

ELITE PHARMACEUTICALS INC /NV/  
Form 10-K  
June 21, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(MARK ONE)

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

**FOR THE FISCAL YEAR ENDED – MARCH 31, 2013**

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 No  
x ..

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 No  
x ..

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

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, 2012, 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 | 41,959,713             | September 30, 2012         |

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 | 394,580,173        | June 13 2013               |

## 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”, “us”, “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.

#### Business Overview and Strategy

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary know-how and technology, particularly as it relates to abuse resistant products. Our strategy includes improving off-patent drug products for life cycle management and developing generic versions of controlled-release drug products with high barriers to entry.

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

- Phentermine 37.5mg tablets (“Phentermine 37.5mg”)
- Lodrane D® Immediate Release capsules (“Lodrane D”)
- Methadone 10mg tablets (“Methadone 10mg”)
- Hydromorphone Hydrochloride 8mg tablets (“Hydromorphone 8mg”)
- Phendimetrazine tartrate 35mg tablets (“Phendimetrazine 35mg”)
- Phentermine 15mg capsules (“Phentermine 15mg”)
- Phentermine 30mg capsules (“Phentermine 30mg”)

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

- Naltrexone HCl (“Naltrexone Generic”)

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

Laboratories LLC (“Ascend”) and is a wholly owned subsidiary of Alkem.

The Precision Dose License Agreement provides for the marketing and distribution, in the United States, Puerto Rico and Canada, of Phentermine 37.5mg, Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA. Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Naltrexone Generic was approved by the US-FDA in January 2013, but not yet launched.

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

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



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

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

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

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

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

## **Strategy**

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

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

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

cash-flow.

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

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

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

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

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

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

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

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

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

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

under review.

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

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

On September 10, 2010, Elite executed a License Agreement with Precision Dose to market and distribute Phentermine 37.5mg ("Phentermine 37.5mg"), Phentermine Capsules, Hydromorphone 8mg, Naltrexone Generic, and certain additional products that require approval from the FDA, through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada (the "Precision Dose License Agreement"). Phentermine 37.5mg tablets were launched in April 2011. Hydromorphone 8mg was launched in March 2012. Phentermine Capsules were launched in April 2013. Naltrexone Generic has been approved by the US-FDA for manufacture by Elite but not yet launched. Precision Dose will have the exclusive right to market the products in the United States and Puerto Rico and a non-exclusive right to market the products in Canada.

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

## **Research and Development**

During each of the last two fiscal years, the Company has conducted research and development activities. We incurred total costs of \$975,250 during the fiscal year ended March 31, 2013 (“Fiscal 2013”) and \$1,735,689 during the fiscal year ended March 31, 2012 (“Fiscal 2012”) in relation to research and development activities.

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

## **Commercial Products**

### **Phentermine**

On April 7, 2011, Elite made the initial shipment of phentermine HCl 37.5 mg tablets to TAGI. This triggered a milestone payment under the Precision Dose License Agreement. Phentermine 15mg and Phentermine 30mg were launched in April 2013. Phentermine 37.5mg tablets and Phentermine 15mg and 30mg capsules are now a commercial product being distributed by our partner, TAGI.

### **Lodrane D® Immediate Release capsules**

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

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

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

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

#### **Methadone 10mg tablets**

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

#### **Hydromorphone 8mg tablets**

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

#### **Phendimetrazine Tartrate 35 mg tablets**

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

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

#### **Approved Products**

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

- . Phentermine HCl 37.5mg tablets (“Phentermine 37.5mg”)
- . Hydromorphone HCl 8mg tablets (“Hydromorphone 8mg”)
- . Naltrexone HCl 50mg tablets (“Naltrexone 50mg”)
- . Phentermine HCl 15mg capsules (“Phentermine 15mg”)
- . Phentermine HCl 30mg capsules (“Phentermine 30mg”)

**Phentermine HCl 37.5mg tablets**

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

**Hydromorphone HCl 8mg tablets**

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

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



### **Naltrexone HCl 50mg tablets**

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

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

### **Phentermine 15mg and Phentermine 30mg**

Elite received approval as of September 28, 2012 from the US-FDA for Phentermine 15mg and Phentermine 30mg. These products were developed by Elite. The commercial launch of Phentermine 15mg and Phentermine 30mg had been delayed due to the sole supplier of the API approved for these products restricting the amount of such API available to Elite. We resolved this issue and the Phentermine 15mg and Phentermine 30mg products were launched in April 2013. The resolution of this issue related to the supply of API, however, required us to pay substantially higher prices than previously paid for the Phentermine API. Elite anticipates that some of the increase in API pricing could be offset with increase manufacturing efficiencies, but also that volumes and profits from these products will be impaired.

### **Contract Manufacturing of Isradipine and Phendimetrazine**

On June 1, 2011, Elite executed a Manufacturing and Supply Agreement (the “Isradipine/ Phendimetrazine Agreement”) with Mikah Pharma, LLC (“Mikah”) to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg (“Isradipine”) and Phendimetrazine Tartrate Tablets USP, 35 mg (“Phendimetrazine”), including (a) developing and preparing the documentation required for the transfer of the manufacturing process to Elite’s facility and the appropriate regulatory filing for the ANDA, and (b) manufacturing finished dosage forms appropriate for commercial sale, marketing and distribution in the United States, its territories, possessions, and commonwealths in accordance with the requirements of the Isradipine/ Phendimetrazine Agreement; Elite is required to perform, at its sole cost and expense, all Technology Transfer, validation and qualification services (including: equipment, methods and facility qualification), validation and stability services required by Applicable Laws to commence manufacturing Isradipine and Phendimetrazine for commercial sale by Mikah or its designees in accordance with the terms of the Isradipine/ Phendimetrazine Agreement. During the term of the Isradipine/ Phendimetrazine Agreement and subject to the provisions therein, Mikah is required to purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Isradipine and Phendimetrazine as Mikah

may order from time to time pursuant to the Isradipine/ Phendimetrazine Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of Isradipine and Phendimetrazine. For the Isradipine product, Elite will also receive a 10% royalty on net profits of the finished Product. The payment is to be calculated and paid quarterly. Elite will also receive a onetime milestone payment for each Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch. The Isradipine/ Phendimetrazine Agreement has a term of five years and automatically renews for additional periods of one year unless Mikah provides written notice of termination to Elite at least six months prior to the expiration of the Term or any Renewal Term.

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

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

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

#### **Development and License Agreement with Hong Kong based company**

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

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

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

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

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

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

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

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

Please note that there can be no assurances that such approvals will be granted or that future manufacturing revenues will be earned by the Company from the manufacture of the Lodrane® Extended Release Products, should such approvals be granted by the FDA. Furthermore, the Company has been advised that ECR has decided not to proceed with the development of the extended release formulations marketed under the Lodrane® brand. The company has received FDA feedback on clinical protocols for the extended release brompheniramine product. It also has filed a Citizen Petition with the FDA related to the extended release brompheniramine/pseudoephedrine product. The Company believes a successful resolution of the Citizen Petition would put this product in a position to move forward with clinical trials and eventually secure the requisite approvals for introduction of the product to the market. The Company may proceed with the development of these formulations and may seek partners in conjunction with such activities, but there can be no assurances that the Company will pursue the development of these formulations, or that such development activities, if pursued, will result in approvals from the FDA. Please also note that the Company does not have ownership of the Lodrane® brand name, and that if any products containing the formulations associated with the Lodrane® brand name are approved and marketed, such would be done under a different brand name.

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

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

#### **Discontinued Development – Isradipine**

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

## **Products Under Development**

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

## **Abuse Resistant and Sustained Release Opioids**

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

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

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

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

**Epic Strategic Alliance Agreement**

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a subsidiary of Epic Pharma LLC (collectively, "Epic") entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009). The Epic Strategic Alliance Agreement expired on June 4, 2012.

Epic is a pharmaceutical company that operates a business synergistic to that of Elite in the research and development, manufacturing and sales and marketing of oral immediate release and controlled-release drug products.



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

Pursuant to the Epic Strategic Alliance Agreement, on June 3, 2009 (the “Initial Closing Date”), Elite and Epic conducted the initial closing (the “Initial Closing”) of the transactions contemplated by the Epic Strategic Alliance Agreement, and Epic and its employees and consultants commenced use of a portion of Elite’s facility located at 165 Ludlow Avenue, Northvale, New Jersey (the “Facility”), for the purpose of developing new generic drug products, all at Epic’s sole cost and expense for a period of at least three years (the “Term”). Although the Term has expired, cooperation between the Company and Epic continued. In addition to the use of the Facility, Epic used Elite’s machinery, equipment, systems, instruments and tools residing at the Facility (collectively the “Personal Property”) in connection with its joint drug development project at the Facility.

During the Term, Epic was permitted to use and occupy a portion of the Facility and use the Personal Property for the purpose of developing (i) at least four controlled-release products (the “Identified CR Products”) and (ii) at least four immediate-release products (the “Identified IR Products”). The identity of each were agreed upon by Epic and Elite.

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

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

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

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of an aggregate of 28,000,000 shares of Common Stock (such shares, the “CR Related Shares”).

With respect to each Identified IR Product and Additional IR Product developed by Epic at the Facility, (i) Elite was to issue and deliver to Epic a seven year warrant to purchase up to 4,000,000 shares of Common Stock, at an exercise price of \$0.0625, following the receipt by Elite from Epic of each written notice of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified IR Products and/or Additional IR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 16,000,000 shares of Common Stock (such warrants, together with the CR Related Warrants, the "Milestone Warrants"), and (ii) Elite was to issue and deliver to Epic 3,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified IR Products and/or Additional IR Products, up to a maximum of an aggregate of 12,000,000 shares of Common Stock (such shares, together with the CR Related Shares, the "Milestone Shares"). The Milestone Warrants may only be exercised by payment of the applicable cash exercise price. Elite has no obligation to register with the United States Securities and Exchange Commission (the "SEC") or any state securities commission the resale of the Milestone Shares, Milestone Warrants or the shares of Common Stock issuable upon exercise of the Milestone Warrants. During the Term and through the date of filing of this Annual Report on Form 10-K, a total of 4,000,000 Milestone Warrants were issued to Epic pursuant to the Epic Strategic Alliance Agreement.

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

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

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

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

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

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

In addition, in accordance with the Strategic Alliance Agreement, Epic has paid to Elite a total of twelve payments of \$62,500 each, for an aggregate purchase price of \$750,000, in exchange for an additional 62.5 shares of Series E Preferred Stock for each payment, and 750 shares of Series E Preferred Stock, in aggregate.

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

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

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

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

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

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

### **Novel Labs Investment**

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

### **Patents**

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

| <b>PATENT</b>   | <b>EXPIRATION DATE</b> |
|---|------------------------|
| U.S. patent 5,837,284 (assigned to Celgene Corporation) | November 2018          |
| U.S. patent 6,620,439                                   | October 2020           |
| U.S. patent 6,635,284 (assigned to Celgene Corporation) | March 2018             |
| U.S. patent 6,926,909                                   | April 2023             |
| U.S. patent 8,182,836                                   | April 2024             |
| U.S. patent 8,425,933                                   | April 2024             |

We have pending applications for three additional U.S. patents and four foreign patents. The pending patent applications are for an opioid agonist and antagonist products that we are developing to be used with controlled-release oxycodone and other opioids to minimize the abuse potential for the opioids. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or

other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

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



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

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

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

## **Trademarks**

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

## ***Government Regulation and Approval***

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

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

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

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

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

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

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

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

and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further delays may be encountered before the products become commercially available.

## **ANDAs**

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

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

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

## **Controlled Substances**

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

## **cGMP**

All facilities and manufacturing techniques used for the manufacture of products for clinical use or for sale must be operated in conformity with cGMP regulations issued by the FDA. We engage in manufacturing on a commercial

basis for distribution of products, and operate our facilities in accordance with cGMP regulations. If we hire another company to perform contract manufacturing for us, we must ensure that our contractor's facilities conform to cGMP regulations.

### **Compliance with Environmental Laws**

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

## Competition

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

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

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

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

deletions by competitors, (vii) a company's reputation as a manufacturer and distributor of quality products, (viii) a company's level of service (including maintaining sufficient inventory levels for timely deliveries), (ix) product appearance and labeling and (x) a company's breadth of product offerings.



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

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

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

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

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

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

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

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

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

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

## Employees

As of the date of this Annual Report on Form 10-K, we had 26 full time employees. Full-time employees are engaged in operations, administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

## 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 in each year since our incorporation in 1990. We achieved a net income of \$1.5 million during Fiscal 2013 and incurred a net loss \$15.1 million during Fiscal 2012. However, please note that such net income and net loss amounts include other income and expense from preferred share and warrant derivatives totaling a net \$3.5 million of other income in Fiscal 2013 and a net \$12.7 million in other expenses for Fiscal 2012. We incurred losses from operations of \$1.6 million and \$2.0 million during Fiscal 2013 and Fiscal 2012, respectively. We expect to continue to incur operating losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

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

The independent auditor's report for the year ended March 31, 2013, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and working capital deficiency raise substantial doubt about our ability to continue as a going concern. As of March 31, 2013, we had cash reserves of approximately \$0.4 million, a working capital deficit of approximately \$2.8 million, and for Fiscal 2013, we had losses from operations totaling \$1.6 million, net other income totaling \$3.5 million and a net income of \$1.5 million.

In addition, as discussed below in "Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight as evidenced by the FDA's removal from the market of our Lodrane® extended release product line", in March 2011. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA's directive. The FDA reclassified our Changes Being Effected in 30 Days supplements ("CBE-30") filed in relation to the transfer of manufacturing of two approved generic products to the Facility to a "prior approval supplemental application". Such reclassifications have resulted in significant delays in the commercialization of these two approved generic products, with accordingly significant delays in our being able to generate revenues, if any, from the manufacture and sale of such approved generic products.

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

In addition, pursuant to the Lincoln Park Purchase Agreement (please see "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; Purchase Agreement with Lincoln Park Capital"), we may direct Lincoln Park to purchase up to \$10,000,000 worth of shares of our common stock under our agreement over a 36 month period generally in amounts up to \$80,000 worth of our shares of our common stock on any such business day. However, Lincoln Park shall not purchase any shares of our common stock on any business day that the closing sale price of our common stock is less than \$0.07 per share, subject to adjustment as set forth in the Purchase Agreement. Assuming a purchase price of \$0.07 per share and the purchase by Lincoln Park of all of the 75,000,000 purchase shares registered under the Lincoln Park Registration Statement, proceeds to us would only be \$5,250,000 and not the full \$10,000,000 allowed by the Lincoln Park Purchase Agreement.

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



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

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

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

We are in default of our obligations on a loan through tax-exempt bonds from the New Jersey Economic Development Authority (“NJEDA”). Our liability under this obligation as of March 31, 2013 was approximately \$3.4 million. Our real property and the improvements thereon are encumbered by a mortgage in favor of as security for a loan through the NJEDA Bonds. We have received Notices of Default from the Trustee in relation to the utilization of the debt service reserve fund for of semi-annual interest payments from March 2009 to the present and for the non-payment of principal amounts due on September 1, 2010, 2011 and 2012. While the Company has replenished all amounts withdrawn from the debt service reserve fund in accordance with the terms of the bond agreement, there can be no assurances of the Company being able to make future semi-annual interest payments without utilizing the debt service reserve fund, nor can there be assurances of the Company being able to replenish the debt service reserve fund in the future. In addition, there can be no assurances of the Company being able to pay the principal payments currently due as well as those which are due in the future

Resolution of our default under the NJED Bonds will have a significant effect on our ability to operate in the future. For more information on the NJEDA Bonds, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; NJEDA Bonds”.

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

ELI-154 and ELI-216 are pre-Phase III and some of our generic products are still at an early stage of development. Other than generic phentermine, which is a commercial drug product, and two additional generic drug products which Elite purchased in 2010, but are not yet commercialized, and a generic product that has been filed but not yet approved by the FDA, we will need to perform additional development work for the additional product candidates in our pipeline before we can seek the regulatory approvals necessary to begin commercial sales.



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

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

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

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

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

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

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

- ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;

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· delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards; slower than expected rate of patient recruitment and enrollment; inability to adequately follow and monitor patients after treatment; difficulty in managing multiple clinical sites;

unforeseen safety issues;  
government or regulatory delays; and  
clinical trial costs that are greater than we currently anticipate.

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

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

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

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

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

· collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;

collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial or abandon a product candidate;

expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;

· collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;

· the terms of our contracts with current or future collaborators and licensees may not be favorable to us in the future;

· a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;

· disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration;

· one or more third-party developers could obtain approval for a similar product prior to the collaborator or licensee resulting in unforeseen price competition in connection with the development product; and

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

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

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

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

fiscal year ended March 31, 2011. The cessation of production of the Lodrane Extended Release Products has had a material adverse effect on Elite's revenues for all periods beginning after March 31, 2011.

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

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

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

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

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

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

Litigation concerning patents and proprietary rights can be protracted and expensive. Companies that produce brand pharmaceutical products routinely bring litigation against applicants that seek FDA approval to manufacture and

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

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



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

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

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

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

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

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

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

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

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

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

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

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

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved. In this regard, the launch of commercial production of Phentermine Capsules was delayed and the sale of the phentermine 37.5 mg tablets hampered as a result of the sole supplier of the API approved for both the Phentermine tablet product and the Phentermine capsule products restricting the amount of API available to us. While we have resolved this issue for the next year, the purchase orders now in place are at a substantially higher price than previously paid, and, while we anticipate that some of the increase in API pricing could be offset with increase manufacturing efficiencies, the volumes and profits from these products will be impaired. This type of supply restriction could prevent us, and our sales and marketing partner, from meeting growing demand for the products and restrict sales of products utilizing the restricted API.

In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers.

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

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

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

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

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

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

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



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

Our success depends in large part on our ability to attract and retain highly qualified scientific, technical and business personnel experienced in the development, manufacture and marketing of oral, controlled-release drug delivery systems and generic products. Our business and financial results could be materially harmed by the inability to attract or retain qualified personnel. In this regard, as of May 24, 2013, Chris Dick, the Company's President, Chief Operating Officer and member of the Board of Directors, stepped down from his positions as President and Chief Operating Officer and a Director. However, Mr. Dick remains as a consultant with Elite to ensure a smooth transition while the Board of Directors conducts a search for a permanent replacement.

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

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

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

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

As a result of our determination not to fund our remaining contributions to Novel at the valuation set forth in the Novel Alliance Agreement and the resulting purchase from us of a portion of our shares of Class A Voting Common Stock of Novel by VGS Pharma, LLC, our remaining ownership interest in equity of Novel was reduced to approximately 10% of the outstanding shares of Novel. Novel may seek to raise additional operating capital in the future and may do so by the issuance of equity. If Novel issues additional equity, our future equity interest in Novel

will decrease and we will be entitled to a decreased portion of any dividends or other distributions which Novel may issue in the future. Novel also has a company sponsored stock option plan and any equity issued from this stock plan will also reduce Elite's equity interest in Novel.

