Relations Department by calling (518) 398-6222 or sending an e-mail message to dianne@elitepharma.com.

ITEM 1A RISK FACTORS

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

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

RISKS RELATED TO OUR BUSINESS

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

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and our presence in the generic pharmaceutical market. As a

result, our potential for future profitability must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

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

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

We have not been profitable and expect future losses.

To date, we have not been profitable and we may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses from operations in each year since our incorporation in 1990. During the past two fiscal years, we incurred net losses from operations of approximately $16.5 million and $5.3 million, 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

Although we believe that we have adequate financial resources on hand as of March 31, 2015 to complete the clinical trials and file a marketing approval application with the FDA for one abuse resistant opioid product and also ensure operations through March 31, 2016, we cannot assure that we will not need additional funding to accomplish our plans to conduct the clinical development and commercialization of a range of multiple abuse resistant opioids on an accelerated pace.

As of March 31, 2015, we had cash reserves of approximately $7.5 million and a working capital surplus of $7.3 million, and, for the fiscal year ended March 31, 2015, we had losses from operations totaling $16.5 million, net other income totaling $45.4 million and a net income of $28.9 million.

During the year ended March 31, 2014, we raised approximately $10 million from the sale of shares to with Lincoln Park Capital Fund, LLC (“Lincoln Park”) pursuant to a prior April 19, 2013 purchase agreement. While that agreement terminated in March 2014 with the sale of all shares covered by that agreement, we entered into a new purchase agreement (the “Purchase Agreement”) with Lincoln Park in April 2014, pursuant to which we could raise up to $40 million (see “Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Lincoln Park Capital” below). As of June 8, 2015, we have sold approximately 55.1 million shares pursuant to the Purchase Agreement, with proceeds of such sales totaling approximately $15.0 million. In addition, Nasrat Hakim, our President and CEO has 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 $0.22 per share (the closing sale price of the common stock on June 8, 2015) and only approximately 49.0 million shares available for purchase, we would receive $25.8 million in gross proceeds from purchases under the Purchase Agreement by Lincoln Park, inclusive of the $15.0 million already

received for sales of shares prior to June 8, 2015.

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

We are anticipating that, with the growth of the current generic product line consisting of generic phentermine tablets and capsules, hydromorphone, naltrexone, methadone, phendimetrazine, isradipine, hydroxyzine 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, if needed, 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, if necessary, and/or 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 depend on a limited number of customers and any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline.

Five customers accounted for substantially all of our accounts receivable as of March 31, 2015. Included in these five customers are three customers that accounted for approximately 89% of accounts receivable as of March 31, 2015. Our dependence on a limited number of customers means that the loss of a major customer or any reduction in orders by a major customer could materially reduce our net revenue and adversely affect our results of operations.

A notice of default was issued by the New Jersey Economic Development Authority in relation to prior obligations of our tax-exempt bonds. Although we are current in our payments under these bonds, if the principal balances due under these bonds are accelerated pursuant to the notice of default, our ability to operate in the future will be materially and adversely affected.

Although we are current in our payments under the NJEDA Bonds, we previously were in default and a notice of default was issued in March 2009. Should the principal balances due under the NJEDA Bonds be accelerated pursuant to such notice of default, our ability to operate in the future will be materially and adversely affected.

For more information on the NJEDA Bonds, see Part II, Item 7 “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, without limitation, 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 ten 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. In addition to modification or revocation of patents in legal proceedings, issued patents may later be modified or revoked by the U.S. Patent and Trademark Office or by analogous foreign offices. 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 be obtained by other entities or become known, obtained or independently developed by our competitors or by other entities. We also cannot be sure that, if patents are not issued with respect to products arising from research, 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.

Please note that in May 2014, Precision Dose Inc, the parent company of TAGI Pharmaceuticals, Inc., commenced an arbitration alleging that we failed to properly supply, price and satisfy gross profit minimums regarding Phentermine 37.5mg tablets, as required by the parties' agreements. We deny Precision Dose's allegations and have counterclaimed that Precision Dose is no longer entitled to exclusivity rights with respect to Phentermine 37.5mg tablets, and is responsible for certain costs, expenses, price increases and lost profits relating to Phentermine 37.5mg tablets and the parties' agreements. Please see "Item 3. Legal Proceedings" below.

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, without limitation:

- 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;

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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, without limitation:

- 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, but not necessarily, 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.

Our pipeline of products under development include products that would be filed as branded pharmaceuticals and if generic manufacturers use litigation and regulatory means to obtain approval for generic versions of one or more of such branded drugs, our sales may be adversely effected.

Under the Hatch-Waxman Act, the FDA can approve an ANDA for a generic bioequivalent version of a previously approved drug, without undertaking the full clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its generic product is bioequivalent to the branded product.