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

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

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2013, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of \$0.17 per share to a low of \$0.07 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including, without limitation:

Results of our clinical trials;  
Approval or disapproval of our ANDAs or NDAs;



- Announcements of innovations, new products or new patents by us or by our competitors;
  - Governmental regulation;
  - Patent or proprietary rights developments;
  - Proxy contests or litigation;
- News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- Economic and market conditions, generally and related to the pharmaceutical industry;
  - Healthcare legislation;
  - Changes in third-party reimbursement policies for drugs;
  - Fluctuations in our operating results; and
- Commercial success of the product of Epic identified under the Epic Strategic Alliance Agreement.

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

On April 19, 2013, we entered into the Lincoln Park Purchase Agreement, pursuant to which Lincoln Park has committed to purchase up to \$10,000,000 of our common stock. Concurrently with the execution of the Lincoln Park Purchase Agreement, we issued 2,929,115 shares of our common stock to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Lincoln Park Purchase Agreement. The purchase shares that may be sold pursuant to the Lincoln Park Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 36-month period commencing after May 9, 2013, the date that the SEC declared effective the registration statement. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

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

In addition, as of June 13, 2013, there were outstanding shares of preferred stock convertible into up to approximately 81.4 million shares of Common Stock and warrants to purchase an aggregate of approximately 139.3 million shares of Common Stock at exercise prices that range from \$0.0625 per share to \$3.25 per share. Additional shares of Common Stock may be issuable as a result of anti-dilution provisions in the outstanding preferred stock and warrants; and, dividends on outstanding preferred stock. In addition, with respect to a product developed by Epic under the Epic Strategic Alliance Agreement, we may issue to Epic up to an aggregate of 3,000,000 additional shares of our Common Stock following the receipt by us from Epic of written notices of Epic's receipt from the FDA of approval for a certain

immediate-release product developed by Epic at the Facility.

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

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

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

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

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

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

Pursuant to the Epic Strategic Alliance Agreement, at present two of our directors are appointees of Epic.

In addition, the terms of the Series E Preferred Stock provide that on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), Epic, as a holder of Series E Preferred Stock, will be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Series E Preferred Stock held by Epic are convertible as of the record Under the Epic Strategic Alliance Agreement. Except as provided by law or by the

other provisions of the Series E Preferred Stock, Epic will vote together with the holders of Common Stock, as a single class. In addition, pursuant to the Epic Strategic Alliance Agreement and the terms of the Series E Preferred Stock, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, we may conduct our operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the terms of the Series E Preferred Stock, we must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein. Accordingly, Epic will have the ability to exert further influence over us and may have the effect of preventing a change of control of Elite. For more detailed information about the Epic Strategic Alliance Agreement please see “Business; Epic Strategic Alliance Agreement.”

Also, as disclosed above in “The issuance of additional shares and securities convertible into or exercisable for shares of Commons Stock pursuant to existing agreements or otherwise will cause existing holders of our Common Stock to experience substantial dilution”, we may issue significant additional shares of Common Stock, Common Stock Warrants and convertible Series E Preferred Stock to Epic upon the happening of certain events.

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

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

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

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

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

The Over-the-Counter Bulletin Board (the “OTCBB”) is a regulated quotation service that displays real-time quotes, last sale prices and volume limitations in over-the-counter securities. Because trades and quotations on the OTCBB involve a manual process, the market information for such securities cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and

intervening price fluctuations may result in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmations may be delayed significantly. Consequently, one may not be able to sell shares of our Common Stock at the optimum trading prices.

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

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

#### **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. We are currently using the Facility as a laboratory, manufacturing, storage and office space.

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

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

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



**ITEM 3 LEGAL PROCEEDINGS**

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

**ITEM 4 MINE SAFETY DISCLOSURES.**

Not Applicable.

**PART II****ITEM MARKET FOR COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS  
5 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, 2013 |        |        |
| March 31, 2013                    | \$0.10 | 0.06   |
| December 31, 2012                 | \$0.12 | 0.05   |
| September 30, 2012                | \$0.14 | 0.10   |
| June 30, 2012                     | \$0.17 | 0.08   |
| Fiscal Year Ending March 31, 2012 |        |        |
| March 31, 2012                    | \$0.13 | \$0.09 |
| December 31, 2012                 | \$0.10 | \$0.07 |
| September 30, 2012                | \$0.14 | \$0.07 |
| June 30, 2011                     | \$0.24 | \$0.07 |

As of June 13, 2013, the last reported sale price of our Common Stock, as reported by the OTCBB, was \$0.07.

### **Holders**

As of June 13, 2013, there were, respectively, approximately 122, 1, 1 and 5 holders of record of our Common Stock, Series C Preferred Stock, Series E Preferred Stock and Series G Preferred Stock.

### **Dividends**

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

Recent Sales of Unregistered Securities

During the quarter ended March 31, 2013, the Company issued an aggregate of 23,989,525 shares of Common Stock, with such shares constituting unregistered securities, consisting of 348,671 shares of Common Stock issued in lieu of cash in payment of interest expense due and owing on Preferred Share derivatives as of December 31, 2012; 1,662,352 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 6,032,000 shares of Common Stock issued pursuant to the exercise of warrants and 15,946,502 shares of Common Stock issued pursuant to the conversion of Series E Preferred Shares.

During April 2013, the Company issued an aggregate of 12,389,116 shares of Common Stock, with such shares constituting unregistered securities and consisting of 358,663 shares of Common Stock issued in lieu of cash in payment of interest expense due and owing on Preferred Share Derivatives as of March 31, 2013 and 12,030,453 shares of Common Stock issued pursuant to the conversion of Series G Preferred Shares.

On April 18, 2013, the Company filed a Certificate of Designations with the Nevada Secretary of State designating a new series of convertible preferred stock – Series G Preferred Stock (the “G Preferred Stock”) and setting forth various rights, preferences, restrictions and other matters related to the G Preferred Stock. 1,375 shares were designated as G Preferred Stock, the same number of the then outstanding shares of the Company's Series C Preferred Stock. On April 19, 2013, the holders of substantially all of the Company's Series C Preferred Stock exchanged all of their shares of Series C Preferred Stock for an identical number of shares of G Preferred Stock. The various rights, preferences, restrictions and other terms of the G Preferred Stock are substantially the same as those of the Series C Preferred Stock, except that the conversion price of the G Preferred was changed. The foregoing description of the Certificate of Designations is qualified in its entirety by reference to the full text of the Certificate of Designations attached as Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on April 22, 2013, with such filing and exhibit being herein incorporated by reference.

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, 2013.

| Plan Category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights<br>(a) | Weighted-average exercise price per share of outstanding options, warrants and rights<br>(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     | 3,939,000  | (1) \$ 1.15  | 6,016,000   |
| Equity compensation plans not approved by security holders | —  | —  | 6,389,684 (2)   |
| Total  | 3,939,000  | \$ 1.15  | 12,405,684  |

(1) Represents options issued under the 2004 Stock Option Plan

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

**2004 Stock Option Plan**

Our 2004 Stock Option Plan (the "*Stock Option Plan*") permits us 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.

Unless earlier terminated by the Board of Directors, the Stock Option Plan (but not outstanding options issued thereunder) terminates on March 1, 2014, after which no further awards may be granted under the Stock Option Plan. The Stock Option Plan is administered by the Board of Directors.

Recipients of options under the Stock Option Plan (“*Optionees*”) are selected by the Board of Directors. The Board of Directors determines the terms of each option grant including (1) the purchase price of shares subject to options, (2) the dates on which options become exercisable and (3) the expiration date of each option (which may not exceed ten years from the date of grant). The minimum per share purchase price of options granted under the Stock Option Plan for Incentive Stock Options is the fair market value (as defined in the Stock Option Plan) or for Nonqualified Options is 85% of fair market value of one share of the Common Stock on the date the option is granted.

Optionees 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. The purchase price upon the exercise of options may be paid in cash, by certified bank or cashier's check, by tendering stock held by the Optionee, as well as by cashless exercise either through the surrender of other shares subject to the option or through a broker. The total number of shares of Common Stock available under the Stock Option Plan, and the number of shares and per share exercise price under outstanding options will be appropriately adjusted in the event of any stock dividend, reorganization, merger or recapitalization or similar corporate event. Subject to limitations set forth in the Stock Option Plan, the terms of option agreements will be determined by the Board of Directors, and need not be uniform among Optionees.

The Board of Directors may at any time terminate the Stock Option Plan or from time to time make such modifications or amendments to the Stock Option Plan as it may deem advisable and the Board of Directors may adjust, reduce, cancel and re-grant an unexercised option if the fair market value declines below the exercise price except as may be required by any national stock exchange or national market association on which the Common Stock is then listed. In no event may the Board of Directors, without the approval of stockholders, amend the Stock Option Plan to increase the maximum number of shares of Common Stock for which options may be granted under the Stock Option Plan or change the class of persons eligible to receive options under the Stock Option Plan.

### **2009 Equity Incentive Plan**

Our 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 Equity Incentive Plan. The Equity Incentive Plan is administered and interpreted by our Compensation Committee (the "Compensation Committee"). Under the 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 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 Equity Incentive Plan, we also are permitted to offer stock awards ("Equity Incentive Plan Stock Awards") to eligible persons. The 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 price of shares sold pursuant to an 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 Equity Incentive Plan (“Equity Incentive Plan Stock Bonuses”), 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**

### **Going concern considerations**

As of March 31, 2013, the Company had a working capital deficit of \$2.8 million, losses from operations totaling \$1.6 million for Fiscal 2013, other income totaling \$2.7 million for Fiscal 2013 and a net income of \$1.5 million for Fiscal 2013. Please note that the Company's other income section of the profit and loss statement is 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, 2014.

In addition, the Company has received Notice of Default from the Trustee of the NJEDA Bonds as a result of the utilization of the debt service reserve being used to pay interest payments as well as the Company's failure to make scheduled principal payment. See "NJEDA Bonds" below.

As of March 31, 2013, we had cash reserves of \$0.4 million. The Lincoln Park Purchase Agreement and Treppel \$1,000,000 bridge revolving credit line (the "Treppel Credit Line") are expected to provide additional funds to permit us to continue development of our product pipeline. There can, however, be no assurances that the Company will receive a sufficient amount of the funds provided for under the Lincoln Park Purchase Agreement (please see "Purchase Agreement with Lincoln Park Capital" below). Even if we were to receive all amounts set forth in the Lincoln Park Purchase Agreement and the Treppel Credit Line, we still most likely will be required to seek additional capital in the future, and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all.

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

For Fiscal 2013, we sustained a negative cash flow from operations of approximately \$1.9 million, compared with a negative cash flow from operations of approximately \$0.4 million achieved during the prior fiscal year. Our working capital deficit at March 31, 2013 was approximately \$2.8 million compared with working capital deficit of approximately \$3.1 million at March 31, 2012. Please note that the working capital deficits include the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling \$3.4 million, is classified as a current liability due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please see "NJEDA Bonds" below.

Cash and cash equivalents at March 31, 2012, were approximately \$0.4 million, a decrease of approximately \$0.3 million from the approximately \$0.7 million at March 31, 2012.

As of March 31, 2013, our principal source of liquidity was approximately \$0.4 million of cash and cash equivalents. Additionally, we may have access to funds through the exercise of outstanding stock options and warrants. There can be no assurance that the exercise of outstanding warrants or options will generate or provide sufficient cash.

**Purchase Agreement with Lincoln Park Capital**

On April 19, 2013 (subsequent to the end of Fiscal 2013), the Company entered into a purchase agreement (the “Lincoln Park Purchase Agreement”), together with a registration rights agreement (the “Lincoln Park Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”).

Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, the Company has the right to sell to, and Lincoln Park is obligated to purchase up to \$10 million in shares of the Company’s common stock (“Common Stock”), subject to certain limitations, from time to time, over the 36-month period commencing on May 9, 2013, the date that the registration statement which the Company agreed to file with the SEC pursuant to the Lincoln Park Registration Rights Agreement was declared effective by the SEC. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase stock in amounts up to \$80,000 on any single business day so long as at least two business days have passed since the most recent purchase, increasing to up to \$500,000 per purchase, depending upon the closing sale price of the Common Stock. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 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 \$0.07 per share, subject to adjustment. The Company’s sales of shares of Common Stock to Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the Common Stock.

In connection with the Purchase Agreement, the Company issued to Lincoln Park 2,929,115 shares of Common Stock and is required to issue up to 2,929,115 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase the Company's shares under the Lincoln Park Purchase Agreement over the term of the agreement. Lincoln Park represented to the Company, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")), and the Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

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.

The foregoing descriptions of the Lincoln Park Purchase Agreement and the Lincoln Park Registration Rights Agreement are qualified in their entirety by reference to the full text of the Lincoln Park Purchase Agreement and the Lincoln Park Registration Rights Agreement, copies of which are attached as Exhibit 10.1 and Exhibit 10.2, respectively, to the Current Report on Form 8-K filed with the SEC on April 22, 2013, with such filing and each exhibit being incorporated herein in its entirety by reference. The representations, warranties and covenants contained in such agreements were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with execution of the agreements.

A Securities Registration on Form S-1 was filed with the SEC on April 25, 2013 and declared effective by the SEC on May 9, 2013 (the "Lincoln Park Registration Statement"), with such filing being herein incorporated by reference. The requisite Prospectus was filed with the SEC on May 10, 2013, with such filing being herein incorporated by reference.



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

On June 12, 2012 (the “Effective Date”), we entered into a bridge loan agreement (the “Loan Agreement”) with Jerry Treppel, our Chairman and CEO. Under the terms of the Loan Agreement, we have the right, in our sole discretion, to a line of credit (the “Credit Line”) in the maximum principal amount of up to \$500,000 at any one time. By amendment, the maximum principal amount was increased to \$1,000,000 in December 2012. Mr. Treppel provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount will be evidenced by a promissory note which shall mature on the earlier of (i) such date as we raise at least \$2,000,000 in gross proceeds from the sale of any of our equity securities or (ii) July 31, 2013, at which time the entire unpaid principal balance plus accrued interest thereon shall be due and payable in full. We may prepay any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Loan Agreement, we may borrow, repay, and reborrow under the Credit Line through maturity. Amounts borrowed under the Credit Line will bear interest at the rate of ten percent (10%) per annum. As of March 31, 2013, the principal balance owed under the Credit Line was \$600,000 with an additional \$13,151 in accrued interest also owed, in accordance with the terms and conditions of the Credit Line. For more detailed information, please see the Loan Agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on June 13, 2012, and the amendment thereto filed as an exhibit to our Current Report on Form 8-K filed with the SEC on December 10, 2012 which forms 8-K and exhibits are incorporated by reference herein.

### **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, 2013, all of the proceeds were utilized by the Company for such stated purposes.

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

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to \$14,132 for the fiscal year March 31, 2013.

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

The interest payments due on March 1<sup>st</sup> and September 1<sup>st</sup> of 2009, 2010 2011 and 2012, as well as the interest payment due on March 1<sup>st</sup> 2013, totaling \$1,033,075 for all nine payments, were paid from the debt service reserved held in the restricted cash account, due to the Company not having sufficient funds to make such payments when they were due.

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

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

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

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

Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on March 1, 2009, September 1, 2009, March 1, 2010, September 1, 2010, March 1, 2011, September 1, 2011, March 1, 2012, September 1, 2012 and March 1, 2013.

The Company does not expect to have sufficient available funds as of September 1, 2013, to make principal payments, totaling \$915,000, and consisting of \$185,000 due on September 1, 2013, plus scheduled principal payments totaling \$730,000, consisting of \$260,000 due on September 1, 2012, and not paid, plus \$245,000 due on September 1, 2011 and not paid plus \$225,000 due on September 1, 2010 and not paid.

The Company has received Notice of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the debt service reserve, and no payment of scheduled principal amounts. Resolution of the Company's default under the NJED Bonds will have a significant effect on our ability to operate in the future.



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

#### **Off-Balance Sheet Arrangements**

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

## **Effects of Inflation**

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

## **Results of Consolidated Operations:**

### **Year Ended March 31, 2013 as compared to the Year Ended March 31, 2012**

Our revenues for Fiscal 2013 were \$3.4 million an increase of \$1.0 million or approximately 40% from revenues for the comparable period of the prior year, and consisted of \$2.2 million in manufacturing fees, \$0.4 million in lab and product development fees and \$0.8 million in royalties and license fees. Revenues for Fiscal 2012 consisted of \$1.1 million in manufacturing fees, \$0.7 million in lab and product development fees, and \$0.6 million in royalties and license fees. Manufacturing fees increased by approximately 98% due to the launch of three new products during Fiscal 2013 and the continued growth of the two products launched during Fiscal 2012. Lab and product development fees decreased by approximately 42% due to decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees increased by approximately 24% due to the growth of the Phentermine and Hydromorphone product revenue streams and the related profit splits earned by the Company from TAGI Pharmaceuticals Inc.

Research and development costs for Fiscal 2013 were \$1.0 million, a decrease of \$0.8 million or approximately 44% from \$1.7 million of such costs for the comparable period of the prior year. The decrease was primarily due to the launch of five new products during a period beginning at the end of Fiscal 2012 and throughout Fiscal 2013. Prior to the launch of a new product, research and development costs are higher, due to the increased resources required to get a new product approved and introduced into the market. Subsequent to launch, these research and development costs are no longer incurred, as the new products are now revenue producing, commercial manufacturing operations. Research and development costs currently being incurred are related to the development of the Company's pipeline of products.

General and administrative expenses for Fiscal 2013 were \$1.5 million an increase of \$0.1 million or approximately 7% from \$1.4 million of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to the introduction of significant new, annual fees being charged to the Company by the US FDA during Fiscal 2013, substantial increases in the cost of providing health insurance benefits to our employees and increased legal fees related to funding activities.

Depreciation and amortization for Fiscal 2013 was \$0.1 million, a decrease of \$0.1 million or approximately 43%, from \$0.2 million for the comparable period of the prior year. The decrease was primarily due to increased utilization of manufacturing assets in commercial production resulting from the growing volumes of our products being sold in the market.

Non-cash compensation through the issuance of stock options and warrants for Fiscal 2013 was \$0.046 million, an increase of \$0.021 million, or approximately 88% from \$0.024 million for the comparable period of the prior year. The increase was due to the issuance of options to purchase an aggregate of 985,000 shares of Common Stock to various employees during Fiscal 2013 and the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for Fiscal 2013 was \$1.6 million, compared to a loss from operations of \$2.0 million for Fiscal 2012.