Our product development pipeline includes a range of abuse resistant opioid products, with full clinical testing activity being currently planned, in progress or successfully completed. In recent years, various generic manufacturers have filed ANDAs seeking FDA approval for generic versions of opioids and opioids with abuse resistant characteristics. In connection with our filings, these manufacturers may challenge the validity and/or enforceability of one or more of the underlying patents protecting our products. While it is the Company’s intention to vigorously defend and pursue all available legal and regulatory avenues in defense of the intellectual property rights protecting our products, it must also be stressed that litigation is inherently uncertain and we cannot predict the timing or outcome of our efforts. There can also be no assurance that our efforts in defense of the intellectual property rights protecting our products will be successful.

If we are not successful in defending our intellectual property rights, or opt to settle, or if a product’s marketing exclusivity rights expire or become otherwise unenforceable, our competitors could ultimately launch generic versions of one or more of our branded products, after such products have been approved by the FDA, which could significantly decrease our revenues and could have a material adverse effect on our business, financial conditions, results of operations and cash flow. Furthermore such a material adverse effect may result in a material adverse effect on our share price.

Agreements between branded pharmaceutical companies and generic pharmaceutical companies are facing increased government scrutiny in the United States and Internationally.

There are numerous and continuing litigation in which generic companies challenge the validity or enforceability of an innovator products patents and/or the applicability of such patents to a generic applicant's products. Settlement of such litigation is a common outcome, with review of such agreements by the U.S. Federal Trade Commission (the "FTC") and the Antitrust Division of the Department of Justice (the "DOJ") being required by law. The FTC has stated publicly its view that some of these settlement agreements violate antitrust laws and has commenced actions against the branded and generic companies that are parties to these agreements. Accordingly, in the event of the Company being party to a settlement agreement, either as the branded, innovator product owner, or as the generic applicant, we may receive formal or informal requests from the FTC for information about a settlement agreement and there is a risk of the FTC alleging a violation of antitrust laws and commencing an action against us.

In addition, the United States Congress has proposed legislation that would limit the types of settlement agreements generic manufacturers can enter into with brand companies. In 2013, the Supreme Court, in *FTC v. Actavis*, determined that reverse payment patent settlements between generic and brand companies should be evaluated under the rule of reason, and provided limited guidance beyond the selection of this standard. Due to the court's non-articulation of a precise rule of lawfulness for such settlements, there may be extensive litigation over what constitutes a reasonable and lawful patent settlement between and brand and generic company.

The impact of such future litigation, if any, legislative proposals and potential future court decisions is uncertain, and there can be no assurances that such impact will not have an adverse effect on the Company's business, its financial condition, results of operations, cash flows and its stock price.

We may incur significant liability if it is determined that we are promoting or have in the past promoted the "off-label" use of drugs.

In jurisdictions including, without limitation, the United States, a company is not permitted to promote drugs for uses that are not described in the product's labeling and that differ from those that were approved or cleared by the FDA. Such users are commonly referred to as "off-label uses". Under what is known as the "practice of medicine", physicians and other healthcare practitioners may prescribe drug products for off-label or unapproved uses. While the FDA does not regulate a physician's choice of medications, treatments, or product uses, the Federal Food Drug and Cosmetic Act ("FFDC") and FDA regulations significantly restrict permissible communications on the subject of off-label uses of drug products by pharmaceutical companies. The FDA, FTC, the Office of the Inspector General of the Department of Health and Human Services ("HHS"), the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons claiming to be harmed by such conduct.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations and judicial case law allows companies to engage in some forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products. Elite believes it and its marketing partners comply with these restrictions.

Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, and *qui tam* relators may take the position that the Company is not in compliance with such requirements, and if such non-compliance is proven, the consequences of such may have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

We have significant intangible assets on our balance sheet. Consequently, potential impairment of intangible assets may have an adverse material effect on our profitability.

Intangible assets represent a significant portion of our assets. As of March 31, 2015, intangible assets were approximately $6.4 million, or approximately 25% of our assets.

GAAP requires that intangible assets be subject to regular impairment analysis to determine if changes in circumstances indicate that the value of the asset as recorded may not be recoverable. Such events or changes in circumstances are an inherent risk in the pharmaceutical industry and often cannot be predicted. However, should a change in circumstance occur, requiring the impairment of an intangible asset, the result of such an impairment may have an adverse material effect on our business, financial condition, results of operations, cash flows and stock price.

Our products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to increased litigation risk and new regulation, including the development of REMS, which may prove difficult or expensive to comply with.

Many of our current products and products under development contain narcotics. Misuse or abuse of such drugs can lead to physical or other hard. The FDA and/or the DEA may impose new regulations concerning the manufacture, storage, transportation, distribution and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of a formal Risk Evaluation and Mitigation Strategy ("REMS"), restrictions on prescription and sale of such products and mandatory reformulation in order to make abuse of such products more difficult. In 2007, Congress passed legislation authorizing the FDA to require companies to undertake post-approval studies in order to assess known or signaled potential serious safety risks and to make any labeling changes necessary to address safety risks. Congress also empowered the FDA to require companies to formulate REMS to confirm a drug's benefits exceed its risks. In 2011, the FDA issued letters to manufacturers of long-acting and extended-release opioids requiring them to develop and submit to the FDA a post-market REMS plan to require that training is provided to prescribers of these products and that information is provided to prescribers that they can use in counseling patients on the risks and benefits of opioid drug use. Elite does not currently own a product that requires a REMS plan, but some of the products in our pipeline may require a REMS plan. The Obama administration has also released a comprehensive action plan to reduce prescription drug abuse, which may include proposed legislation to amended existing controlled substances laws to require healthcare practitioners who request DEA registration to prescribe controlled substances to receive training on opioid prescribing practices as a condition of registration. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse.

Such new regulations or requirements may be difficult or cost prohibitive for us to comply with, resulting in delays in the commercialization of new products, and decreased profitability of existing and new products. Such occurrences may have material adverse effects on our business, financial condition, results of operations, cash flows and stock price.

The growth of Elite will depend on developing, commercializing and marketing new products.

Our future revenues and profitability is significantly dependent on our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. Accordingly, we must continually develop, test, file,

receive marketing authorization and manufacture new products. While we are currently developing products and have plans in place for future products beyond those currently in development, there can be no assurances that any of these products will receive marketing authorization and achieve commercialization. In addition, even if a product receives marketing authorization, there can be no assurances that there will be future revenues or profits, or that any such future revenues or profits would be in amounts that provide adequate return on the significant investments made to secure the marketing authorization and create/support the infrastructure required for the commercial manufacture of such product.

We are engaged in the research and development of pharmaceutical products with the objective of achieving marketing authorizations that enable us to manufacture and sell pharmaceuticals in accordance with specific government regulations. Due to the inherent risk associated with pharmaceutical product research and development, particularly with respect to new/innovative drugs, our research and development expenditures and efforts may not result in a successful regulatory approval and commercialization of new products. Furthermore, after we submit a regulatory application, the relevant government authority may require that we conduct additional studies, resulting in an inability for us to reasonably predict the total research and development costs for a new product.

Circumstances in which the Company is unable to successfully commercialize new products in a timely manner, or circumstances in which the profitability of a new product is not sufficient with respect to the costs and investments required to develop such product may have a material adverse effect on our business, financial condition, results of operations, cash flows and stock price.

If our manufacturing facilities are unable to manufacture our products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse impact on our business.

If our manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect our ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, record-keeping and quality assurance and control so that their products meet applicable specifications and other requirements product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects our manufacturing facilities to possible legal or regulatory action, including, without limitation, shutdown, which may adversely affect our ability to manufacture product. Were we not able to manufacture products at our manufacturing facilities because of regulatory, business or any other reason, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on our business, results of operations, financial condition, cash flows, competitive position and stock price.

The DEA limits the availability of the active ingredients used in many of our current products and products in development, as well as the production and distribution of these products, and, as a result, our procurement, production and distribution quotas may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active

ingredients in some of our current products and products in development, including, without limitation, hydromorphone, methadone, phentermine, phendimetrazine and oxycodone, are listed by the DEA as Scheduled substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. Furthermore, the DEA limits the availability of the active ingredients used in many of our current products and products in development and we and/or our contract customers and suppliers, must annually apply to the DEA for procurement quotas in order to obtain and distribute these substances. As a result, our procurement and production quotas may not be sufficient to meet commercial demand or to complete clinical trials. Moreover, the DEA may adjust these quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Any delay or refusal by the DEA in establishing our quotas, or modification of our quotas, for controlled substances could delay or result in the stoppage of our clinical trials or product launches, or could cause trade inventory disruptions for those products that already been launched, which could have a material adverse effect on our business, financial position, cash flows and stock price.

If we are unable to maintain an effective system of internal control over financial reporting, we may be unable to accurately report our financial results.

Management and our independent registered public accounting firm have determined that there were material weaknesses in our internal controls over financial reporting resulting from a lack of segregation of duties in the Payroll, Accounting and Procure to Pay cycles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The reasons for these material weaknesses and our plans to rectify these weaknesses are described in Part II, Item 9A “Controls and Procedures” of this Report. There can be no assurance that we will be able to cure these weaknesses or that these weaknesses will not contribute to, or cause, possible material weaknesses in the future or, that we will be able to implement effectively new or improved controls. In addition, our management or our independent registered public accounting firm may determine that our internal control over financial reporting is not effective in the future.

A lack of effective internal control over financial reporting could cause us to fail to provide accurate financial statements or fail to meet our reporting obligations, either of which could cause investors to lose confidence in our reported financial information, and have a negative effect on the trading price of our common stock.

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, 2015, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.49 per share to a low of $0.20 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 that commenced on May 1, 2014. 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 June 8, 2015, there were outstanding shares of preferred stock convertible into approximately 142.9 million shares of Common Stock and warrants to purchase an aggregate of approximately 70.7 million shares of Common Stock at exercise prices of $0.625 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

We own a facility located at 165 Ludlow Avenue, Northvale, New Jersey ("165 Ludlow") which contains approximately 15,000 square feet of floor space. This real property and the improvements thereon are encumbered by a mortgage in favor of the New Jersey Economic Development Authority ("NJEDA") as security for a loan through tax-exempt bonds from the NJEDA to Elite. The mortgage contains certain customary provisions including, without limitation, the right of NJEDA to foreclose upon a default by Elite. The NJEDA has declared the payment of this bond to be in default (For more information on the NJEDA Bonds, see Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; NJEDA Bonds"). We are currently using the Facility as a laboratory, manufacturing, storage, distribution and office space.