Other expenses for Fiscal 2013 were a net income of \$2.7 million, an increase in other net income of \$16.3 million from the net other expense of \$13.6 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 and outstanding warrants during Fiscal 2013 totaling \$3.5 million, as compared to a net derivative expense of \$12.7 million for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company's convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company's Common Stock as of March 31, 2013 was \$0.0761, as compared to a closing price of \$0.0900 as of March 31, 2012. Closing prices on the various dates on which shares of convertible preferred stock were converted to common stock ranged from \$0.08 to \$0.17 during the year ended March 31, 2013. 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, 2013.

As a result of the foregoing, our net income for Fiscal 2013 was \$1.5 million, compared to a net loss of \$15.1 million for Fiscal 2012.

### **Material Changes in Financial Condition**

Our working capital (total current assets less total current liabilities) deficiency was reduced to \$2.8 million as of March 31, 2013 from a working capital deficiency of \$3.1 million as of March 31, 2012, primarily due to the loss from operations sustained during Fiscal 2013 being financed by approximately \$1.0 million in cash warrant exercises (a capital financing), and the issuance of Series E Preferred Stock (a non-current derivative liability financing). Capital and non-current 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 \$1.9 million for Fiscal 2013, primarily due to our net income of \$1.5 million, offset by non-cash other income items totaling \$4.1 million included in the net income, combined with increases in accounts receivable and inventory of \$0.3 million and \$1.1 million respectively.

### **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.

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

None

**ITEM 9A CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

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 Securities Exchange Act of 1934 (the “Exchange Act”) as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective so that the information required to be disclosed by us in reports filed under the Exchange Act is (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.

Management has determined that, as of March 31, 2013, there were material weaknesses in both the design and effectiveness of our internal control over financial reporting. 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 deficiencies in our internal controls over financial reporting and disclosure controls and procedures are related to the lack of segregation of duties due to the size of our accounting department, which replaced an outside accounting firm and non-employee Chief Financial Officer on July 1, 2009, and limited enterprise resource planning systems. When our financial position improves, we intend to hire additional personnel and implement enterprise resource planning systems required to remedy such deficiencies.

**Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting has been designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America (“GAAP”).

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets; provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, that receipts and expenditures are being made only in accordance with authorization of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements or fraudulent actions. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm because we are not an accelerated filer or a large accelerated filer.

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on that assessment under those criteria, management has determined that, at March 31, 2013, there were material weaknesses in both the design and effectiveness of our internal control over financial reporting. 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 deficiencies in our internal controls over financial reporting and disclosure controls and procedures are related to the lack of segregation of duties due to the size of our accounting department, which replaced an outside accounting firm and non-employee Chief Financial Officer on July 1, 2009, and limited enterprise resource planning systems. When our financial position improves, we intend to hire additional personnel and implement enterprise resource planning systems required to remedy such deficiencies.

### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of Fiscal 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **ITEM 9B OTHER INFORMATION**

None

### **PART III**



**ITEM 10 DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The following sets forth biographical information about each of our directors and executive officers as of the date of this report:

| <b>Name</b>                | <b>Age</b> | <b>Position</b>                                  | <b>Director / Officer Since</b> |
|----------------------------|------------|--|---------------------------------|
| Jerry Treppel <sup>1</sup> | 59         | Chairman and Chief Executive Officer             | November 2008                   |
| Barry Dash, Ph. D.         | 81         | Director   | April 2005                      |
| Ashok G. Nigalaye, Ph.D.   | 61         | Chief Scientific Officer and Director            | June 2009 <sup>2</sup>          |
| Jeenarine Narine           | 62         | Director   | June 2009                       |
| Jeffrey Whitnell           | 57         | Director   | October 2009                    |
| Carter J. Ward             | 49         | Chief Financial Officer, Secretary and Treasurer | July 2009                       |

- (1) Mr. Treppel also served as Chairman of the Board since November 6, 2008 and CEO since September 15, 2009.
- (2) Dr. Nigalaye has served as a Director since June 2009 and as Chief Scientific Officer since September 2009.

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

Chris Dick served as the Company's President, Chief Operating Officer and a Director until he stepped down from these positions in May 2013.

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

Jerry Treppel has served as a Director since October 28, 2008, Chairman of the Board since November 6, 2008 and Chief Executive Officer since September 15, 2009. Mr. Treppel served as the managing member of Wheaten Capital Management LLC, a capital management company focusing on investment in the health care sector from 2003 to 2009. From October 2008 to March 2013, Mr. Treppel served as managing director of Ledgemont Capital Group LLC, a boutique merchant bank that provides access to capital and corporate advisory services to public and private companies. In April 2013, Mr. Treppel joined ArcLight Advisors LLC, a boutique investment bank specializing in health care, as a Managing Director. Over the past 20 years, Mr. Treppel was an equity research analyst focusing on the specialty pharmaceuticals and generic drug sectors at several investment banking firms including Banc of America Securities, Warburg Dillon Read LLC (now UBS), and Kidder, Peabody & Co. He previously served as a healthcare services analyst at various firms, including Merrill Lynch & Co. He also held administrative positions in the healthcare services industry early in his career. From 2003 to 2009, Mr. Treppel served as a member of the board of directors of Akorn, Incorporated (NASDAQ: AKRX), a specialty pharmaceutical company engaged in the development, manufacturing and marketing of branded and multi-source pharmaceutical products and vaccines. Mr. Treppel also served as the Chair of Akorn's Nominating and Corporate Governance Committee and as a member of its Audit Committee and Compensation Committee. Mr. Treppel holds a BA in Biology from Rutgers College in New Brunswick, N.J., an MHA in Health Administration from Washington University in St. Louis, Mo., and an MBA in Finance from New York University. Mr. Treppel has been a Chartered Financial Analyst (CFA) since 1988. Mr. Treppel's knowledge of the pharmaceutical industry as well as his education credentials and his experience as a member of the board of directors of Akorn, Incorporated led to the conclusion that he is qualified to serve as a director.

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

Chris Dick has served as Chief Operating Officer since October 2008, acting Chief Executive Officer from November 2008 to September 15, 2009, and President since April 2009; Director from October 20, 2008 to June 24, 2009, and since October 23, 2009. Mr. Dick began at Elite in November 2002 as Vice President of Business Development. Since March 2006, Mr. Dick has been Executive Vice President of Corporate Development. From 1999 to 2002, Mr. Dick served as Director of Business Development for Elan Drug Delivery, Inc. responsible for licensing and business development of Elan's portfolio of drug delivery technologies. From 1978 to 1999, he held various business and technical positions at FMC Corporation which included responsibility for business development and marketing for EnTec, a drug delivery business unit within FMC Corporation's Pharmaceutical Division and marketing for its pharmaceutical functional coatings product line. Mr. Dick holds an M.B.A. from the Stern School of Business, New York University, and a B.S. and M.S. in Chemical Engineering from Cornell University. Mr. Dick's experience and qualifications in the pharmaceutical industry, specifically in the area of business and product development, provides specific attributes and qualifications to serve as a director, President and COO for the Company. Mr. Dick stepped down from his positions as Director, President and Chief Operating Officer in March 2013.

Dr. Ashok G. Nigalaye has served as a Director since June 24, 2009, member of the Compensation Committee since October 23, 2009 and Chief Scientific Officer since September 15, 2009. Dr. Nigalaye was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since December 2010, Dr. Nigalaye has been the Chairman and Chief Executive Officer of Epic Pharma, LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement. From July 2008 to December 2010, Dr. Nigalaye served as Epic Pharma's President and Chief Executive Officer. From August 1993 to February 2008, Dr. Nigalaye served as Vice President of Scientific Affairs and Operations of Actavis Totowa LLC, a manufacturer of generic pharmaceuticals, where he was responsible for

directing and organizing company activities relating to pharmaceutical drug manufacturing, regulatory affairs and research and development. Dr. Nigalaye currently serves as a director of GTI Inc., a privately held company. Dr. Nigalaye holds a B.S. in Pharmacy from the University of Bombay, an M.S. in Industrial Pharmacy from Long Island University, and a Ph.D. in Industrial Pharmacy from St. John's University. Dr. Nigalaye is also a licensed pharmacist in the State of New York. Dr. Nigalaye's extensive education in pharmaceutical sciences and experience as a director and officer of pharmaceutical companies led to the conclusion that he is qualified to serve as a director.

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

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

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

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

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

## Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires our Officers, Directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended March 31, 2013, three of our Officers and Directors and two entities that had beneficial ownership of more than ten percent of a registered class of equity securities had not complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in Fiscal 2013. Specifically, as follows:

| <b>Name</b>          | <b>Late Filings</b> | <b>No. of Transactions</b> |
|----------------------|---------------------|----------------------------|
| Ashok Nigalaye       | 3                   | 4                          |
| Ram Potti            | 3                   | 4                          |
| Jeenarine Narine     | 3                   | 4                          |
| Epic Investments LLC | 3                   | 4                          |
| Epic Pharma LLC      | 3                   | 4                          |

## Committees of the Board

The Board of Directors has an Audit Committee, a Compensation Committee and a Nominating Committee.

### Audit Committee

During Fiscal 2013, the members of the Audit Committee were Jeffrey Whitnell (Chairman of the Audit Committee), Ram Potti and Dr. Barry Dash. We deem Messrs. Whitnell and Dash to be independent and Mr. Whitnell to be qualified as an audit committee financial expert. The Board of Directors has determined that Messrs. Whitnell and Dash are independent directors as (i) defined in Rule 10A-3(b)(1)(ii) under the Exchange Act and (ii) under Sections 803A(2) and 803B(2)(a) of the NYSE MKT LLC Company Guide (although our securities are not listed on the NYSE MKT LLCE or any other national exchange). Mr. Potti resigned as a Director and member of Audit Committee in December 2012. His seat on the Audit Committee has not been replaced. As of March 31, 2013, the Audit Committee accordingly consists of Mr. Whitnell and Dr. Dash.

### Nominating Committee

During Fiscal 2013, the members of the Nominating Committee were Ram Potti, Dr. Barry Dash and Jeenarine Narine. There were no material changes to the procedures by which security holders may recommend nominees to our Board of Directors since the filing of our last Annual Report on Form 10-K. Mr. Potti resigned as a Director and

member of Nominating Committee in December 2012. His seat on the Nominating Committee has not been replaced. As of March 31, 2013, the Nominating Committee accordingly consists of Mr. Narine and Dr. Dash.

#### Compensation Committee

During Fiscal 2013, the members of the Compensation Committee were Dr. Barry Dash (Chairman of the Nominating Committee), Dr. Ashok Nigalaye and Jeffrey Whitnell.

#### **Code of Conduct and Ethics**

At the first meeting of the Board of Directors following the annual meeting of stockholders held on June 22, 2004, the Board of Directors adopted a Code of Business Conduct and Ethics that is applicable to the Company's directors, officers and employees. A copy of the Code of Business Conduct and Ethics is available on our website at [www.elitepharma.com](http://www.elitepharma.com), under Investor Relations.



## **ITEM 11 EXECUTIVE COMPENSATION**

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

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

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

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

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

The Company formed the Compensation Committee in June 2007. Since the formation of the Compensation Committee all elements of the executives' compensation are determined by the Compensation Committee, which is comprised of a two independent non-employee directors, and one director who is also the Company's Chief Scientific Officer. However, the Compensation Committee's decisions concerning the compensation of the Company's Chief Executive Officer are subject to ratification by the independent directors of the Board of Directors. As of March 31, 2013, the members of the Compensation Committee were Barry Dash, Ashok Nigalaye and Jeffrey Whitnell. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants.

### **Named Executive Officers and Key Employees**

The named executive officers and key employees for the fiscal year ending March 31, 2013 are:

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

These individuals are referred to collectively in this report as the "Named Executive Officers".

Please note that Chris C. Dick stepped down from his positions as President and Chief Operating Officer in May 2013.

## **Our executive compensation program**

### **Overview**

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

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

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

### **Base Salary**

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

### **Bonuses**

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

### **Stock Options**

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

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

### **Retirement and Deferred Compensation Benefits**

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

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

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

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

## **Perquisites**

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

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

### **Jerry Treppel**

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

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

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

Under the First Treppel Agreement, Elite has also agreed to indemnify Mr. Treppel to the fullest extent permitted by law in accordance with the By-Laws of Elite against (a) reasonable expenses, including attorneys’ fees, incurred by him in connection with any threatened, pending, or completed civil, criminal, administrative, investigative, or arbitral action, suit, or proceeding (and any appeal therein) seeking to hold him liable for actions taken in his

capacity as Chairman of the Board, and (b) reasonable payments made by him in satisfaction of any judgment, money decree, fine (including assessment of excise tax with respect to an employee benefit plan), penalty or settlement for which he may have become liable in any such action, suit or proceeding, provided that any such expenses or payments are not the result of Mr. Treppel's gross negligence, willful misconduct or reckless actions.

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

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

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

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

#### **Chris C. Dick**

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

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

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

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

The Board of Directors of the Company increased Mr. Dick's base salary to \$205,000 retroactive to January 1, 2013. This \$5,000 increase to be paid in restricted shares of the Company's Common Stock. The Common Stock component

of Mr. Dick's compensation is to be computed on a quarterly and pro-rata basis, with the number of shares issued equal to the quotient of the quarterly amount due of \$7,500 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

Mr. Dick stepped down from his employment with the Company on May 24, 2013 and accordingly, the Dick Employment Agreement was terminated. Mr. Dick continues to consult for the Company.



### **Carter J. Ward**

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

The Board of Directors increased Mr. Ward’s base salary to \$155,000 retroactive to January 1, 2013. This \$5,000 increase to be paid by the issuance of restricted shares of Common Stock. The Common Stock component of Mr. Ward’s compensation is to be computed on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of \$7,500 divided by the average daily closing price of the Company’s Common Stock for the quarter just ended.

### **Hedging Policy**

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

### **Options Exercises and Stock Vested**

No options have been exercised by our Named Executive Officers during the 2013 Fiscal Year.

### **Pension Benefits**

We do not provide pension benefits to the Named Executive Officers

### **Nonqualified Deferred Compensation**

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

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

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

### Compensation of named executive officers

#### Summary Compensation Table

| Name<br>And<br>Principal<br>Position                                  | Fiscal<br>Year      | Salary<br>(\$)         | Bonus<br>(\$)      | Option<br>Awards<br>(\$) | All<br>Other<br>Compensation<br>(\$) | Total<br>(\$)          |
|---|---------------------|------------------------|--------------------|--------------------------|--------------------------------------|------------------------|
| Jerry Treppel<br>Chairman of the Board and<br>Chief Executive Officer | 2013 <sup>(1)</sup> | —                      | —                  | —                        | 30,000                               | <sup>(2)</sup> 30,000  |
|   | 2012 <sup>(1)</sup> | —                      | —                  | —                        | 30,000                               | <sup>(2)</sup> 30,000  |
| Chris Dick<br>President and<br>Chief Operating Officer                | 2013 <sup>(1)</sup> | 201,250 <sup>(3)</sup> | —                  | —                        | 8,400                                | <sup>(4)</sup> 209,650 |
|   | 2012 <sup>(1)</sup> | 200,000 <sup>(3)</sup> | —                  | —                        | 8,400                                | <sup>(4)</sup> 208,400 |
| Carter J. Ward<br>Chief Financial Officer<br>Secretary and Treasurer  | 2013 <sup>(1)</sup> | 151,250 <sup>(5)</sup> | —                  | —                        | —                                    | 151,250                |
|   | 2011 <sup>(1)</sup> | 150,000 <sup>(5)</sup> | 600 <sup>(6)</sup> | —                        | —                                    | 150,600                |

- (1) Represents the fiscal years ended March 31, 2013 and 2012, respectively.

Represents compensation due to Mr. Treppel for his service as Chairman of the Board of Directors. Mr. Treppel (2) receives no salary or additional compensation for his service as Chief Executive Officer. Compensation due to Mr. Treppel is paid via the issuance of Common Stock, pursuant to the Company's Director compensation policy.

A total of 284,662 shares of Common Stock were issued to Mr. Treppel in payment of compensation due to him for Fiscal 2012. A total of 202,998 shares of Common Stock were issued to, and 90,200 shares of Common Stock are due and owing to, Mr. Treppel in payment of compensation due to him for Fiscal 2013.

Represents total salaries due to Mr. Dick pursuant to the Dick Employment. Of the total salary amount, \$175,000 was paid in cash as salary in accordance with the Company's payroll practices, and \$25,000 annually is to be paid via the issuance of Common Shares in lieu of cash through December 31, 2012 and \$30,000 annually is to be paid (3) via the issuance of Common Shares in lieu of cash since January 1, 2013. A total of 237,220 shares of Common Stock were issued to Mr. Dick in payment of salaries due to him for Fiscal 2012. A total of 169,165 shares of Common Stock were issued to, and 90,200 shares of Common Stock are due and owing to, Mr. Dick in payment of salaries due to him for Fiscal 2013.

- (4) Represents amounts paid for auto allowance

Represents total salaries due to Mr. Ward pursuant to the Ward Employment. Of the total salary amount, \$125,000 was paid in cash as salary in accordance with the Company's payroll practices, and \$25,000 is to be paid annually via the issuance of Common Shares in lieu of cash through December 31, 2012 and \$30,000 annually is to be paid (5) via the issuance of Common Shares in lieu of cash since January 1, 2013. A total of 237,220 shares of Common Stock were issued to Mr. Ward in payment of salaries due to him for Fiscal 2012. A total of 169,165 shares of Common Stock were issued to, and 90,200 shares of Common Stock are due and owing to, Mr. Ward in payment of salaries due to him for Fiscal 2013.

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

**Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information concerning stock option awards held by Named Executive Officers as of March 31, 2013:

| Name                  | Number of securities underlying unexercised options Exercisable (#) |      | Number of securities underlying unexercised options Unexercisable (#) | Equity Incentive Plan Awards: Number of securities underlying unexercised unearned options (#) | Options Exercise Price (\$) | Option Expiration Date |
|-----------------------|---|------|---|--|-----------------------------|------------------------|
| <u>Chris Dick</u>     | 10,000  | (1)  | —   | —  | 2.21                        | 6/13/2013              |
|                       | 10,000  | (1)  | —   | —  | 2.21                        | 6/13/2013              |
|                       | 10,000  | (1)  | —   | —  | 2.21                        | 6/13/2013              |
|                       | 40,000  | (2)  | —   | —  | 2.80                        | 7/14/2015              |
|                       | 250,000   | (3)  | —   | —  | 2.25                        | 11/13/2016             |
|                       | —   |      | —   | 150,000  | (4) 2.25                    | 11/13/2016             |
|                       | —   |      | —   | 150,000  | (4) 2.25                    | 11/13/2016             |
|                       | —   |      | —   | 200,000  | (6) 2.25                    | 11/13/2016             |
|                       | 200,000   | (7)  | —   | —  | 0.10                        | 1/17/2020              |
|                       |   |      | —   | 150,000  | (8) 0.12                    | 6/19/2022              |
| <u>Jerry Treppel</u>  | 60,000  | (9)  | —   | —  | 0.06                        | 12/1/2018              |
|                       | 60,000  | (10) | —   | —  | 0.06                        | 12/1/2018              |
|                       | 60,000  | (11) | —   | —  | 0.06                        | 12/1/2018              |
| <u>Carter J. Ward</u> | 200,000   | (7)  | —   | —  | 0.10                        | 1/17/2020              |
|                       |   |      | —   | 150,000  | (8) 0.12                    | 6/19/2022              |

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

(2) Options vested on July 14, 2005.

(3) Options vested on November 3, 2006.

(4)

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

These options vest as follows: upon the commencement of the first Phase III clinical trial relating to the first (6) “Non-Generic Opioid Product” developed by the Company as to 125,000 options and relating to the second “Non-Generic Opioid Product” developed by the Company as to 75,000 options.

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

(8) Total of 200,000 options granted with such options vesting in annual increments on June 19, 2013, 2014 and 2015, with each increment equal to one-third of the total options granted.

(9) Options vested on December 1, 2009

(10) Options vested on December 1, 2010

(11)

Options vest on December 1, 2011

**DIRECTOR COMPENSATION**

The following table sets forth information concerning director compensation for the year ended March 31, 2013:

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

Represents directors fees earned during the quarters ended June 30, 2012, September 30, 2012 and December 31, (1)2012. Each Director received 135,332 shares of Common Stock in payment of these director fees, pursuant to the Company's policy regarding payment of Directors' fees.

(2) Represents directors fees earned during the quarter ended March 31, 2013 for which 60,133 shares of Common Stock is due and owing to each Director.

\*

Mr. Potti resigned as a director in December 2012.

## **Director Fee Compensation**

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

## **Director Equity Compensation**

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

Members of the Board of Directors during the fiscal years ended March 31, 2013 and March 31, 2012 did not receive any options or equity compensation for serving as directors other than shares of Common Stock earned in lieu of cash in relation to Director and Chairman fees due.

## **Other**

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

## **ITEM 12 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information, as of June 13, 2013 (except as otherwise indicated), regarding beneficial ownership of our Common Stock by (i) each person who is known by us to own beneficially more than 5% of the Common Stock, (ii) each of our directors and nominees for director, (iii) each of the Named Executive Officers (as defined below) and (iv) all our directors and executive officers as a group. As of June 13, 2013, we had 394,597,274 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 1,600 shares of Series E Preferred Stock outstanding as of June 13, 2013 are entitled to vote, on an as-converted basis, with the Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting). As of June 13, 2013 there were 24 shares of Series C Preferred Stock outstanding and 1,085 shares of Series G Preferred Stock outstanding, with all such shares of Series C and Series G Preferred Stock being nonvoting.

As of June 13, 2013, none of the individuals listed below beneficially owned any shares of Series G Preferred Stock or Series E Preferred Stock, except for the following (as further described in the footnotes to the table): (a) 1,600 shares of Series E Preferred Stock were beneficially owned by Messrs. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti.



As used in the table below and elsewhere in this annual report on Form 10-K, the term beneficial ownership with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the 60 days immediately following June 13, 2013. Except as otherwise indicated, the stockholders listed in the table have sole voting and investment powers with respect to the shares indicated.

| Name and Address<br>Of<br>Beneficial Owner of Common Stock               | Amount<br>and<br>Nature of<br>Beneficial<br>Ownership*** |     | Percent (%)<br>of Class<br>Beneficially<br>Owned |   |
|--|--|-----|--|---|
| Barry Dash, Director   | 985,972  | (1) | **   |   |
| Jerry Treppel, Chairman of the Board and Chief Executive Officer         | 3,526,599  | (2) | **   |   |
| Ashok G. Nigalaye, Chief Scientific Officer and Director *               | 167,800,280  | (3) | 27   | % |
| Jeenarine Narine, Director *   | 158,702,719  | (3) | 26   | % |
| Ram Potti * (8)  | 159,245,478  | (3) | 26   | % |
| Jeffrey Whitnell, Director   | 817,426  | (4) | **   |   |
| Carter J. Ward, Chief Financial Officer                                  | 2,907,304  | (5) | **   |   |
| Chris Dick (9)   | 1,618,223  | (6) | **   |   |
| Epic Investments LLC<br>227-15 North Conduit Ave.<br>Laurelton, NY 11413 | 147,927,298  | (3) | 24   | % |
| Epic Pharma LLC<br>227-15 North Conduit Ave.<br>Laurelton, NY 11413      | 147,927,298  | (3) | 24   | % |
| All Directors and Officers as a group                                    | 188,431,225  | (7) | 30   | % |

\*The address is c/o Epic Investments LLC, 227-15 North Conduit Ave., Laurelton, NY 11413.

\*\*Less than 1%

\*\*\* As of June 13, 2013

(1)

Includes vested options to purchase 120,000 shares of Common Stock, warrants to purchase 12,434 shares of Common Stock, 794,405 shares of Common Stock and 60,133 shares of Common Stock which is due and owing to Dr. Dash as of March 31, 2013 for Director's fees earned by Dr. Dash for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

(2) Includes 2,131,399 shares of Common Stock, warrants to purchase up to 1,125,000 shares of Common Stock, options to purchase up to 180,000 shares of Common Stock and 90,200 shares of Common Stock which is due and owing to Mr. Treppel as of March 31, 2013 for Chairman's fees earned by Mr. Treppel for the quarter then ended, pursuant to the Company's policy regarding payment of the Chairman's fee.

(3) Includes 1,600 shares of Series E Preferred Stock convertible into 65,737,420 shares of Common Stock, 9,008,212 shares of Common Stock and warrants to purchase up to 73,181,666 shares of Common Stock held by Epic Investments, LLC, a Delaware limited liability company. Messrs. Nigalaye, Narine and Potti are executive officers and equity owners of Epic Pharma, LLC, a Delaware limited liability company, and Epic Investments, LLC, a Delaware limited liability company. Epic Pharma, LLC is an equity owner of Epic Investments, LLC. Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti share voting and investment control over, and are indirect beneficial owners of, the shares. The interest of Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti in the shares is limited, and each disclaims beneficial ownership of such shares except to the extent of its pecuniary interest in Epic Investments, LLC. Please note that the number of shares of Common Stock held by Epic Investments, LLC was compiled from Statements of Changes in Beneficial Ownership on Form 4 that were filed by Epic Investments LLC since June of 2009.

In addition to beneficial interests related to Epic Investments, Dr. Nigalaye owns 12,055,183 shares of common stock, warrants to purchase up to 7,757,666 shares of common stock, and 60,133 shares of Common Stock which is due and owing to Dr. Nigalaye as of March 31, 2013 for Director's fees earned by Dr. Nigalaye for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

In addition to beneficial interests related to Epic Investments, Mr. Narine owns 5,957,622 shares of common stock, warrants to purchase up to 4,757,666 shares of common stock and 60,133 shares of Common Stock which is due and owing to Mr. Narine as of March 31, 2013 for Director's fees earned by Mr. Narine for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

In addition to beneficial interests related to Epic Investments, Mr. Potti owns 6,227,180 shares of common stock and warrants to purchase up to 5,091,000 shares of common stock.

(4) Includes 757,293 shares of Common Stock and 60,133 shares of Common Stock which is due and owing to Mr. Whitnell as of March 31, 2013 for Director's fees earned by Mr. Whitnell for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

(5) Includes vested options to purchase 250,000 shares of Common Stock, warrants to purchase 666,667 shares of Common Stock, 1,900,437 shares of Common Stock and 90,200 shares of Common Stock due and owing to Mr. Ward as of March 31, 2013, for salaries earned for the quarter then ended pursuant to the employment agreement between the Company and Mr. Ward dated November 13, 2009. In addition, Mr. Ward has been granted options to purchase 100,000 shares of Common Stock under the Company's 2004 Equity Incentive Plan which were not vested as of June 13, 2013. These options to purchase 100,000 shares of Common Stock are not included as part of Mr. Ward's beneficial ownership as they do not vest within 60 days. These 100,000 non-vested options, having an exercise price of \$0.12 per share, are scheduled to vest in increments of 50,000 shares each on June 19, 2014 and

2015.

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(6) Includes vested options to purchase 490,000 shares of Common Stock, 971,423 shares of Common Stock, and 156,800 shares of Common Stock due and owing to Mr. Dick as of June 13, 2013 for salaries earned for the period beginning on January 1, 2013 through May 24, 2013, the date Mr. Dick stepped down from his positions with the Company.

(7) Includes 1,600 shares of Series E Preferred Stock convertible into 65,737,420 shares of Common Stock, warrants to purchase up to 87,501,099 shares of Common Stock, and vested options to purchase up to 1,040,000 shares of Common Stock, 33,574,974 shares of Common Stock and 577,732 shares of Common Stock which are due and owing as of June 13, 2013, to the Company's Chairman, Directors and Chief Financial Officer in payment of Chairman's Fees, Directors Fees or salary, as appropriate for the quarter ended March 31, 2013 for those directors that were active as of June 13, 2013 or for the period beginning on January 1, 2013 and ending May 24, 2013 with regards to Mr. Dick, in accordance with the Company's policy regarding payment of Chairman's fees, Director fees or employment contract with the Chief Financial Officer.

(8) Mr. Potti was previously a Director of the Company, resigning in December 2012.

(9) Mr. Dick was the President, Chief Operating Officer and a Director of the Company until May 2013.

## ITEM 13 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

### Certain Related Person Transactions

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

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC, as disclosed in Item 1. "Business: Epic Strategic Alliance Agreement" in Part I and Item 10. "Directors, Executive Officers and Corporate Governance" and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which disclosures are incorporated herein by reference. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, each were elected as members of our Board of Directors, effective June 24, 2009, as the three directors that Epic is entitled to designate for appointment to the Board pursuant to the terms of the Epic Strategic Alliance Agreement. Messrs. Nigalaye, Narine and Potti are also officers of Epic Pharma, LLC, in the following capacities:

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

The Strategic Alliance Agreement expired on June 4, 2012.

On December 31, 2012, Mr. Potti resigned as a Director of the Company. His seat on the Board of Directors was not filled.

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

With regards to synergies related to raw materials usage, the strategic alliance allowed the Company to purchase such raw materials from Epic, at the Epic acquisition cost, without markup. In all cases, the acquisition cost of Epic was lower than those costs available to the Company, mainly as a result of efficiencies of scale generated by significantly larger volumes purchased by Epic during the course of their normal operations. During the fiscal years ended March 31, 2013 and March 31, 2012, an aggregate amount of \$71,480 and \$15,552, respectively, in such materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma's acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC's acquisition cost.

With regards to synergies related to regulatory and operational resources, the strategic alliance allowed the Company to utilize Epic's substantial resources and technical competencies on an "as needed" basis at a cost equal to Epic's actual cost for only the resources utilized by the Company. Without such access to Epic's resources, the Company would have to invest significant amounts in human resources and fixed assets as well as incur substantial costs with third party providers to provide the same resources provided by Epic and necessary for the operations of the Company.

During the fiscal years ended March 31, 2013 and March 31, 2012, an aggregate amount of \$31,354 and \$133,003, respectively, was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company.

During the fiscal years ended March 31, 2013 and March 31, 2012, the Company incurred a total of \$362,347 and \$275,768, respectively in contract manufacturing and/or packaging costs for the Company's Phentermine, Hydromorphone, Methadone and Immediate Release Lodrane products.

During the fiscal years ended March 31, 2013 and 2012, equipment purchases from Epic totaled \$-0- and \$52,000, respectively.

Total purchases from Epic by the Company during the fiscal years ended March 31, 2013 and 2012 were \$465,181 and \$476,323, respectively.

***Transaction with Jerry Treppel***

On June 12, 2012 (the “Effective Date”), we entered into a bridge loan agreement (the “Loan Agreement”) with Jerry Treppel, our Chairman and CEO. Under the terms of the Loan Agreement, we have the right, in our sole discretion, to a line of credit (the “Credit Line”) in the maximum principal amount of up to \$500,000 at any one time. By amendment, the maximum principal amount was increased to \$1,000,000 in December 2012. Mr. Treppel provided the Credit Line for the purpose of supporting the acceleration of our product development activities. The outstanding amount will be evidenced by a promissory note which shall mature on the earlier of (i) such date as we raise at least \$2,000,000 in gross proceeds from the sale of any of our equity securities or (ii) July 31, 2013, at which time the entire unpaid principal balance plus accrued interest thereon shall be due and payable in full. We may prepay any amounts owed without penalty. Any such prepayments shall first be attributable to interest due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Loan Agreement, we may borrow, repay, and reborrow under the Credit Line through maturity. Amounts borrowed under the Credit Line will bear interest at the rate of ten percent (10%) per annum. As of March 31, 2013, the principal balance owed under the Credit Line was \$600,000 with an additional \$13,151 in accrued interest also owed, in accordance with the terms and conditions of the Credit Line. For more detailed information, please see the Loan Agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on June 13, 2012, and the amendment thereto filed as an exhibit to our Current Report on Form 8-K filed with the SEC on December 10, 2012 which forms 8-K and exhibits are incorporated by reference herein.



## Director Independence

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

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

## ITEM 14 PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Company's independent registered public accounting firm is Demetrius Berkower LLC ("*Demetrius*").

The following table presents fees, including reimbursements for expenses, for professional audit services rendered by Demetrius for the audits of our financial statements and interim reviews of our quarterly financial statements for Fiscal 2013 and Fiscal 2012.

|                    | Fiscal 2013 | Fiscal 2012 |
|--------------------|-------------|-------------|
| Audit Fees         | 76,000      | 76,250      |
| Audit-Related Fees | —           | 3,000       |
| Tax Fees           | —           | —           |
| All Other Fees     | 1,150       | 475         |

### Audit Fees

Represents fees for professional services provided for the audit of our annual financial statements, services that are performed to comply with generally accepted auditing standards, and review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

**Audit-Related Fees**

Represents the fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements.

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The Audit Committee has determined that Demetrius' rendering of these audit-related services was compatible with maintaining auditor's independence. The Board of Directors considered Demetrius to be well qualified to serve as our independent public accountants. The Committee also pre-approved the charges for services performed in Fiscal 2013 and 2012.

The Audit Committee pre-approves all auditing services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the "de minimus" provisions of Section 10A (i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES.**

(a) The following are filed as part of this Annual Report on Form 10-K

(1) The financial statements and schedules required to be filed by Item 8 of this Annual Report on Form 10-K and listed in the Index to Consolidated Financial Statements.

(2) The Exhibits required by Item 601 of Regulation S-K and listed below in the “Index to Exhibits required by Item 601 of Regulation S-K.”

(b) The Exhibits are filed with or incorporated by reference in this Annual Report on Form 10-K

(c) None

**Index to Exhibits required by Item 601 of Regulation S-K.**

**Exhibit**

**Description**

- | <b>No.</b> | <b>Description</b>  |
|------------|---|
| 2.1        | Agreement and Plan of Merger between Elite Pharmaceuticals, Inc., a Delaware corporation (“Elite-Delaware”) and Elite Pharmaceuticals, Inc., a Nevada corporation (“Elite-Nevada”), incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.   |
| 3.1(a)     | Articles of Incorporation of Elite-Nevada, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.  |
| 3.1(b)     | Certificate of Incorporation of the Company, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the “Form S-4”), (b) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company’s Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008.* |
| 3.1(c)     |   |

Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.\*

- 3.1(d) Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.\*

- 3.1(e) Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.\*

- 3.1(f) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(g) Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(h) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.\*
- 3.1(i) Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*
- 3.1(j) Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*
- 3.1(k) Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.\*
- 3.1(l) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 3.1(m) Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*
- 3.1(n) Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated June 24, 2010 and filed with the SEC on July 1, 2010.\*
- 3.1(o) Certificate of Designations of the Series G Convertible Preferred Stock as filed with the Secretary of State of the State of Nevada on April 18, 2013, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013 .
- 3.2(a) By-Laws of Elite-Nevada, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on January 9, 2012.

- 3.2(b) By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").\*
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.\*
- 4.2 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.3 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.4 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.5 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.6 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.\*
- 4.7 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.\*
- 4.8 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference as Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*
- 4.9 Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.\*
- 4.10 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the "Series C Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*

- 4.11 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.\*
- 4.12 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.13 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the "Series D Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.14 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.\*
- 4.15 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.16 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.\*
- 4.17 Form of specimen certificate for Series G Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
- 10.1 2004 Employee Stock Option Plan approved by stockholders on June 22, 2004, incorporated by reference to Exhibit A to the Proxy Statement filed on Schedule 14A with respect to the Annual Meeting of Stockholders held on June 22, 2004.
- 10.2 Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
- 10.3 Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
- 10.4 Product Development and Commercialization Agreement, dated as of June 21, 2005, between the Company and IntelliPharmaceuticals, Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated June 21, 2005 and originally filed with the SEC on June 27, 2005, as amended on the Current Report on Form 8-K/A filed September 7, 2005, as further amended by the Current Report on Form 8-K/A filed December 7, 2005 (Confidential Treatment granted with respect to portions of the Agreement).



- 10.5 Agreement, dated December 12, 2005, by and among the Company, Elite Labs, and IntelliPharmaCeutics Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated December 12, 2005, and originally filed with the SEC on December 16, 2005, as amended by the Current Report on Form 8-K/A filed March 7, 2006 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.6 Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority (“NJEDA”) and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.7 Series A Note in the aggregate principal amount of \$3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.8 Series B Note in the aggregate principal amount of \$495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.9 Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.10 Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.11 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.12 Form of Registration Rights Agreement, between the Registrant and signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.13 Form of Placement Agent Agreement, between the Registrant and Indigo Securities, LLC, incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated March 15, 2006, and filed with the SEC on March 16, 2006.
- 10.14 Financial Advisory Agreement between the Registrant and Indigo Ventures LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated July 12, 2006 and filed with the SEC on July 18, 2006.
- 10.15 Seconded Amended and Restated Employment Agreement between the Registrant and Bernard Berk, incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.

10.16 Employment Agreement between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.

10.17 Employment Agreement between the Registrant and Chris Dick, incorporated by reference as Exhibit 10.3 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.

10.18 Product Collaboration Agreement between the Registrant and ThePharmaNetwork LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated November 10, 2006 and filed with the SEC on November 15, 2006. (Confidential Treatment granted with respect to portions of the Agreement).

10.19 Strategic Alliance Agreement among the Registrant, VGS Pharma (“VGS”) and Veerappan S. Subramanian (“VS”), incorporated by reference as Exhibit 10(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.20 Advisory Agreement, between the Registrant and VS, incorporated by reference as Exhibit 10(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.21 Registration Rights Agreement between the Registrant, VGS and VS, incorporated by reference as Exhibit 10(c) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.22 Employment Agreement between Novel Laboratories Inc. (“Novel”) and VS, incorporated by reference as Exhibit 10(d) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.23 Stockholders’ Agreement between Registrant, VGS, VS and Novel, incorporated by reference as Exhibit 10(e) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

10.24 Amended and Restated Employment Agreement, between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated February 9, 2007 and filed with the SEC on February 14, 2007.