We entered into a lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey ("135 Ludlow"), consisting of approximately 15,000 square feet of floor space. The lease term began on July 1, 2010. On July 14, 2014, this lease was modified, with the material terms of the modification including the Company occupying the entire 35,000 square feet in the building, with such expansion being necessary to support our growing commercial operations.

The lease, as modified, includes an initial term which expires on December 31, 2016 and two tenant renewal options of five years each, with such options being at the sole discretion of the Company. The property related to this lease is used for the manufacture, packaging, storage and distribution of pharmaceutical raw materials, finished goods and related documents and materials. The property requires significant construction and qualification as a prerequisite to achieving suitability for its intended future use. Storage, manufacturing and distribution operations at the initial 15,000 square foot section in January 2013. Such operations continue, currently.

The additional 20,000 square feet for which leasehold rights were secured pursuant to the July 2014 lease modification, require significant leasehold improvements and qualification as a prerequisite for its intended future use. These improvements are currently in progress.

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

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

ITEM 3 LEGAL PROCEEDINGS

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

Arbitration with Precision Dose, Inc.

On May 9, 2014, Precision Dose Inc, the parent company of TAGI Pharmaceuticals, Inc., commenced an arbitration against the Company alleging that the Company failed to properly supply, price and satisfy gross profit minimums regarding Phentermine 37.5mg tablets, as required by the parties’ agreements. Elite denies Precision Dose’s allegations and has counterclaimed that Precision Dose is no longer entitled to exclusivity rights with respect to Phentermine 37.5mg tablets, and is responsible for certain costs, expenses, price increases and lost profits relating to Phentermine 37.5mg tablets and the parties’ agreements. As of the date of filing of this annual report on Form 10-K this arbitration proceeding was ongoing.

Please see the risk factor in Item 1A titled “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.”

ITEM 4 MINE SAFETY DISCLOSURES.

Not Applicable.

PART II

ITEM 5 MARKET FOR COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Common Stock is quoted on the Over-the-Counter Bulletin Board (OTCBB) under the ticker symbol "ELTP". The following table shows, for the periods indicated, the high and low bid prices per share of our Common Stock as by OTC Bulletin Board. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Quarter Ended	High	Low
Fiscal Year Ending March 31, 2015		
March 31, 2015	$0.33	0.20
December 31, 2014	$0.34	0.17
September 30, 2014	$0.45	0.28
June 30, 2014	$0.51	0.27
Fiscal Year Ending March 31, 2014		
March 31, 2014	$0.94	0.14
December 31, 2013	$0.14	0.10
September 30, 2013	$0.16	0.07
June 30, 2013	$0.08	0.07

As of June 8, 2015, the last reported sale price of our Common Stock, as reported by the OTCBB, was $0.22.

Holders

As of June 8, 2015, there were, respectively, approximately 127 and 1 holders of record of our Common Stock and Series I Preferred Stock.

Dividends

We have never paid cash dividends on our Common Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business.

Recent Sales of Unregistered Securities

During the quarter ended March 31, 2015, the Company issued an aggregate of 6,602,847 shares of Common Stock, with such shares constituting unregistered securities, consisting of 2,766,563 shares of Common Stock issued to Directors and Officers in payment of Directors Fees and Salaries in accordance with the Company's policy on Director

Compensation, or the employment agreements with officers of the Company, as appropriate; and 3,836,284 shares of Common Stock issued pursuant to the exercise of warrants

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Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth certain information regarding Elite's equity compensation plans as of March 31, 2015.

Plan Category		Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	(1)	---	---	3,000,000	
Equity compensation plans not approved by security holders		---	---	3,029,227	(2)
Total		---	**---**	**6,029,227**	

(1) Represents securities reserved and available for grant under the 2014 Equity Incentive Plan

(2) Represents securities reserved and available for grant under the 2009 Equity Incentive Plan

2014 Equity Incentive Plan

Our 2014 Equity Incentive Plan (the "2014 Plan") was adopted by the Board on March 17, 2014, to attract, motivate and retain officers, employees, consultants, and directors by issuing common stock based incentives to directors, officers, employees and consultants who are selected for participation. By relating incentive compensation to increases in shareholder value, it is hoped that these individuals will both continue in the long-term service of the Company and be motivated to experience a heightened interest and participate in the future success of Company operations. An aggregate of 3,000,000 common shares are reserved for grant and issuance pursuant to the 2014 Plan. The 2014 Plan is administered and interpreted by our Compensation Committee (the "Administrator"). Awards under the 2014 Plan may be granted in any one or all of the following forms: (i) incentive stock options ("ISOs") intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"); (ii) non-qualified stock options ("NSOs"); (iii) stock appreciation rights, which may be granted in tandem with options or on a stand-alone basis; (iv) shares of restricted stock; (v) shares of unrestricted stock; (vi) performance shares, and (vii) performance units.

Options may not be granted under the 2014 Plan at an exercise price of less than the fair market value of the common stock on the date of grant and the term of options cannot exceed ten years. ISOs may only be granted to persons who are employees of the Company. The exercise price of an ISO granted to a holder of more than 10% of the common stock must be at least 110% of the fair market value of the common stock on the date of grant, and the term of these options cannot exceed five years.

The Administrator also may grant stock appreciation rights. Stock appreciation rights represent the right to receive upon exercise an amount payable in cash or common stock equal to (A) the number of shares with respect to which the stock appreciation right is being exercised multiplied by (B) the excess of (i) the fair market value of a share of common stock on the date the award is exercised over (ii) the exercise price specified in the award agreement.

Under the performance award component of the 2014 Plan, participants may be granted an award denominated in shares of common stock or in dollars. Achievement of the performance targets, or multiple performance targets established by the Administrator relating to corporate, group, unit or individual performance based upon standards set by the Administrator shall entitle the participant to payment at the full amount or a portion of the amount specified with respect to the award, at the discretion of the Administrator based on its evaluation of the performance of the target goals applicable to such award. Payment may be made in cash, common stock or any combination thereof, as determined by the Administrator, and shall be adjusted in the event the participant ceases to be an employee of the Company before the end of a performance cycle by reason of death, disability or retirement.

Under the stock component of the 2014 Plan, the Administrator may, in selected cases, grant to a plan participant a given number of shares of restricted stock or unrestricted stock. Restricted stock under the 2014 Plan is common stock restricted as to sale pending fulfillment of such vesting schedule and employment requirements as the Administrator shall determine. Prior to the lifting of the restrictions, the participant will nevertheless be entitled to receive distributions in liquidation and dividends on, and to vote the shares of, the restricted stock. The 2014 Plan provides for forfeiture of restricted stock for breach of conditions of grant.

The 2014 Plan also permits the board of directors (and not the Compensation Committee) to grant awards of NSOs, restricted stock or unrestricted stock to non-employee directors. The board may authorize individual grants or adopt one or more formulas for grants of awards to the non-employee directors. All options granted to non-employee directors must have an exercise price equal to the fair market value at the date of grant.

The exercise price of awards may be paid in cash, in shares of common stock (valued at fair market value at the date of exercise), by delivery of a notice of exercise together with irrevocable instructions to a broker to deliver to the Company the proceeds of the sale of common stock or of a loan from the broker sufficient to pay the exercise price, by having the Company withhold from shares being exercised the number of shares having a fair market value equal to the exercise price for all shares being exercised, or by a combination of the foregoing means of payment, as may be determined by the Administrator.

2009 Equity Incentive Plan

Our 2009 Equity Incentive Plan was adopted by the Board on November 24, 2009, to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to the success of Elite and its subsidiaries, by offering them an opportunity to participate in our future performance through awards of Options, the right to purchase Common Stock and Stock Bonuses. An aggregate of 8,000,000 common shares are reserved for grant and issuance pursuant to the 2009 Equity Incentive Plan. The 2009 Equity Incentive Plan is administered and interpreted by our Compensation Committee (the "Compensation Committee"). Under the 2009 Equity Incentive Plan, we are permitted to grant both incentive stock options ("*Incentive Stock Options*" or "*ISOs*") within the meaning of Section 422 of the Internal Revenue Code (the "*Code*") to employees, and other options which do not qualify as Incentive Stock Options (the "*Non-Qualified Options*") to employees, officers, Directors of and consultants to Elite. The per share purchase price of options granted under the 2009 Equity Incentive Plan may not be less than the fair market

value of the shares on the date of the grant, provided that the exercise price of any ISO granted to a ten percent stockholder will not be less than 110% of the fair market value on the date of the grant. Recipients of ISO's and Non-Qualified Options have no voting, dividend or other rights as stockholders with respect to shares of Common Stock covered by options prior to becoming the holders of record of such shares.

Under the 2009 Equity Incentive Plan, we also are permitted to offer stock awards ("2009 Equity Incentive Plan Stock Awards") to eligible persons. The 2009 Equity Incentive Plan defines such stock awards as an offer by us to sell to an eligible person shares that may or may not be subject to restrictions. The purchase of price of shares sold pursuant to an 2009 Equity Incentive Plan Stock Award may not be less than the fair market value of the shares on the grant date, provided, however, that the number of shares issued for the payment of employee and officers' salaries, or directors' fees will be computed using the average daily closing price, which is defined as the simple average of the closing price of each trading day in the quarter or other applicable period for which payment is due.

We also are permitted to award stock bonuses under the 2009 Equity Incentive Plan, which defines such stock bonuses as an award of shares for extraordinary services rendered to the Company.

Issuer Purchases of Equity Securities

None.

ITEM 6 SELECTED FINANCIAL DATA

Not applicable.

ITEM 7 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

General

The following discussion and analysis should be read with the financial statements and accompanying notes, included elsewhere in this Annual Report on Form 10-K and the information described in Item 1A "Risk Factors" and in "Special Note Regarding Forward Looking Statements" above. The following discussion is intended to assist the reader in understanding and evaluating our financial position.