10.25 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.26 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.27 Form of Placement Agent Agreement, between the Company and Oppenheimer & Company, Inc., incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.

10.28 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.29 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.

10.30 Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.

10.31 Consulting Agreement, dated as of September 4, 2007, between the Registrant, Bridge Ventures, Inc. and Saggi Capital, Inc., incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.

10.32 Employment Agreement, dated as of January 3, 2008, by and between the Registrant and Dr. Stuart Apfel, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated January 3, 2008 and filed with the SEC on January 9, 2008.

10.33 Form of Securities Purchase Agreement, between the Company and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.34 Form of Placement Agent Agreement, between the Company, ROTH Capital Partners, LLC and Boenning & Scattergood, Inc., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.

10.35 Separation Agreement and General Release of Claims, dated as of October 20, 2008, by and between the Company and Stuart Apfel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

10.36 Consulting Agreement, dated as of October 20, 2008, by and between the Company and Paralex Clinical Research, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

10.37 Separation Agreement and General Release of Claims, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.

10.38 Consulting Agreement, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.

- 10.39 Separation Agreement and General Release of Claims, dated as of November 5, 2008, by and between the Company and Bernard J. Berk, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 6, 2008 and filed with the SEC on November 6, 2008.
- 10.40 Amendment to Employment Agreement, dated as of November 10, 2008, by and between the Company and Chris Dick, incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ended September 30, 2008 and filed with the SEC on November 14, 2008.
- 10.41 Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
- 10.42 Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.
- 10.43 Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.
- 10.44 Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 10.45 Employment Agreement, dated as of July 1, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K dated July 1, 2009 and filed with the SEC on July 8, 2009.
- 10.46 Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.
- 10.47 Employment Agreement, dated as of November 13, 2009, by and between the Company and Chris Dick, , incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.48 Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.49 Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.

10.50 Stipulation of Settlement and Release, dated as of June 25, 2010, by and among the Company, Midsummer Investment, Ltd., Bushido Capital Master Fund, LP, BCMF Trustees, LLC, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010

10.51 Amendment Agreement, dated as of June 25, 2010, by and among the Company, and the investors signatory thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010

10.52 Amendment Agreement, dated as of June 2010, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated June 25, 2010 and filed with the SEC on July 1, 2010

10.53 Asset Purchase Agreement dated as of May 18, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010.

10.54 Asset Purchase Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company, incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

10.55 Master Development and License Agreement, dated as of August 27, 2010, by and among Mikah Pharma LLC and the Company incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

10.56 Purchase Agreement, dated as of September 10, 2010, by and among Epic Pharma LLC and the Company, incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

10.57 License Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.8 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).

- 10.58 Manufacturing and Supply Agreement, dated as of September 10, 2010, by and among Precision Dose Inc. and the Company, incorporated by reference to Exhibit 10.9 to the Quarterly Report on Form 10-Q, for the period ended September 30, 2010 and filed with the SEC on November 15, 2010 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.59 Product Development Agreement between the Company and Hi-Tech Pharmacal Co., Inc. dated as of January 4, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated January 4, 2011 and filed with the SEC on January 10, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.60 Settlement Agreement between the Company and ThePharmaNetwork, LLC, dated as of March 11, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 11, 2011 and filed with the SEC on March 17, 2011.
- 10.61 Manufacturing & Supply Agreement between the Company and Mikah Pharma LLC, dated as of June 1, 2011, incorporated by reference to Exhibit 10.70 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.62 Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.63 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount Mikah Pharma LLC and the Company (Confidential Treatment granted with respect to portions of the Agreement), incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for three and nine months ended December 31, 2011.
- 10.64 Settlement Agreement between the Company and ThePharmaNetwork, LLC, dated as of March 11, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 11, 2011 and filed with the SEC on March 17, 2011.
- 10.65 Securities Purchase Agreement with Socius dated December 30, 2011, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
- 10.66 Amendment to Agreement with Socius dated February 28, 2012, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K/A filed with the SEC February 29, 2012.
- 10.67 Manufacturing & Supply Agreement between the Company and Mikah Pharma LLC, dated as of June 1, 2011, incorporated by reference to Exhibit 10.70 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).

- 10.68 Manufacturing & Supply Agreement between the Company and ThePharmaNetwork, LLC, dated as of June 23, 2011, incorporated by reference to Exhibit 10.71 to the Annual Report on Form 10-K, for the period ended March, 31, 2011 and filed with the SEC on June 29, 2011 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.69 Amendment, dated as of November 1, 2011, to the Master Development and License Agreement, dated as of August 27, 2010, by and amount Mikah Pharma LLC and the Company (Confidential Treatment granted with respect to portions of the Agreement), incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q for three and nine months ended December 31, 2011.
- 10.70 Treppel \$500,000 Bridge Loan Agreement dated June 12, 2012, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on June 13, 2012.
- 10.71 December 5, 2012 amendment to the Treppel Bridge Loan Agreement incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on December 10, 2012.
- 10.72 Development And License Agreement between the Company and a Hong Kong-based client dated March 16, 2012 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.73 Letter Agreement between the Company and ThePharmaNetwork LLC, dated September 21, 2012 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.74 Purchase Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013 , incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
- 10.75 Registration Rights Agreement between the Company and Lincoln Park Capital LLC dated April 19, 2013 , incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 18, 2013 and filed with the SEC on April 22, 2013.
- 21 Subsidiaries of the Company.\*\*
- 23 Consent of Demetrius & Company LLC, Independent Registered Public Accounting Firm\*\*
- 101\*\*\* The following materials from Elite Pharmaceuticals' Annual Report on Form 10-K, related to the audited financial statements as and for the fiscal years ended March 31, 2013 and 2012, formatted in eXtensible Business Reporting Language ("XBRL"): (i) the Consolidated Statements of Income; (ii) the Consolidated Balance Sheets; (iii) the Consolidated Statements of Cash Flows; and (iv) Notes to Consolidated Financial Statements.\*\*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*\*
- 32.1\*\*\*\* Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*\*





32.2\*\*\*\* Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002\*\*

\* On January 5, 2011, the Company changed its domicile from Delaware to Nevada. All corporate documents from Delaware have been superseded by Nevada corporate documents filed or incorporated by reference herein. All outstanding Delaware securities certificates are now outstanding Nevada securities certificates.

\*\* Filed herewith.

\*\*\* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Act of 1934 and otherwise are not subject to liability.

\*\*\*\* These exhibits are furnished with this Annual Report on Form 10-K and are not deemed filed with the Securities and Exchange Commission and are not incorporated by reference in any filing of Elite Pharmaceuticals, Inc. under the Securities Act or the Securities Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filings.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELITE  
PHARMACEUTICALS,  
INC.

By: /s/ Jerry Treppel  
Jerry Treppel  
Chief Executive Officer

Dated: June 21, 2013

By: /s/ Carter J. Ward  
Carter J. Ward  
Chief Financial Officer

Dated: June 21, 2013

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <b>Signature</b>     | <b>Title</b>                                  | <b>Date</b>   |
|----------------------|---|---------------|
| /s/ Jerry Treppel    | Chairman, Chief Executive Officer             | June 21, 2013 |
| /s/ Carter J. Ward   | Chief Financial Officer, Treasurer, Secretary | June 21, 2013 |
| /s/ Barry Dash       | Director                                      | June 21, 2013 |
| /s/ Jeenarine Narine | Director                                      | June 21, 2013 |
| /s/ Ashok Nigalaye   | Director                                      | June 21, 2013 |
| /s/ Jeffrey Whitnell | Director                                      | June 21, 2013 |

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

**FOR THE YEARS ENDED MARCH 31, 2013 AND 2012**

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## REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To The Board of Directors and

Shareholders of Elite Pharmaceuticals, Inc. & Subsidiaries

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiaries (“the Company”) as of March 31, 2013 and 2012 and the related consolidated statements of operations, stockholders' deficit and cash flows for each of the years in the two-year period ended March 31, 2013. The Company’s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2013 and 2012 and the results of their operations and their cash flows for each of the years in the two year period ended March 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

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

/s/Demetrius Berkower LLC

Wayne, New Jersey

June 21, 2013

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****March 31, 2013 and 2012**

|  | 2013                     | 2012                     |
|--|--------------------------|--------------------------|
| <b>ASSETS</b>  |                          |                          |
| <b>CURRENT ASSETS</b>  |                          |                          |
| Cash and cash equivalents  | \$ 369,023               | \$ 668,407               |
| Accounts receivable (net of allowance for doubtful accounts of -0- and -0- respectively)                         | 665,154                  | 396,847                  |
| Inventories (net of reserve of \$93,338)   | 1,358,146                | 304,882                  |
| Prepaid expenses and other current assets  | 151,051                  | 127,704                  |
| <br>Total Current Assets   | <br>2,543,374            | <br>1,497,840            |
| <br><u>PROPERTY AND EQUIPMENT</u> , net of accumulated depreciation of \$5,068,522 and \$4,659,670, respectively | <br>4,028,943            | <br>4,284,786            |
| <br><u>INTANGIBLE ASSETS</u> – net of accumulated amortization of \$-0- and \$-0-, respectively                  | <br>694,426              | <br>642,848              |
| <br><b>OTHER ASSETS</b>  |                          |                          |
| Investment in Novel Laboratories, Inc.   | 3,329,322                | 3,329,322                |
| Security deposits  | 14,314                   | 14,913                   |
| Restricted cash – debt service for EDA bonds   | 267,820                  | 280,585                  |
| EDA bond offering costs, net of accumulated amortization of \$107,519 and \$93,030, respectively                 | 246,934                  | 261,423                  |
| <br>Total Other Assets   | <br>3,858,390            | <br>3,886,243            |
| <br><b>TOTAL ASSETS</b>  | <br><b>\$ 11,125,133</b> | <br><b>\$ 10,311,717</b> |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****March 31, 2013 and 2012**

|   | 2013                | 2012                 |
|---|---------------------|----------------------|
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>  |                     |                      |
| <b>CURRENT LIABILITIES</b>  |                     |                      |
| EDA bonds payable   | \$3,385,000         | \$3,385,000          |
| Short term loans and current portion of long-term debt  | 606,296             | 13,316               |
| Accounts payable and accrued expenses   | 1,325,126           | 1,066,494            |
| Deferred revenues – current   | 13,333              | 13,333               |
| Preferred share derivative interest payable   | 27,500              | 70,966               |
| Total Current Liabilities   | 5,357,255           | 4,549,109            |
| <b>LONG TERM LIABILITIES</b>  |                     |                      |
| Deferred revenues   | 152,223             | 165,558              |
| Other long term liabilities   | 91,571              | 87,404               |
| Derivative liability – preferred shares   | 6,334,621           | 8,506,106            |
| Derivative liability – warrants   | 7,862,848           | 11,987,222           |
| Total Long Term Liabilities   | 14,441,263          | 20,746,290           |
| <b>TOTAL LIABILITIES</b>  | <b>19,798,518</b>   | <b>25,295,399</b>    |
| <b>STOCKHOLDERS' DEFICIT</b>  |                     |                      |
| Common stock – par value \$0.001, Authorized 690,000,000 shares. Issued 374,493,959 shares and 331,649,738 shares, respectively. Outstanding 374,393,959 shares and 331,549,738 shares, respectively. | 374,495             | 331,650              |
| Additional paid-in-capital  | 119,690,336         | 114,910,812          |
| Accumulated deficit   | (128,431,375)       | (129,919,303)        |
| Treasury stock at cost (100,000 common shares)  | (306,841 )          | (306,841 )           |
| <b>TOTAL STOCKHOLDERS' DEFICIT</b>  | <b>(8,673,385 )</b> | <b>(14,983,682 )</b> |
| <b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>  | <b>\$11,125,133</b> | <b>\$10,311,717</b>  |

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

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

|  | Years Ended  |                 |
|--|--------------|-----------------|
|  | March 31,    |                 |
|  | 2013         | 2012            |
| <b>REVENUES</b>  |              |                 |
| Manufacturing Fees   | \$2,214,271  | \$1,120,050     |
| Royalties & Profit Splits  | 806,365      | 648,211         |
| Lab Fee Revenues   | 382,889      | 655,857         |
| Total Revenues   | 3,403,526    | 2,424,118       |
| <br>   |              |                 |
| <b>COSTS OF REVENUES</b>   | 2,315,154    | 1,013,674       |
| <br>   |              |                 |
| Gross Profit   | 1,088,372    | 1,410,444       |
| <br>   |              |                 |
| <b>OPERATING EXPENSES</b>  |              |                 |
| Research and Development   | 975,250      | 1,735,689       |
| General and Administrative   | 1,513,468    | 1,410,192       |
| Non-cash compensation through issuance of stock options                      | 45,866       | 24,453          |
| Depreciation and Amortization  | 116,921      | 206,248         |
| Total Operating Expenses   | 2,651,505    | 3,376,582       |
| <br>   |              |                 |
| <b>(LOSS) FROM OPERATIONS</b>  | (1,563,133 ) | (1,966,138 )    |
| <br>   |              |                 |
| <b>OTHER INCOME / (EXPENSES)</b>   |              |                 |
| Interest expense, net  | (253,745 )   | (229,592 )      |
| Change in fair value of warrant derivatives                                  | 4,089,491    | (1,444,075 )    |
| Change in fair value of preferred share derivatives                          | (561,684 )   | (11,227,957 )   |
| Interest expense attributable to preferred share derivatives                 | (139,219 )   | (424,465 )      |
| Discount in Series E issuance attributable to beneficial conversion features | (437,500 )   | (250,000 )      |
| Total Other Income / (Expense)   | 2,697,343    | (13,576,088 )   |
| <br>   |              |                 |
| <b>INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES</b>                       | 1,134,210    | (15,542,226 )   |
| <br>   |              |                 |
| <b>CREDIT FOR INCOME TAXES</b>   | 353,718      | 483,952         |
| <br>   |              |                 |
| <b>NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>                 | \$1,487,928  | \$(15,058,274 ) |
| <br>   |              |                 |
| <b>NET INCOME (LOSS) PER SHARE</b>   |              |                 |
| Basic  | \$0.00       | \$(0.06 )       |
| Diluted  | \$(0.00 )    | \$(0.06 )       |
| <br>   |              |                 |
| <b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>                  |              |                 |
| Basic  | 349,075,642  | 259,163,279     |



Diluted

526,880,118 259,163,279

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

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**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEAR ENDED MARCH 31, 2012**

|  | Common Stock |            | Additional         | Treasury Stock |             | Accumulated     | Stockholders'  |
|--|--------------|------------|--------------------|----------------|-------------|-----------------|----------------|
|  | Shares       | Amount     | Paid-In<br>Capital | Shares         | Amount      | Deficit         | Deficit        |
| Balance at March 31, 2011  | 180,545,657  | \$ 180,546 | \$97,116,044       | 100,000        | \$(306,841) | \$(114,861,029) | \$(17,871,280) |
| Net Loss   |              |            |                    |                |             | (15,058,274 )   | (15,058,274)   |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expense | 8,410,384    | 8,410      | 627,769            |                |             |                 | 636,179        |
| Conversion of Series B, Series C, Series D and Series E Preferred Shares into Common Shares    | 140,493,195  | 140,493    | 17,023,687         |                |             |                 | 17,164,181     |
| Non-cash compensation through the issuance of stock options                                    |              |            | 24,452             |                |             |                 | 24,452         |
| Costs associated with raising capital  |              |            | (342,169 )         |                |             |                 | (342,169 )     |
| Common shares issued in payment of Directors' Fees   | 1,505,613    | 1,506      | 144,388            |                |             |                 | 145,894        |
| Common shares issued in payment of employee salaries   | 694,889      | 695        | 66,641             |                |             |                 | 67,336         |

|  |             |           |               |         |             |                 |                |
|--|-------------|-----------|---------------|---------|-------------|-----------------|----------------|
| Proceeds received<br>in exchange for<br>beneficial<br>conversion<br>provisions<br>embedded in Series<br>E Preferred Shares |             |           |               | 250,000 |             |                 | 250,000        |
| Balance at March<br>31, 2012   | 331,649,738 | \$331,650 | \$114,910,812 | 100,000 | \$(306,841) | \$(129,919,303) | \$(14,983,682) |

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

**ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY****FOR THE YEAR ENDED MARCH 31, 2013**

|  | Common Stock |           | Additional         | Treasury Stock |             | Accumulated     | Stockholders'  |
|--|--------------|-----------|--------------------|----------------|-------------|-----------------|----------------|
|  | Shares       | Amount    | Paid-In<br>Capital | Shares         | Amount      | Deficit         | Deficit        |
| Balance at March 31, 2012  | 331,649,738  | \$331,650 | \$114,910,812      | 100,000        | \$(306,841) | \$(129,919,303) | \$(14,983,682) |
| Net Income   |              |           |                    |                |             | 1,487,928       | 1,487,928      |
| Common shares issued in lieu of cash in payment of preferred share derivative interest expense | 1,860,943    | 1,861     | 180,824            |                |             |                 | 182,684        |
| Conversion of Series B, Series C and Series E Preferred Shares into Common Shares              | 29,863,563   | 29,865    | 3,140,807          |                |             |                 | 3,170,671      |
| Non-cash compensation through the issuance of stock options                                    |              |           | 45,866             |                |             |                 | 45,866         |
| Costs associated with raising capital (net of adjustments)                                     |              |           | 240,144            |                |             |                 | 240,144        |
| Issuance of Common Shares pursuant to the exercise of warrants                                 | 9,293,227    | 9,293     | 590,091            |                |             |                 | 599,384        |
| Common shares issued in payment  | 1,200,588    | 1,201     | 94,846             |                |             |                 | 96,047         |

of Directors' Fees

|  |             |           |               |         |             |                 |                |
|--|-------------|-----------|---------------|---------|-------------|-----------------|----------------|
| Common shares issued in payment of employee salaries   | 625,900     | 626       | 49,446        |         |             |                 | 50,072         |
| Proceeds received in exchange for beneficial conversion provisions embedded in Series E Preferred Shares |             |           | 437,500       |         |             |                 | 437,500        |
| Balance at March 31, 2013  | 374,493,959 | \$374,495 | \$119,690,336 | 100,000 | \$(306,841) | \$(128,431,375) | \$(8,673,385 ) |