Critical Accounting Policies and Estimates

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and

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

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

Liquidity and Capital Resources

Cash and Working Capital

As of March 31, 2015, the Company had cash on hand of $7.5 million and a working capital surplus of $7.3 million. The Company believes that such resources, combined with the Company's access to the remaining balance of the equity line with Lincoln Park Capital, and approximately $400,000 available under the Hakim Credit Line are sufficient to fund operations through the current operating cycle. For the fiscal year ended March 31, 2015, it had losses from operations totaling $16.5 million, net other income totaling $45.4 million and a net income of $28.9 million. Please note that the Company's other income/(expenses) are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that such fair values strongly correlate to and vary inversely with the market share price of the Company's Common Stock.

The Company does not anticipate being profitable for the fiscal year ending March 31, 2016, due in large part to its plans to conduct clinical development and commercialization activities on a range of abuse deterrent opioid products, on an accelerated and simultaneous basis. Such activities require the investment of significant amounts in clinical trials, safety and efficacy studies, bioequivalence studies, product manufacturing, regulatory expertise and filings, as well as investments in manufacturing and lab equipment and software. In order to finance these significant expenditures, the Company entered into two purchase agreements with Lincoln Park Capital Fund, LLC ("Lincoln Park"), with such agreements providing the company with equity lines totaling $50 million. We believe this amount of financing, if received, is sufficient to fund the commercialization of the abuse deterrent opioid products identified. Please see below for further details on the financing transactions with Lincoln Park.

In addition, the Company had previously received Notices of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments as well as the company's failure to make scheduled principal payments. All monetary defaults have been cured during Fiscal 2015 and the Company is current on all NJEDA Bond interest and principal payments. See "NJEDA Bonds" below and the Risk Factor in Part I, Item 1A entitled "A notice of default was issued by the New Jersey Economic Development Authority in relation to prior obligations of our tax-exempt bonds. Although we are current in our payments under these bonds, If the principal balances due under these bonds are accelerated pursuant to the notice of default, our ability to operate in the future will be materially and adversely affected".

Lincoln Park Capital

Pursuant to an April 19, 2013 purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") we had the right to sell to and Lincoln Park was obligated to purchase up to $10 million in shares of the Company's Common

Stock, subject to certain limitations, from time to time, over the 36 month period commencing on May 9, 2013. We raised the entire $10 million from the sale of shares to Lincoln Park pursuant to that agreement. That agreement terminated in March 2014 with the sale of all shares covered by that agreement.

On April 10, 2014, we entered into another Purchase Agreement and a 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 million 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 a registration statement to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement. That registration statement was declared effective by the SEC on May 1, 2014 A post-effective amendment to that Registration Statement was subsequently filed with the SEC and declared effective on July 1, 2014.

Upon execution of the Purchase Agreement, we have issued 1,928,641 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement as consideration for its commitment to purchase additional shares of our common stock under that 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 million of our common stock is purchased by Lincoln Park. Through June 8, 2015, we have sold to Lincoln Park an aggregate of 55,153,207 shares under the Purchase Agreement for aggregate gross proceeds of approximately $15.0 million. In addition, we have issued an additional 2,649,494 Commitment Shares.

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 (a “Regular Purchase”) up to 500,000 shares of our common stock on any such business day, increasing up to 800,000 shares, depending upon the closing sale price of the common stock, provided that in no event shall Lincoln Park purchase more than $760,000 worth of our common stock on any single business day. The purchase price of shares of Common Stock related to the future Regular Purchase funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 10 business days leading up to such time), but in no event will shares be sold to Lincoln Park on a day the Common Stock closing price is less than the floor price of $0.10 per share, subject to adjustment.

In addition to Regular Purchases, on any business day on which we have properly submitted a Regular Purchase notice and the closing sale price is not below $0.15, we may purchase (an “Accelerated Purchase”) an additional “accelerated amount” under certain circumstances. The amount of any Accelerated Purchase cannot 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 (i) 97% of the volume weighted average price during the purchase date; or (ii) the closing sale price of our common stock on the purchase date.

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.

Our sales of shares of Common Stock to Lincoln Park under the Lincoln Park Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of Common Stock.

The Lincoln Park Purchase Agreement and the Lincoln Park Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties. The Company has the right to terminate the Lincoln Park Purchase Agreement at any time, at no cost or penalty. Actual sales of shares of Common Stock to Lincoln Park under the Lincoln Park Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, without limitation, market conditions, the trading price of the Common Stock and determinations by the Company as to appropriate sources of funding for the Company and its operations. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. Lincoln Park has no right to require any sales by the Company, but is obligated to make purchases from the Company as it directs in accordance with the Lincoln Park Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares.

The net proceeds under the Purchase Agreement to the Company will depend on the frequency and prices at which the Company sells shares of its stock to Lincoln Park. The Company expects that any proceeds received by the Company from such sales to Lincoln Park under the Lincoln Park Purchase Agreement will be used for general corporate purposes and working capital requirements.

Hakim $1,000,000 Bridge Revolving Credit Line

On October 15, 2013 (the "Hakim Credit Line Effective Date"), we entered into a bridge loan agreement (the "Hakim Loan Agreement") with Nasrat Hakim, our President and CEO. Under the terms of the Hakim Loan Agreement, we have the right, in our sole discretion, to a line of credit ("Hakim Credit Line") in the maximum principal amount of up to $1,000,000 at any one time. Mr. Hakim provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount will be evidenced by a promissory note which shall mature on June 30, 2015, at which time the entire unpaid principal balance plus accrued interest thereon shall be due and payable in full. We may prepay any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on January 1, April 1, July 1 and October 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Hakim Loan Agreement, we may borrow, repay, and reborrow under the Hakim Credit Line through maturity. Amounts borrowed under the Hakim Credit Line will bear interest at the rate of ten percent (10%) per annum. As of March 31, 2015, the principal balance owed under the Credit Line was $583,071 with an additional $18,105 in accrued interest being also owed, in accordance with the terms and conditions of the Credit Line.

Convertible Note Payable to Mikah Pharma LLC

On August 1, 2013, Elite Laboratories Inc. ("Elite Labs"), a wholly owned subsidiary of the Company, executed an asset purchase agreement (the "Mikah Purchase Agreement") with Mikah Pharma LLC ("Mikah"), an entity that is wholly owned by Mr. Nasrat Hakim, who, in conjunction with this transaction, was appointed as Elite's CEO, President and a Director on August 2, 2012, and acquired from Mikah a total of 13 Abbreviated New Drug Applications ("ANDAs") consisting of 12 ANDAs approved by the FDA and one ANDA under active review with the FDA, and all amendments thereto (the "Acquisition") for aggregate consideration of $10,000,000, inclusive of imputed interest payable pursuant to a non-interest bearing, secured convertible note due in August 2016 (the "Mikah Note"). Please see "Elite's Acquisition of a 13 Abbreviated New Drug Applications ("ANDAs")" in Part I, Item 1 Business, above for more information on the Acquisition. The Mikah Note was amended on February 7, 2014 to make it convertible into shares of the Company's Series I Convertible Preferred Stock.

The Mikah Note, as amended, was interest free and due and payable on the third anniversary of its issuance. Subject to certain limitations, the principal amount of the Mikah Note was convertible at the option of Mikah into shares of Common Stock at a rate of $0.07 (approximately 14,286 shares per $1,000 in principal amount), the closing market price of the Company's Common Stock on the date that the asset purchase agreement and Note were executed and/or

into shares of the Company's Series I Convertible Preferred Stock at the rate of 1 share of Series I Preferred Stock for each $100,000 of principal owed on the Mikah Note. The conversion rate was adjustable for customary corporate actions such as stock splits and, subject to certain exclusions, includes weighted average anti-dilution for common stock transactions at prices below the then applicable conversion rate. Pursuant to a security agreement (the "Security Agreement"), repayment of the Mikah Note was secured by the ANDAs acquired in the Acquisition.

On February 7, 2014, Mikah converted the principal amount of $10,000,000, representing the entire principal balance due under the Mikah Note, into 100 shares of the Company's Series I Preferred Stock.

Please also refer to our audited financial statements and notes to financial statements as and for the fiscal year ended March 31, 2015 for further details.

Despite having entered into the Hakim Credit Line Agreement and the Lincoln Park Purchase Agreement we still may be required to seek additional capital in the future and there can be no assurances that Elite will be able to obtain such additional capital on favorable terms, if at all.

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

Cash at March 31, 2015 was approximately $7.5 million, an increase of approximately $0.6 million from the approximately $6.9 million balance of cash at March 31, 2014.

As of March 31, 2015, our principal source of liquidity was approximately $6.9 million of cash. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants and, as mentioned above, from the Lincoln Park Purchase Agreement, and the Hakim Credit Line. There can be no assurance that any of these sources will generate or provide sufficient cash.

NJEDA Bonds

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing $4,155,000, evidenced by a 6.5% Series A Note in the principal amount of $3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of $495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of March 31, 2015, all of the proceeds were utilized by the Company for such stated purposes.

Interest is payable semiannually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a Debt Service Reserve Fund of $366,000 in relation to the Series A Notes.

Bond issue costs of $354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,177 for the fiscal year ended March 31, 2015.

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

As of the date of filing of this Annual Report on Form 10-K, there are no interest or principal amounts in arrears. The Series B Notes were retired, at par in July 2014.

Off-Balance Sheet Arrangements

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

Effects of Inflation

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

Results of Consolidated Operations:

Year Ended March 31, 2015 as compared to the Year Ended March 31, 2014

Our revenues for Fiscal 2015 were $5.0 million, an increase of $0.4 million or approximately 9% from revenues for the comparable period of the prior year, and consisted of $3.9 million in manufacturing fees, $0.005 million in lab and product development fees and $1.1 million in license fees.