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

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

|  | YEARS ENDED MARCH 31, |                     |
|--|-----------------------|---------------------|
|  | 2013                  | 2012                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>  |                       |                     |
| Net Income (Loss)  | \$ 1,487,928          | \$ (15,058,274 )    |
| Adjustments to reconcile net loss to cash used in operating activities:              |                       |                     |
| Depreciation and amortization  | 423,340               | 484,151             |
| Change in fair value of warrant derivative liability                                 | (4,089,491 )          | (1,444,075 )        |
| Change in fair value of preferred share derivative liability                         | 561,684               | 11,227,957          |
| Discount in Series E issuance attributable to embedded beneficial conversion feature | 437,500               | 250,000             |
| Preferred share derivative interest satisfied by the issuance of common stock        | 182,684               | 636,179             |
| Salaries and Directors Fees satisfied by the issuance of common stock                | 146,119               | 213,230             |
| Non-cash compensation satisfied by the issuance of common stock and options          | 45,866                | 24,452              |
| Non-cash rent expense  | 9,112                 | 11,090              |
| Non-cash lease accretion   | 1,356                 | 1,276               |
| Changes in Assets and Liabilities  |                       |                     |
| Accounts receivable  | (268,305 )            | 174,820             |
| Inventories  | (1,053,264 )          | 311,480             |
| Prepaid and other current assets   | (22,748 )             | 19,231              |
| Accounts payable, accrued expenses and other current liabilities                     | 251,611               | (133,749 )          |
| Deferred revenues and Customer deposits  | (13,335 )             | —                   |
| Derivative interest payable  | (43,466 )             | —                   |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>   | <b>(1,943,409 )</b>   | <b>(394,082 )</b>   |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>  |                       |                     |
| Purchases of property and equipment  | (119,489 )            | (201,777 )          |
| Cost of leasehold improvements   | (33,519 )             | (421,556 )          |
| Costs incurred for intellectual property assets                                      | (51,578 )             | (45,292 )           |
| Withdrawals from restricted cash, net  | 12,765                | 10,835              |
| <b>NET CASH USED IN INVESTING ACTIVITIES</b>   | <b>(191,822 )</b>     | <b>(657,790 )</b>   |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>  |                       |                     |
| Proceeds from issuance of Series E Convertible Preferred Stock                       | 437,500               | 250,000             |
| Proceeds from Executions of Cash Warrants  | 564,500               | —                   |
| Proceeds from draws against Treppel Credit Line                                      | 600,000               | —                   |
| Other loan payments  | (6,297 )              | (13,411 )           |
| Costs associated with raising capital, net of adjustments                            | 240,144               | (342,169 )          |
| <b>NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES</b>                           | <b>1,835,847</b>      | <b>(105,580 )</b>   |
| <b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>                                       | <b>(299,384 )</b>     | <b>(1,157,451 )</b> |
| <b>CASH AND CASH EQUIVALENTS – beginning of period</b>                               | <b>668,407</b>        | <b>1,825,858</b>    |

|   |            |            |
|---|------------|------------|
| CASH AND CASH EQUIVALENTS – end of period               | \$ 369,023 | \$ 668,407 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION       |            |            |
| Cash paid for interest                                  | 237,874    | 228,317    |
| Cash paid for taxes                                     | 6,099      | 2,849      |
| SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES |            |            |
| Loan to purchase equipment                              | —          | 13,200     |

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

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## **NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **BASIS OF PRESENTATION**

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

### **PRINCIPLES OF CONSOLIDATION**

The consolidated financial statements include the accounts of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries, (collectively the "Company") including its wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs") for the years ended March 31, 2013 ("Fiscal 2013") and 2012 ("Fiscal 2012"). Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2013, the financial statements of all wholly-owned entities are consolidated and all significant intercompany accounts are eliminated upon consolidation.

### **NATURE OF BUSINESS**

Elite Pharmaceuticals, Inc. was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. was incorporated on August 23, 1990 under the laws of the State of Delaware. On January 5, 2012, Elite Pharmaceuticals was reincorporated under the laws of the State of Nevada. Elite Labs engages primarily in researching, developing and licensing proprietary controlled-release drug delivery systems and products. The Company is also equipped to manufacture controlled-release products on a contract basis for third parties and itself if and when the products are approved; however the Company has concentrated on developing orally administered controlled-release products. These products include drugs that cover therapeutic areas for pain, allergy and infection. The Company also engages in research and development activities for the purpose of obtaining Food and Drug Administration approval, and, thereafter, commercially exploiting generic and new controlled-release pharmaceutical products. The Company also engages in contract research and development on behalf of other pharmaceutical companies.

### **CASH AND CASH EQUIVALENTS**

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company places its cash and cash equivalents with high-quality, U.S. financial institutions and, to date has not experienced losses on any of its balances.

### **INVENTORIES**

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



LONG-LIVED ASSETS

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

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

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

Costs incurred to acquire intangible assets such as for the application of patents and trademarks are capitalized and amortized on the straight-line method, based on their estimated useful lives ranging from five to fifteen years, commencing upon approval of the patent and trademarks. Such costs are charged to expense if the patent or trademark is unsuccessful.

#### RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense as incurred.

#### CONCENTRATION OF CREDIT RISK

The Company maintains cash balances, which, at times, may exceed the amounts insured by the Federal Deposit Insurance Corp. Uninsured balances at March 31, 2013 are \$369,023. Management does not believe that there is any significant risk of losses.

The Company in the normal course of business extends credit to its customers based on contract terms and performs ongoing credit evaluations. An allowance for doubtful accounts due to uncertainty of collection is established based on historical collection experience. Amounts are written off when payment is not received after exhaustive collection efforts. During Fiscal 2013 and Fiscal 2012 the Company generated all its revenues from six companies. The termination of the contracts with either of such four companies will result in the loss of a significant amount of revenues currently being earned.

#### USE OF ESTIMATES

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not

limited to, the recognition of revenue, the amount of the allowance for doubtful accounts receivable and the fair value of intangible assets, stock-based awards and derivatives.

### INCOME TAXES

The Company uses the liability method for reporting income taxes, under which current and deferred tax liabilities and assets are recorded in accordance with enacted tax laws and rates. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Under the liability method, the amounts of deferred tax liabilities and assets at the end of each period are determined using the tax rate expected to be in effect when taxes are actually paid or recovered. Further tax benefits are recognized when it is more likely than not, that such benefits will be realized. Valuation allowances are provided to reduce deferred tax assets to the amount considered likely to be realized.

GAAP prescribes a recognition threshold and measurement attribute for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. GAAP requires that the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. No adjustments related to uncertain tax positions were recognized during Fiscal 2013 and Fiscal 2012.

The Company recognizes interest and penalties related to uncertain tax positions as a reduction of the income tax benefit. No interest and penalties related to uncertain tax positions were accrued as of March 31, 2013 and March 31, 2012.

The Company operates in multiple tax jurisdictions within the United States of America. Although we do not believe that we are currently under examination in any of our major tax jurisdictions, we remain subject to examination in all of our tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2013, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2009 and forward, and State, 2005 and forward. The Company did not record unrecognized tax positions for the years ended March 31, 2013 and 2012.

#### EARNINGS PER COMMON SHARE

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

#### REVENUE RECOGNITION

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

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

Revenues derived from providing research and development services under contracts with other pharmaceutical companies are recognized when earned. These contracts provide for non-refundable upfront and milestone payments.

Because no discrete earnings event has occurred when the upfront payment is received, that amount is deferred until the achievement of a defined milestone. Each nonrefundable milestone payment is recognized as revenue when the performance criteria for that milestone have been met. Under each contract, the milestones are defined, substantive effort is required to achieve the milestone, the amount of the non-refundable milestone payment is reasonable, commensurate with the effort expended, and achievement of the milestone is reasonably assured.

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

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### TREASURY STOCK

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

### FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of current assets and liabilities approximate fair value due to the short-term nature of these instruments. The carrying amounts of noncurrent assets are reasonable estimates of their fair values based on management's evaluation of future cash flows. The long-term liabilities are carried at amounts that approximate fair value based on borrowing rates available to the Company for obligations with similar terms, degrees of risk and remaining maturities.

### STOCK-BASED COMPENSATION

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

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

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

The compensation expense recognized for the years ended March 31, 2013 and 2012 was \$45,866 and \$24,453, respectively.

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## FAIR VALUE MEASUREMENTS

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

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

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These Level 2: include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs that reflect the reporting entity’s own assumptions.

## RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

The Company believes that all recently issued accounting pronouncements and other authoritative guidance for which the effective date is in the future either will not have an impact on its accounting or reporting or that such impact will not be material to its financial statements.

## NOTE 2 MANAGEMENT’S LIQUIDITY PLANS

The Company reported a net profits of approximately \$1.5 million for Fiscal 2013 and a net loss of approximately \$15.1 million for Fiscal 2012. At March 31, 2013, the Company had a working capital deficiency of approximately \$2.8 million and an accumulated deficit of approximately \$128.6 million, consolidated assets of approximately \$11.1 million, and negative stockholders’ equity of approximately \$8.8 million. The Company has not generated any significant operating profits to date. During the fiscal year ended March 31, 2013, the Company raised \$437,500 of net proceeds from the sale of Series E Preferred Stock and \$564,500 from the exercise of cash warrants.



On June 12, 2012, Elite entered into a bridge loan agreement, as amended on December 5, 2012, (the “Treppel Credit Line Agreement”) with Jerry Treppel, the Company’s Chairman and CEO. Under the terms of the Treppel Credit Line Agreement, Elite has the right, in its sole discretion to a line of credit (the “Treppel Credit Line”) in the maximum principal amount of up to \$1,000,000, at any one time. Mr. Treppel provided the Treppel Credit Line for the purpose of supporting the acceleration of Elite’s product development activities. The outstanding amount is evidenced by a promissory note which shall mature on the earlier of (i) such date as Elite raises at least two million dollars in gross proceeds from the sale of any of its equity securities or (ii) July 31, 2013, at which time the entire unpaid principal balance, plus accrued interest thereon shall be due and payable in full. Elite may prepay any amounts owed without penalty. Any such prepayments shall first be due and owing and then to principal. Interest only shall be payable quarterly on July 1, October 1, January 1 and April 1 of each year. Prior to maturity or the occurrence of an Event of Default as defined in the Treppel Credit Line Agreement, the Company may borrow, repay and reborrow under the Treppel Credit Line through maturity. Amounts borrowed under the Treppel Credit Line bear interest at the rate of ten percent (10%) per annum. For more detailed information, please refer to the Current Reports on Form 8-K filed with the SEC on June 13, 2012 and December 10, 2012, with such filings being herein incorporated by reference.

As of the March 31, 2013, the principal balance of the Treppel Credit Line was \$600,000.

On April 19, 2013, subsequent to the end of Fiscal 2013, the Company entered into a purchase agreement (the “LPC Purchase Agreement”), together with a registration rights agreement (the “LPC Registration Rights Agreement”), with Lincoln Park Capital Fund, LLC (“LPC”).

Under the terms and subject to the conditions of the LPC Agreement, the Company has the right to sell to and LPC is 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, the date that the registration statement, which the Company agreed to file with the Securities and Exchange Commission (the “SEC”) pursuant to the LPC Registration Rights Agreement, was declared effective by the SEC. The Company may direct LPC, at its sole discretion and subject to certain conditions, to purchase stock in amounts of up to \$80,000 on any single business day, so long as at least two business days have passed since the most recent purchase, increasing to up to \$500,000 per purchase, depending upon the closing sale price of the Common Stock. The purchase price of the shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 business days leading up to such time), but in no event will shares be sold to LPC on a day the Common Stock closing price is less than the floor price of \$0.07 per share, subject to adjustment. The Company’s sales of shares of Common Stock to LPC under the LPC Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by LPC and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of Common Stock.

A Current Report on Form 8-K was filed with the SEC on April 22, 2013 with regards to the LPC Purchase Agreement and LPC Registration Rights Agreement with such filing being herein incorporated by reference. A Securities Registration Statement on Form S-1 was filed with the SEC on April 25, 2013, with such filing being herein incorporated by reference. The registration statement was declared effective by the SEC on May 9, 2013, with such filings being herein incorporated by reference.

The Company’s strategy is to continue to be engaged in the development and manufacturing of oral controlled-release products. It will continue to develop generic versions of controlled-release drug products with high barriers to entry and assist partner companies in the life cycle management of products to improve off-patent drug products. The Company has four products currently being sold commercially. In addition, the Company has a generic product which was purchased and for which the Company is in the process of transferring the manufacture of such product to its facility in Northvale, New Jersey, and a pipeline of products under development.

As of March 31, 2013, the Company's principal source of liquidity was approximately \$0.4 million of cash and cash equivalents. The Company may also receive funds through the exercise of outstanding stock options and warrants and, subsequent to March 31, 2013, entered into the LPC Purchase Agreement and LPC Registration Rights Agreement, which could provide up to \$10 million from the sale shares of the Company's Common Stock to LPC. The Company also is exploring raising additional funds through the sale of its equity or debt securities or otherwise. However, there can be no assurance of the exercise of any outstanding options or warrants, the sale of shares of Common Stock pursuant to the LPC Purchase Agreement, the raising of funds pursuant to any new funding arrangements, or that any cash received from such sources will be material to contribute sufficient amounts to continue operating activities. Even if the Company were to receive the amounts enumerated in the LPC Purchase Agreement or from the exercise of outstanding options and warrants, there can be no assurances that the Company will not be required to seek additional capital in the future and that the Company will be able to obtain such additional capital on favorable terms, if at all.

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

### **NOTE 3 INVENTORIES**

Inventories are recorded at the lower of cost or market. Inventories at March 31, 2013 and 2012 consist of the following:

|                                   | 2013        | 2012      |
|-----------------------------------|-------------|-----------|
| Finished Goods                    | \$—         | \$—       |
| Work-in-Process                   | 676,726     | 25,200    |
| Raw Materials                     | 774,758     | 373,020   |
|                                   | 1,451,484   | 398,220   |
| Less: Inventory Valuation Reserve | (93,338 )   | (93,338 ) |
|                                   | \$1,358,146 | \$304,882 |

The Inventory Valuation Reserve as of March 31, 2013 and March 31, 2012, consists of raw materials with an aggregate cost of \$93,338 being expired materials with no commercial value

### **NOTE 4 - PROPERTY AND EQUIPMENT**

Property and equipment at March 31, 2013 and 2012 consists of the following:

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|   | 2013        | 2012        |
|---|-------------|-------------|
| Laboratory manufacturing, and warehouse equipment | \$5,563,694 | \$5,448,732 |
| Office equipment                                  | 67,414      | 64,927      |
| Furniture and fixtures                            | 49,804      | 49,804      |
| Transportation equipment                          | 66,855      | 66,855      |
| Land, building and improvements                   | 3,349,696   | 3,314,138   |
|   | 9,097,463   | 8,944,456   |
| Less: Accumulated depreciation and amortization   | (5,068,522) | (4,659,670) |
|   | \$4,028,941 | \$4,284,786 |

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Depreciation and amortization expense amounted to \$423,340 and \$484,156 for the years ended March 31, 2013 and 2012, respectively.

#### **NOTE 5 - INTANGIBLE ASSETS**

Costs to acquire intangible assets, such as asset purchases of Abbreviated New Drug Applications (“ANDA’s”) which are approved by the FDA or costs incurred in the application of patents are capitalized and amortized on the straight-line method, based on their estimated useful lives ranging from five to fifteen years, commencing upon approval of the patent or site transfers required for commercialization of an acquired ANDA. Such costs are charged to expense if the patent application or ANDA site transfer is unsuccessful.

As of March 31, 2013 and 2012, the following costs were recorded as intangible assets on the Company’s balance sheet:

|   | 2013    | 2012    |
|---|---------|---------|
| Intangible assets at beginning of fiscal year             |         |         |
| Patent application costs                                  | 192,848 | 147,556 |
| ANDA acquisitions   | 450,000 | 450,000 |
| Less: Accumulated Amortization                            | —       | —       |
| Net Intangible Assets at beginning of fiscal year         | 642,848 | 597,556 |
| Intangible asset costs capitalized during the fiscal year |         |         |
| Patent application costs                                  | 51,578  | 45,292  |
| ANDA acquisition costs                                    | —       | —       |
| Total cost of intangible assets capitalized               | 51,578  | 45,291  |
| Amortization of intangible assets during fiscal year      |         |         |
| Patent application costs                                  | —       | —       |
| ANDA acquisition costs                                    | —       | —       |
| Total amortization of intangible assets                   | —       | —       |
| Impairment of intangible assets during the fiscal year    |         |         |
| Patent application costs                                  | —       | —       |
| ANDA acquisition costs                                    | —       | —       |
| Accumulated amortization of impaired assets               | —       | —       |
| Net impairment of intangible assets                       | —       | —       |
| Intangible assets at end of fiscal year                   |         |         |
| Patent application costs                                  | 244,424 | 192,848 |
| Trademarks  | —       | —       |
| ANDA acquisition costs                                    | 450,000 | 450,000 |

|                                |                     |
|--------------------------------|---------------------|
| Less: Accumulated Amortization | —                   |
| Net Intangible Assets          | \$694,424 \$642,848 |

The costs incurred in patent applications totaling \$51,578 and \$45,292 for Fiscal 2013 and Fiscal 2012, respectively, were all related to our abuse resistant and extended release opioid product lines. The Company is continuing its efforts to achieve approval of such patents. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

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

On April 23, 2013, the USPTO issued Patent No. 8,425,933 entitled “Abuse-Resistant Oral Dosage Forms and Method of Use Thereof”. A Current Report on Form 8-K was filed with the SEC on April 23, 2013, with such filing being herein incorporated by reference.

The ANDA acquisition costs of \$450,000 recorded as of the beginning of Fiscal 2012 and included as a part of intangible assets as of March 31, 2013 and March 31, 2012, are related to our acquisition of the ANDA for Phentermine 37.5mg tablets.

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

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

As of June 2013, the US-FDA website lists 19 products approved in the name of Novel and an additional 8 products approved in the name of the Novel's marketing arm, Gavis Pharmaceuticals (“Gavis”). Market data also list three additional products being marketed by Gavis. There are accordingly a total of 30 products currently identified as being approved/marketed by Novel and Gavis, with such total representing an increase of 4 products as compared to a comparable point in the prior year.

Furthermore, Novel has provided to the Company, copies of its prior year tax returns and management prepared forecasts showing growing revenues.

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

branded product were approximately \$80 million according to Wolters Kluwer.

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

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

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

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

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

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

A review and assessment of all documents available, public announcements by Novel and communications with the management of Novel does not indicate the existence of impairment indicators. Accordingly, the Company determined that no impairment is required in the valuation of its investment in Novel as of March 31, 2013. The valuation of the Company's investment in Novel remains at \$3,329,322, an amount equal to the valuation as of March 31, 2012 with no impairment write downs.

#### **NOTE 7 - 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") via the issuance of the following:

| Description   | Principal Amount On Issue Date | Interest Rate | Maturity          |
|---------------|--------------------------------|---------------|-------------------|
| Series A Note | \$3,660,000                    | 6.50 %        | September 1, 2030 |
| Series B Note | 495,000                        | 9.0 %         | 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, 2013, 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 as follows:

| Description            | Amount    |
|------------------------|-----------|
| Series A Note Proceeds | \$366,000 |
| Series B Note Proceeds | 49,500    |
| Total                  | \$415,500 |

The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets.

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Bond issue costs were paid from the bond proceeds and are being amortized over the life of the bonds. These costs and amortization activity are summarized as follows:

| Description              | Balances                | Amortization           | Balances                                  |
|--------------------------|-------------------------|------------------------|---|
|                          | As of<br>March 31, 2012 | Expense<br>Current YTD | As of<br>Current<br>Balance Sheet<br>Date |
| Bond Issue Costs         | \$ 354,453              |                        | \$ 354,453                                |
| Accumulated Amortization | (93,030 )               | (14,489 )              | (107,519 )                                |
| Unamortized Balance      | \$ 261,423              |                        | \$ 246,934                                |

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

Due to the Company not having sufficient funds, the following withdrawals were made from the debt service reserve, with the funds being used to make interest payments due to the holders of the NJEDA Bonds:

| Payment Date      | Amount     |
|-------------------|------------|
| March 1, 2009     | \$ 120,775 |
| September 1, 2009 | 120,775    |
| March 1, 2010     | 113,075    |
| September 1, 2010 | 113,075    |
| March 1, 2011     | 113,075    |
| September 1, 2011 | 113,075    |
| March 1, 2012     | 113,075    |
| September 1, 2012 | 113,075    |
| March 1, 2013     | 113,075    |

Due to the Company not having sufficient funds, a the following withdrawal was made from the debt service reserve, with the funds being used to make a principal payment due to the holders of the NJEDA Bonds:

| Payment Date      | Amount    |
|-------------------|-----------|
| September 1, 2009 | \$210,000 |

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

In addition, the Company did not have sufficient funds available to make the principal payments due on September 1, 2010, September 1, 2011 and September 1, 2012. These principal payments are summarized as follows:

| Payment Date      | Amount                   |
|-------------------|--------------------------|
| September 1, 2010 | \$225,000 <sup>(1)</sup> |
| September 1, 2011 | 470,000 <sup>(2)</sup>   |
| September 1, 2012 | 730,000 <sup>(3)</sup>   |

- (1) The Company request to withdraw funds from the debt service reserve to pay the amount due on September 1, 2010 was denied by the Trustee and accordingly, the principal payment due on such date was not made.  
The principal payment due on September 1, 2011, included the amount due and September 1, 2010 and not paid.
- (2) There were not sufficient funds available in the debt service reserve and the principal payment due on September 1, 2011 was not made.  
The principal payment due on September 1, 2012, included the amount due and September 1, 2011 and not paid.
- (3) There were not sufficient funds available in the debt service reserve and the principal payment due on September 1, 2012 was not made.

The Company has received Notices of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the debt service reserve and non-payment of principal amounts due on September 1, 2010, 2011 and 2012. Resolution of the Company's default under the NJED Bonds will have a significant effect on our ability to operate in the future.

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

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

|  | 2013        | 2012        |
|--|-------------|-------------|
| Refinanced NJEDA Bonds                       | \$3,385,000 | \$3,385,000 |
| Current portion                              | (3,385,000) | (3,385,000) |
| Long term portion, net of current maturities | \$—         | \$—         |

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

| YEAR ENDING MARCH 31, | AMOUNT    |
|-----------------------|-----------|
| 2014                  | \$915,000 |
| 2015                  | 195,000   |
| 2016                  | 210,000   |
| 2017                  | 220,000   |
| 2018                  | 85,000    |
| Thereafter            | 1,760,000 |

\$3,385,000

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

Loans payable and long term debt consisted of the following:

|   | March 31, 2013    |             | March 31, 2012  |                |
|---|-------------------|-------------|-----------------|----------------|
|   | Current           | Long-Term   | Current         | Long-Term      |
| Note payable to First Niagara Bank in 60 monthly installments of \$1,180, including interest at the rate of 9.00% per annum; Final payment in September 2012 ; Secured by vehicle purchased with proceeds of loan | \$ —              | \$ —        | \$6,923         | \$ —           |
| Capital lease payable to Shimadzu Financial Services; 24 payments of \$594; Final payment due in March 2014   | 6,295             | —           | 6,393           | 6,295          |
| Balance due on Treppel Credit Line (note 2)   | 600,000           | —           | —               | —              |
| <b>TOTAL</b>  | <b>\$ 606,295</b> | <b>\$ —</b> | <b>\$13,316</b> | <b>\$6,295</b> |

**NOTE 9 - LEASES OF RENTAL PROPERTIES**

The following leases for rental properties were operative during the year ended March 31, 2013:

|                                       |  |
|---------------------------------------|--|
| Effective Date                        | 135 Ludlow Ave<br>(see note 10)<br>July 1, 2010              |
| Termination Date                      | December 31, 2015  |
| Lease term                            | 5 years with 2 tenant<br>renewal options for 5<br>years each |
| Rent expense for the 2012 Fiscal Year | \$90,338   |
| Rent expense for the 2013 Fiscal Year | \$90,338   |
| Minimum 5 Year Lease Payments*        |  |
| Fiscal year ended March 31, 2014      | 83,259   |
| Fiscal year ended March 31, 2015      | 85,344   |
| Fiscal year ended March 31, 2016      | 87,363   |
| Fiscal year ended March 31, 2017      | 89,112   |
| Fiscal year ended March 31, 2018      | 90,894   |

\$435,972

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

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

Summary of Rent Expense – 135 Ludlow Avenue

|                                     | Fiscal Year<br>Ended<br>March 31, 2013 | Fiscal Year<br>Ended<br>March 31, 2012 |
|-------------------------------------|--|--|
| Rent Expense                        | \$ 90,338                              | \$ 90,338                              |
| Actual lease payments               | 81,228                                 | 79,248                                 |
| Increase in deferred rent liability | 9,110                                  | 11,090                                 |
| Balance of deferred rent liability  | 68,263                                 | 59,154                                 |

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

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

The lease includes an initial term of 5 years and 6 months and the Company has the option to renew the lease for two additional 5 year terms. The property related to this lease will be used for the storage of pharmaceutical finished goods, raw materials, equipment and documents as well as pharmaceutical manufacturing, packaging and distribution activities.

This property required significant leasehold improvements and qualification as a prerequisite to achieving suitability for such intended future use and in January 2013, the Company began shipping commercial product that was manufactured and packaged at the 135 Ludlow Avenue facility.

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

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

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

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**NOTE 12 - DEFERRED REVENUES**

Deferred revenues in the aggregate amount of \$165,556, consisting of a current component of \$13,333 and a long term component of \$152,223 represents the unamortized amount of a \$200,000 advance payment received for a licensing agreement with a fifteen year term beginning in September 2010 and ending in August 2025. The advance payment was recorded as deferred revenue when received and is earned, on a straight line basis over the fifteen year life of the license. The current component is equal to the amount of revenue to be earned during the 12 month period immediately subsequent to the balance date and the long term component is equal to the amount of revenue to be earned thereafter.

**NOTE 13 - RELATED PARTY TRANSACTION – BORROWING AGAINST TREPPEL CREDIT LINE**

Activity on the Treppel Credit Line Agreement during Fiscal 2013 and Fiscal 2012 is summarized as follows:

|  | Fiscal 2013 | Fiscal 2012 |
|--|-------------|-------------|
| Balance of Credit Line at beginning of Fiscal Year | \$ —        | \$ —        |
| Draws on credit line                               | 600,000     | —           |
| Repayment of credit line                           | —           | —           |
| Balance of Credit Line at end of Fiscal Year       | \$ 600,000  | \$ —        |
| Interest expense accrued                           | \$ 22,493   | \$ —        |
| Interest expense paid                              | 9,342       | —           |
| Interest owed as of March 31,                      | \$ 13,151   | \$ —        |

For further details on the Treppel Credit Line, please refer to Note 2 of these financial statements as well as Current Reports on Form 8-K filed with the SEC on June 13, 2012 and December 10, 2012.

**NOTE 14 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE**

Preferred share derivative interest payable as of March 31, 2013 consisted of \$27,500 in derivative interest accrued as of March 31, 2013. The full amount of derivative interest payable as of March 31, 2013 was paid via the issuance of 358,663 shares of Common Stock, in lieu of cash, in April 2013.

Preferred share derivative interest payable as of March 31, 2012 consisted of \$70,965 in derivative interest accrued as of March 31, 2012. The full amount of derivative interest payable as of March 31, 2012 was paid via the issuance of

802,789 shares of Common Stock, in lieu of cash, in April 2012.

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**NOTE 15 - DERIVATIVE LIABILITIES – PREFERRED SHARES**

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

The Preferred Stock Derivative Liabilities are measured at fair market value, using the market approach and a level 1 fair value hierarchy, on a recurring basis as of March 31, 2013 and March 31, 2012, in accordance with the valuation techniques discussed in ASC 820.

## Preferred Stock Derivative Liabilities – Fiscal 2013

|   | Series B | Series C  | Series E    | Total            |
|---|----------|-----------|-------------|------------------|
| Preferred shares Outstanding as of March 31, 2013                     | —        | 1,375     | 1,800       | 3,175            |
| Underlying common shares into which Preferred may convert             | —        | 9,166,669 | 74,074,075  | 83,240,744       |
| Closing price on valuation date                                       | \$0.0761 | \$0.0761  | \$0.0761    | \$0.0761         |
| Preferred stock derivative liability at March 31, 2013                | \$—      | \$697,584 | \$5,637,037 | \$6,334,621      |
| <b>Change in preferred stock derivative liability for Fiscal 2013</b> |          |           |             | <b>\$561,684</b> |

The change of \$561,684 in value of the preferred stock derivative liability occurring during Fiscal 2013 is included in the amount reported in the “Other Income/(Expense)” section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income. During Fiscal 2013 there was a net increase in the value of the preferred stock derivative liability, so therefore the amount shown above represents another expense item on the income statement.

## Preferred Stock Derivative Liabilities – Fiscal 2012

|  | Series B  | Series C    | Series E    | Total        |
|--|-----------|-------------|-------------|--------------|
| Preferred shares Outstanding as of March 31, 2012              | 797       | 2,666       | 1,750       | 5,213        |
| Underlying common shares into which Preferred may convert      | 5,310,393 | 17,773,333  | 71,428,571  | 94,512,297   |
| Closing price on valuation date                                | \$0.09    | \$0.09      | \$0.09      | \$0.09       |
| Preferred stock derivative liability at March 31, 2012         | \$477,935 | \$1,599,600 | \$6,428,571 | \$8,506,106  |
| Change in preferred stock derivative liability for Fiscal 2012 |           |             |             | \$11,227,957 |

The change of \$11,227,957 in value of the preferred stock derivative liability occurring during the 2012 Fiscal Year is included in the amount reported in the “Other Income/(Expense)” section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

**NOTE 16 - DERIVATIVE LIABILITIES - WARRANTS**

To date, the Company has authorized the issuance of Common Stock Purchase Warrants, with terms of five to seven years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements. Exercise prices range from \$0.0625 to \$0.25 per warrant. The warrants expire at various times through April 25, 2018.

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

|   | Fiscal Year 2013 |                                 | Fiscal Year 2012 |                                 |
|---|------------------|---------------------------------|------------------|---------------------------------|
|   | Warrant Shares   | Weighted Average Exercise Price | Warrant Shares   | Weighted Average Exercise Price |
| Balance at beginning of year            | 161,478,979      | \$ 0.09                         | 155,325,048      | \$ 0.15                         |
| Warrants issued                         | —                | —                               | 4,000,000        | \$ 0.06                         |
| Warrant Adjustments                     | —                | —                               | 3,379,551        | —                               |
| Warrant exercises, forfeited or expired | 22,134,040       | \$ 0.20                         | 1,225,620        | \$ 3.00                         |
| Ending Balance                          | 139,344,939      | \$ 0.08                         | 161,478,979      | \$ 0.09                         |

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

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The Warrant Derivative Liabilities are measured at fair market value, using the market approach and a level 3 fair value hierarchy, on a recurring basis as of March 31, 2013 and March 31, 2012, in accordance with the valuation techniques discussed in ASC 820.

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

|  | March 31<br>2013 | March 31<br>2012 |
|--|------------------|------------------|
| Risk-Free interest rate  | .04% - .77%      | .05% - 1.3%      |
| Expected volatility  | 106% - 168%      | 57% - 181%       |
| Expected life (in years)   | 0.5 – 5.1        | 0.1 – 6.1        |
| Expected dividend yield  | —                | —                |
| Number of warrants   | 139,344,939      | 161,478,979      |
| Fair value – Warrant Derivative Liability                          | \$7,862,848      | \$11,987,222     |
| Change in warrant derivative liability for the twelve months ended | \$(4,089,491     | ) \$1,444,075    |

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

The changes of \$(4,089,491) and \$1,444,075 in value of the warrant derivative liability occurring during the years ended March 31, 2013 and 2012, respectively, are included in the amounts reported in the "Other Income/(Expense)" section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

The following table summarizes, as of March 31, 2013, the warrant activity subject to Level 3 inputs which are measured on a recurring basis:

Fair value measurements of warrants using significant unobservable inputs

(Level 3)



|   | Fiscal 2013  | Fiscal 2012  |
|---|--------------|--------------|
| Balance at Beginning of Fiscal Year       | \$11,987,222 | \$10,543,145 |
| Warrants Issued                           | —            | 815,761      |
| Warrants Exercised                        | (707,216 )   | —            |
| Change in fair value of warrant liability | (3,417,158 ) | 628,316      |
| Balance at End of Fiscal Year             | 7,862,848    | \$11,987,222 |

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**NOTE 17 - BENEFICIAL CONVERSION FEATURES OF SERIES E PREFERRED SHARES**

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

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

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

During Fiscal 2013, the Company issued a total of 437.5 shares of Series E Preferred Stock which included a conversion option at a price that was less than the market price of the Company's Common Stock on the date of issuance of the Series E Preferred Stock.

The valuation of the beneficial conversion feature, and detachable warrants, where applicable, for Series E Preferred Share issuances during Fiscal 2013 and Fiscal 2012 is summarized as follows:

|   | Fiscal 2013 | Fiscal 2012 |
|---|-------------|-------------|
| Series E Shares Issued                              | 437.5       | 250         |
| Detachable Warrants Issued                          | —           | —           |
| Gross Proceeds Received                             | \$ 437,500  | \$ 250,000  |
| Gross Valuation of Warrants Issued                  | —           | —           |
| Gross Valuation of Beneficial Conversion            | \$ 437,500  | \$ 763,619  |
| Proceeds Allocated to Warrants                      | —           | —           |
| Proceeds Allocated to Beneficial Conversion Feature | \$ 437,500  | \$ 250,000  |
| Total Allocation of Proceeds                        | \$ 437,500  | \$ 250,000  |

**NOTE 18 - COMMON STOCK**

During Fiscal Years 2013 and 2012, the Company issued a total of 42,844,221 shares and 151,104,071 shares of Common Stock, respectively, with such issuances of Common Stock being summarized as follows:

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| Description  | Fiscal Year<br>2013 | Fiscal Year<br>2012 |
|--|---------------------|---------------------|
| Common Shares issued in lieu of cash payment in payment of preferred share derivative interest expenses totaling \$182,684 and \$636,179 for Fiscal 2013 and Fiscal 2012, respectively   | 1,860,943           | 8,410,374           |
| Common Shares issued pursuant to the conversion of Series B, Series C, and Series E Convertible Preferred Share derivatives, with such derivative liabilities totaling \$3,170,670 and \$17,164,181, for Fiscal 2013 and Fiscal 2012, respectively, at the time of their conversion. | 29,863,563          | 140,493,195         |
| Common Shares issued in payment of Director's fees totaling \$96,047 and \$145,894 for Fiscal 2013 and Fiscal 2013, respectively   | 1,200,588           | 1,505,613           |
| Common shares issued in payment of employee salaries totaling \$50,072 and \$67,336 for Fiscal 2013 and Fiscal 2012, respectively.   | 625,900             | 694,889             |
| Common shares issued pursuant to warrants exercised  | 9,293,227           | —                   |
| Total Common Shares issued during Fiscal 2013 and 2012   | 42,844,221          | 151,104,071         |
| Common Shares outstanding at March 31,   | 374,493,949         | 331,649,738         |

**NOTE 19 - PER SHARE INFORMATION**

Basic earnings per share of common stock ("Basic EPS") is computed by dividing the net income(loss) by the weighted-average number of shares of common stock outstanding. Diluted earnings per share of common stock ("Diluted EPS") is computed by dividing the net income(loss) by the weighted-average number of shares of common stock and dilutive common stock equivalents and convertible securities then outstanding. GAAP requires the presentation of both Basic EPS and Diluted EPS, if such Diluted EPS is not anti-dilutive, on the face of the Company's Consolidated Statements of Operations. As the Company had a net loss for Fiscal Year 2012, Diluted EPS is not presented as the effect of the Company's common stock equivalents and convertible securities is anti-dilutive.

**Basic EPS is calculated as follows:**

|   | Fiscal Year<br>2013 | Fiscal Year<br>2012 |
|---|---------------------|---------------------|
| Numerator   |                     |                     |
| Net Income (Loss) attributable to common shareholders | \$1,487,928         | \$(15,167,289)      |
| Denominator   |                     |                     |

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|  |             |             |
|--|-------------|-------------|
| Weighted average shares of common stock outstanding  | 349,075,642 | 259,163,279 |
| Net (Loss) per Share – Basic   | \$0.00      | \$(0.06 )   |
| Potentially dilutive securities excluded from the calculation of diluted loss per share for Fiscal 2012 ( in accordance with GAAP) |             |             |
| Stock Options  | —           | 2,999,000   |
| Convertible Preferred Stock  | —           | 94,512,298  |
| Warrants   | —           | 161,478,979 |

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**Diluted EPS (for Fiscal 2013) is calculated as follows:**

|   | Fiscal Year<br>2013 |
|---|---------------------|
| Numerator   |                     |
| Net Income attributable to common shareholders                        | \$1,487,928         |
| Adjustments to Net Income   |                     |
| Reversal of Change in Value of Preferred Share Derivatives            | 561,684             |
| Reversal of Change in Value of Warrant Derivatives                    | (4,089,491 )        |
| Reversal of Derivative Interest Expense                               | 139,219             |
| Net loss attributable to common shareholders on a diluted basis       | \$(1,900,660 )      |
| Denominator   |                     |
| Weighted average shares of common stock outstanding                   | 349,075,642         |
| Dilutive effects of convertible preferred stock, warrants and options |                     |
| Convertible preferred Stock   | 83,240,744          |
| Warrants  | 94,421,813          |
| Stock Options   | 141,919             |
| Weighted average shares outstanding – diluted                         | 526,880,118         |
| Diluted EPS   | \$(0.00 )           |

**NOTE 20 - STOCK-BASED COMPENSATION**

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

**Stock-based Director Compensation**

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

During Fiscal 2013, the Company issued 1,200,588 shares of Common Stock to its Directors in payment of Director's fees in the aggregate amount of \$130,000 and related to the calendar year ending on December 31, 2012. On the date of their issuance, the Common Shares had a value of \$96,047, based upon the closing price of the Company's Common Stock on such date. Please note that the shares issued during Fiscal 2013, include those shares owed and not yet issued at the end of Fiscal Year 2012.