Revenues for Fiscal 2014 consisted of $3.0 million in manufacturing fees, $0.08 million in lab and product development fees, and $1.5 million in license fees. Manufacturing fees increased by approximately 30% as a result of the continued growth in the Company’s generic product sales combine with the launch of Isradipine product line in

January 2015.

Licensing fees decreased by approximately 26% or $0.4 million, from $1.5 million in Fiscal 2014 to $1.2 million in Fiscal 2015. This decrease is due to Fiscal 2014 license fee revenues including a one-time milestone of $0.6 million earned pursuant to the Epic Agreement.

Research and development costs for Fiscal 2015 were approximately $14.8 million, an increase of approximately $10.9 million or approximately 275% from $4.0 million of such costs for the comparable period of the prior year. The increase was primarily due to increased activities related to the development of Elite's abuse deterrent opioid products. Spending included clinical and lab studies (such as category 1, category 2 and category 3 testing as described under the FDA's draft Guidance for Industry, Abuse-Deterrent Opioids – Evaluation and Labeling, January 2013), process development, analytical development, and regulatory development for products in our pipeline.

General and administrative expenses for Fiscal 2015 were $2.9 million an increase of $0.8 million or approximately 40% from $2.1 million of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to significant increases in regulatory and regulatory compliance costs, including, without limitation, increased fees paid to the US-FDA and the hiring of additional staff to support regulatory compliance activities, additional costs incurred in relation to compliance with the Sarbanes-Oxley Act and significant increases in legal fees, insurance and employee benefits. Please note that these higher levels of overhead costs are expected to continue.

Depreciation and amortization for Fiscal 2015 was $0.6 million, an increase of $0.1 million or approximately 23%, from $0.5 million for the comparable period of the prior year. The increase was primarily due to the expansion and upgrading of the Northvale Facility, which has required substantial investments in property, plant and equipment.

Non-cash compensation through the issuance of stock options and warrants for Fiscal 2015 was approximately $0.3 million, an increase of $0.17 million, or approximately 205% from $0.09 million for the comparable period of the prior year. The increase was due to the issuance of options to purchase an aggregate of 2,590,000 shares of Common Stock to various employees during Fiscal 2015, primarily pursuant to employment agreements, and the timing of the amortization schedule established at the time of issuance of the related stock options

As a result of the foregoing, our loss from operations for Fiscal 2015 was $16.5 million, compared to a loss from operations of $5.3 million for Fiscal 2014.

Other expenses for Fiscal 2015 were a net income of $45.4 million, an increase in net other income of $137.0 million from the net other expense of $91.5 million for the comparable period of the prior year. The increase in other income was due to derivative income relating to changes in the fair value of our preferred shares, outstanding warrants and convertible note payable derivatives during Fiscal 2015 totaling $44.1 million, as compared to a net derivative expense of $89.5 million for the comparable period of the prior year, a $133.6 million overall increase in other income. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company’s Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company’s convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company’s Common Stock as of March 31, 2015 was $0.25, as compared to a closing price of $0.41 as of March 31, 2014. These variances in the closing price of the Company’s Common Stock as compared with the closing price at the end of the immediately preceding fiscal year end were significant factors in the derivative income recorded during the year ended March 31, 2015.

As a result of the foregoing, our net income for Fiscal 2014 was $28.9 million, compared to a net loss of $96.6 million for Fiscal 2014.

Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities) increased by $3.5 million from $3.8 million as of March 31, 2014 to $7.3 million as of March 31, 2015, with such increase being primarily due to the loss from operations sustained during Fiscal 2015 being financed by capital financings that included $13.2 million in proceeds from the sale of Common Stock pursuant to the Purchase Agreement with Lincoln Park, $0.8 million in proceeds from

the exercise of cash warrants and options and $5.0 million in proceeds from the sale of the Company's investment in Novel Labs, offset in large part by purchases of fixed assets and leasehold improvements totaling $1.9 million and the retirement of $1.3 million in NJEDA Bonds and other loans. Please note that capital financings provide cash to the Company without a corresponding current liability and accordingly have an accretive effect on working capital.

We experienced negative cash flows from operations of $15.1 million for Fiscal 2015, primarily due to our net income of $28.9 million, offset by non-cash other income items totaling $43.2 million included in the net income, combined with increases in accounts payable and accrued liabilities of $1.2 million (resulting in a positive effect on cash flow), and offset by increases in accounts receivable, inventory and prepaid expenses of $2.1 million (resulting in a negative effective on cash flow).

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Attached hereto and filed as a part of this Annual Report on Form 10-K are our Consolidated Financial Statements, beginning on page F-1.

ITEM 9 CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed or submitted under the Securities Exchange Act of 1934 (“the Exchange Act”), (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii) accumulated and communicated to our management to allow for timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Under the supervision and with the participation of our management, including the Chief Executive and Chief Financial Officers, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive and Chief Financial Officers concluded that, due to a material weakness in our internal control over financial reporting, as described below, our disclosure controls and procedures were not effective as of March 31, 2015.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, with such controls being as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, the Company's principal executive and principal financial offers and effected by the Company's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, with such being in accordance with generally accepted accounting principles ("GAAP").