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

As of March 31, 2013, the Company owes its Directors a total of 327,635 shares of Common Stock in payment of Directors Fees totaling \$27,500 for the three months ended March 31, 2013. The Company anticipates that these shares of Common Stock will be issued during the fiscal year ended March 31, 2014.

#### Stock-based Employee Compensation

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

During Fiscal Year 2013, the Company issued a total of 625,900 shares of Common Stock to its President, Chief Financial Officer and certain other employees in payment of salaries in the aggregate amount of \$67,917 and related to the period calendar year ended December 31, 2012. On the date of their issuance, the Common Shares had a value of \$50,072, based upon the closing price of the Company's Common Stock on such date. Please note that the shares issued during Fiscal 2013, include those shares owed and not yet issued at the end of Fiscal 2012.

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

As of March 31, 2013, the Company owes its President, Chief Financial Officer and certain other employees a total of 288,913 shares of Common Stock in payment of salaries totaling \$24,250 for the three months ended March 31, 2013, with such amount being recorded in accrued expenses. The Company anticipates that these shares of Common Stock will be issued during the fiscal year ended March 31, 2014.

#### Stock option based Employee Compensation



During Fiscal 2013, the Company issued, to various employees, options to purchase a total of 985,000 shares Common Stock, in aggregate (the "2013 Options"). The 2013 Options have an exercise price of \$0.12 per share, vest equally over a three year period which commences one year from the date of grant and expire ten years from the date of grant. The fair value of the 2013 Options was \$113,842, computed using the Black-Scholes options pricing model on the grant date. Such fair value is being amortized by the Company, on a straight line basis, over the vesting period and recorded on the Company's Statement of Income as "Non-cash compensation through the issuance of stock options".

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

Stock option based employee compensation is summarized as follows:

|   | Fiscal Year<br>2013 | Fiscal Year<br>2012 |
|---|---------------------|---------------------|
| Non-cash compensation expense related to the 2010 Options         | \$ 17,405           | \$ 24,453           |
| Non-cash compensation expense related to the 2013 Options         | 28,461              | —                   |
| Total non-cash compensation through the issuance of stock options | \$ 45,866           | \$ 24,453           |

#### **NOTE 21 - STOCK OPTION PLANS**

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

Transactions under the plans for the years indicated were as follows:

|                                  | Fiscal Year 2013 |  | Fiscal Year 2012 |  |
|----------------------------------|------------------|--|------------------|--|
|                                  | Options          | Weighted<br>Average<br>Exercise<br>Price | Options          | Weighted<br>Average<br>Exercise<br>Price |
| Outstanding at beginning of year | 2,999,000        | \$ 1.53                                  | 3,057,000        | \$ 1.51                                  |
| Options Granted                  | 985,000          | \$ 0.12                                  | —                | —  |

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|                            |           |         |           |         |
|----------------------------|-----------|---------|-----------|---------|
| Options Exercised          | —         | —       | —         | —       |
| Options Expired/Forfeited  | (45,000 ) | \$ 1.59 | (58,000 ) | \$ 0.10 |
| Outstanding at end of year | 3,939,000 | \$ 0.86 | 2,999,000 | \$ 1.53 |

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The following table summarizes information about stock options outstanding at March 31, 2013:

| Range          | Options Outstanding | Weighted Average Remaining Contractual Life (Years) | Weighted Average Exercise Price | Options Exercisable | Weighted Average Exercise Price |
|----------------|---------------------|---|---------------------------------|---------------------|---------------------------------|
| \$ 0.01 – 1.00 | 1,890,000           | 8.3   | \$ 0.11                         | 905,000             | \$ 0.09                         |
| 1.01 – 2.00    | 99,000              | 4.8   | \$ 1.08                         | 99,000              | \$ 1.08                         |
| 2.01 – 3.00    | 1,950,000           | 3.2   | \$ 2.22                         | 1,450,000           | \$ 2.21                         |
| \$ 0.01 – 3.00 | 3,939,000           | 5.5   | \$ 1.18                         | 2,454,000           | \$ 1.38                         |

As of March 31, 2013, there were 5,535,100 options available for future grant under our Stock Option Plan.

## **NOTE 22 - INCOME TAXES**

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

|   | Year Ended March 31, |            |
|---|----------------------|------------|
|   | 2013                 | 2012       |
| Federal:                                |                      |            |
| Current                                 | \$—                  | \$—        |
| Deferred                                | —                    | —          |
| State                                   |                      |            |
| Current                                 | \$(6,099 )           | \$(2,849 ) |
| Deferred                                |                      | —          |
| Sale of New Jersey Net Operating Losses | 359,817              | \$486,801  |
| Net Credit for Income Taxes             | \$353,718            | \$483,952  |

The Major components of deferred tax assets and liabilities at March 31, 2013 and 2012 are as follows:

March 31,

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|                                  | 2013         | 2012         |
|----------------------------------|--------------|--------------|
| <b>Federal</b>                   |              |              |
| Net Operating Loss Carry forward | \$17,968,000 | \$16,826,617 |
| Valuation Allowance              | (17,968,000) | (16,826,617) |
|                                  | \$—          | \$—          |
| <b>State</b>                     |              |              |
| Net Operating Loss Carryforwards | \$2,420,000  | \$897,589    |
| Valuation Allowance              | (2,420,000 ) | 897,589      |
|                                  | \$—          | \$—          |

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At March 31, 2013 and 2012, a 100% valuation allowance is provided, as it is uncertain if the deferred tax assets will provide any future benefits because of the uncertainty about the Company's ability to generate the future taxable income necessary to use the net operating loss carryforwards.

**NOTE 23 - REMOVAL OF LODRANE PRODUCTS FROM THE US MARKET**

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

| <b>Product</b>        | <b>Active Ingredient , Strength</b>                     |
|-----------------------|---|
| Lodrane® 24 Capsules  | Brompheniramine maleate, 12mg                           |
| Lodrane® 24D Capsules | Brompheniramine maleate, 12mg/pseudoephedrine HCl, 90mg |

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

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

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

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

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

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

**NOTE 24 - MAJOR CUSTOMERS**

Six customers accounted for substantially all of the Company's revenues for Fiscal 2013. Included in these six customers are three customers that accounted for approximately 90 percent of revenues for Fiscal 2012, and three additional customers that had little or no related revenues for Fiscal 2012.

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**NOTE 25 - TRANSACTIONS WITH RELATED PARTIES**

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

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC, as disclosed in this Annual Report Form 10-K under Item 7 of Part II of this Annual Report on Form 10-K, under the heading “Epic Strategic Alliance Agreement,” Item 9B and Item 10, under the heading “Directors and Executive Officers,” and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which disclosures are incorporated herein by reference. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, each were elected as members of our Board of Directors, effective June 24, 2009, as the three directors that Epic is entitled to designate for appointment to the Board pursuant to the terms of the Epic Strategic Alliance Agreement. Mr. Potti resigned from his position as Director of the Company on December 31, 2012. Messrs. Nigalaye, Narine and Potti are also officers of Epic Pharma, LLC, in the following capacities:

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

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

With regards to synergies related to raw materials usage, the strategic alliance allowed the Company to purchase such raw materials from Epic, at the Epic acquisition cost, without markup. In all cases, the acquisition cost of Epic was lower than those costs available to the Company, mainly as a result of efficiencies of scale generated by significantly larger volumes purchased by Epic during the course of their normal operations. During Fiscal 2013 and Fiscal 2012, an aggregate amount of \$71,480 and \$15,552, respectively, in such materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma’s acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC’s acquisition cost.

With regards to synergies related to regulatory and operational resources, the strategic alliance allowed the Company to utilize Epic’s substantial resources and technical competencies on an “as needed” basis at a cost equal to Epic’s actual cost for only the resources utilized by the Company. Without such access to Epic’s resources, the Company would have to invest significant amounts in human resources and fixed assets as well as incur substantial costs with third party providers to provide the same resources provided by Epic and necessary for the operations of the Company.



During Fiscal 2013, an aggregate amount of \$31,354 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company. During Fiscal 2012, an aggregate amount of \$133,003 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company.

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During Fiscal 2013, the Company incurred a total of \$362,347 in contract manufacturing and/or packaging costs to Epic Pharma for the Company's Phentermine, Hydromorphone, Methadone and Immediate Release Lodrane products. During Fiscal 2012, the Company incurred a total of \$275,678 in these costs.

During the fiscal years ended March 31, 2013 and 2012, equipment purchases from Epic totaled \$-0- and \$52,000, respectively.

Total purchases from Epic by the Company during the fiscal years ended March 31, 2013 and 2012 were \$465,181 and \$476,323, respectively.

#### **NOTE 27 - CONVERSIONS OF PREFERRED STOCK DERIVATIVES TO COMMON STOCK**

The Amended Certificate of Designations of the Series B 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series B Preferred Derivatives"), the Series C 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series C Preferred Derivatives"), the Series D 8% Convertible Preferred Stock of Elite Pharmaceuticals (the "Series D Preferred Derivatives") and the Series E Convertible Preferred Stock Derivatives (the "Series E Preferred Derivatives", and together with the Series B Preferred Derivatives, the Series C Preferred Derivatives and the Series D Preferred Derivatives, the "Preferred Derivatives") include provisions entitling the holders of these Preferred Derivatives to convert shares of the Preferred Derivatives into shares of Common Stock. The Preferred Derivatives are classified as a liability to the Company, and the liability represented by those shares of Preferred Derivatives being converted must be valued at the time of such conversion, with increases/(decreases) in the value of preferred share derivative liabilities being appropriately recorded and reflected in the Other Income section of the Company's Statement of Operations. The amount of equity recorded as a result of the conversion of Preferred Derivatives is equal to the value of such Preferred Derivatives being converted, at the time of the conversion, with such amount also representing the decrease in the Preferred Share Derivative Liability on the Company's Balance Sheet.

Conversions of Preferred Derivatives during Fiscal 2013 and Fiscal 2012, are summarized as follows:

|   | Fiscal 2013 | Fiscal 2012  |
|---|-------------|--------------|
| <b>Series B Derivatives</b>   |             |              |
| Number of Derivative Shares Converted   | 797         | 99           |
| Number of Common Shares issued pursuant to conversion   | 5,310,387   | 660,001      |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | 690,350     | \$72,600     |
| Change in value of preferred share derivative liability recorded at time of conversion  | 212,415     | \$(39,600 )  |
| Par value of Common Shares issued   | 5,310       | \$660        |
| Additional paid in capital recorded as a result of the conversions  | 685,040     | \$71,940     |
| <b>Series C Preferred Derivatives</b>   |             |              |
| Number of Derivative Shares Converted   | 1,291       | 2,752        |
| Number of Common Shares issued pursuant to conversion   | 8,606,667   | 18,346,673   |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | 1,204,600   | \$1,712,667  |
| Change in value of preferred share derivative liability recorded at time of conversion  | 414,280     | \$(518,387 ) |
| Par value of Common Shares issued   | 8,607       | \$18,347     |
| Additional paid in capital recorded as a result of the conversions  | 1,195,993   | \$1,694,321  |
| <b>Series D Preferred Derivatives</b>   |             |              |
| Number of Derivative Shares Converted   | —           | 4,063        |
| Number of Common Shares issued pursuant to conversion   | —           | 58,042,862   |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | —           | \$9,473,715  |
| Change in value of preferred share derivative liability recorded at time of conversion  | —           | \$4,946,372  |
| Par value of Common Shares issued   | —           | \$58,043     |
| Additional paid in capital recorded as a result of the conversions  | —           | \$9,415,672  |
| <b>Series E Preferred Derivatives</b>   |             |              |
| Number of Derivative Shares Converted   | 388         | 1,563        |
| Number of Common Shares issued pursuant to conversion   | 15,946,502  | 63,443,670   |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | 1,275,720   | \$5,905,197  |
| Change in value of preferred share derivative liability recorded at time of conversion  | —           | \$1,166,521  |
| Par value of Common Shares issued   | 15,947      | \$63,444     |
| Additional paid in capital recorded as a result of the conversions  | 1,259,774   | \$5,841,754  |
| <b>Total Preferred Derivatives</b>  |             |              |
| Number of Derivative Shares Converted   | 2,475       | 8,477        |
| Number of Common Shares issued pursuant to conversion   | 29,863,556  | 140,493,206  |
| Value of Preferred Derivative shares at time of conversion (represents decrease in derivative liability resulting from conversions) | 3,170,671   | \$17,164,180 |
| Change in value of preferred share derivative liability recorded at time of conversion  | 626,696     | \$5,554,906  |
| Par value of Common Shares issued   | 29,864      | \$140,493    |

|  |           |              |
|--|-----------|--------------|
| Additional paid in capital recorded as a result of the conversions | 3,140,807 | \$17,023,687 |
|--|-----------|--------------|

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**Note 28 CONTINGENCIES**

On March 1, 2013, the Company did not renew its Directors and Officers insurance policy. As of the date of filing this Annual Report on Form 10-K, management has not been notified any claims against the Company

**NOTE 29 -SUBSEQUENT EVENTS**

The Company has evaluated subsequent events from the balance sheet date through June 21, 2013, the date the accompanying financial statements were issued. The following are material subsequent events:

Common shares issued in lieu of cash in payment of derivative interest expense due as of March 31, 2013

Derivative interest expense related to the Preferred Share derivatives due and payable as of March 31, 2013 were paid during April 2013 through the issuance of 358,663 shares of common stock.

Purchase Agreement with Lincoln Park Capital

On April 19, 2013 (subsequent to the end of Fiscal 2013), the Company entered into a purchase agreement (the “Lincoln Park Purchase Agreement”), together with a registration rights agreement (the “Lincoln Park Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”).

Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, the Company has the right to sell to, and Lincoln Park is obligated to purchase up to \$10 million in shares of the Company’s common stock (“Common Stock”), subject to certain limitations, from time to time, over the 36-month period commencing on May 9, 2013, the date that the registration statement which the Company agreed to file with the SEC pursuant to the Lincoln Park Registration Rights Agreement was declared effective by the SEC. The Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase stock in amounts up to \$80,000 on any single business day so long as at least two business days have passed since the most recent purchase, increasing to up to \$500,000 per purchase, depending upon the closing sale price of the Common Stock. The purchase price of shares of Common Stock related to the future funding will be based on the prevailing market prices of such shares at the time of sales (or over a period of up to 12 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 \$0.07 per share, subject to adjustment. The Company’s sales of shares of Common Stock to Lincoln Park and its affiliates, at any single point in time, of more than 9.99% of the then outstanding shares of the Common Stock.

In connection with the Purchase Agreement, the Company issued to Lincoln Park 2,929,115 shares of Common Stock and is required to issue up to 2,929,115 additional shares of Common Stock pro rata as the Company requires Lincoln Park to purchase the Company’s shares under the Lincoln Park Purchase Agreement over the term of the agreement. Lincoln Park represented to the Company, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the “Securities Act”)), and the

Company sold the securities in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The securities sold may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

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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.

The foregoing descriptions of the Lincoln Park Purchase Agreement and the Lincoln Park Registration Rights Agreement are qualified in their entirety by reference to the full text of the Lincoln Park Purchase Agreement and the Lincoln Park Registration Rights Agreement, copies of which are attached as Exhibit 10.1 and Exhibit 10.2, respectively, to the Current Report on Form 8-K filed with the SEC on April 22, 2013, with such filing and each exhibit being incorporated herein in its entirety by reference. The representations, warranties and covenants contained in such agreements were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with execution of the agreements.

A Securities Registration on Form S-1 was filed with the SEC on April 25, 2013 and declared effective by the SEC on May 9, 2013 (the “Lincoln Park Registration Statement”), with such filing being herein incorporated by reference. The requisite Prospectus was filed with the SEC on May 10, 2013, with such filing being herein incorporated by reference.

#### Issuance of Series G Preferred Stock and Conversion of Series C Preferred Stock

On April 18, 2013, the Company filed a Certificate of Designations with the Nevada Secretary of State designating a new series of convertible preferred stock – Series G Preferred Stock (the “G Preferred Stock”) and setting forth various rights, preferences, restrictions and other matters related to the G Preferred Stock. 1,375 shares were designated as G Preferred Stock, the same number of the then outstanding shares of the Company’s Series C Preferred Stock. On April 19, 2013, the holders of substantially all of the Company’s Series C Preferred Stock exchanged all of their shares of Series C Preferred Stock for an identical number of shares of G Preferred Stock. The various rights, preferences, restrictions and other terms of the G Preferred Stock are substantially the same as those of the Series C Preferred

Stock, except that the conversion price of the G Preferred was changed. The foregoing description of the Certificate of Designations is qualified in its entirety by reference to the full text of the Certificate of Designations attached as Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on April 22, 2013, with such filing and exhibit being herein incorporated by reference.

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#### Conversion of Series G to Common

During the period beginning on April 1, 2013 and up to June 21, 2013, an aggregate of 266 shares of G Preferred Stock were converted into Common Stock, with an aggregate of 3,800,000 shares of Common Stock being issued accordingly.

#### Shares issued to Lincoln Park

During the period beginning on April 1, 2013 and up to June 21, 2013, an aggregate of 4,785,084 shares of Common Stock were issued to Lincoln Park in accordance with sales of Common Stock made pursuant to the Lincoln Park Purchase Agreement together with the Lincoln Park Registration Rights Agreement.

#### Initial Shipment of Phentermine Capsules

On April 11, 2013, the Company made the initial shipment of Phentermine HCl capsules 15mg and 30mg, under the license, manufacturing and supply agreement with its sales and marketing partner, triggering a milestone payment. Elite's sales and marketing partner will distribute the product as part of a multi-product distribution agreement.

A Current Report on Form 8-K was filed with the SEC on April 11, 2013, with such filing being herein incorporated by reference.

#### Issuance of U.S. Patent for Abuse Resistant Drug Formulation

On April 23, 2013, the Company announced the issuance of U.S. Patent No. 8,425,933, entitled "Abuse-Resistant Oral Dosage Forms and Method of Use Thereof" by the United States Patent and Trademark Office. This is the second issued U.S. patent covering Elite's abuse resistant technology for opioid products. Elite has additional patents pending in the U.S., Canada and Europe.

A Current Report on Form 8-K was filed with the SEC on April 23, 2013, with such filing being herein incorporated by reference.

#### Change in Executive Leadership

Effective May 24, 2013, Mr. Chris Dick stepped down as the Company's President and Chief Operating Officer and as a member of the Board of Directors. Mr. Dick will remain as a consultant with Elite to ensure a smooth transition while the Board of Directors conducts a search for a permanent replacement.

A Current Report on Form 8-K was filed with the SEC on May 21, 2013, with such filing being herein incorporated by reference.

Filing of Citizen Petition with the FDA

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

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

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

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

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