ELITE PHARMACEUTICALS INC /NV/
Form 10-K
June 29, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED – MARCH 31, 2012

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 001 – 15697

ELITE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

165 Ludlow Avenue, Northvale, New Jersey 07647

(Address of principal executive offices)

(201) 750 – 2646

(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Exchange on Which Registered
None	

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

Common Stock, $0.001 par value

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

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

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

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

Yes ¨ No x

State the aggregate market value of the voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (for purposes of determining this amount, only directors, executive officers and, based on Schedule 13(d) filings as of September 30, 2011, 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	25,732,686	September 30, 2010

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	346,216,612	June 22, 2012

DOCUMENTS INCORPORATED BY REFERENCE

None.

FORWARD LOOKING STATEMENTS

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

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PART I

ITEM 1 BUSINESS

General

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

Business Overview and Strategy

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology and the development and manufacture of generic pharmaceuticals. 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. Our technology is applicable to develop delayed-, sustained- or targeted-release pellets, capsules, tablets, granules and powders.

We have four products currently being sold commercially, as follows:

- Phentermine 37.5mg tablets
- Methadone 10mg tablets
- Lodrane D® Immediate Release capsules
- Hydromorphone Hydrochloride 8mg tablets

During the fiscal years ended March 31, 2011 ("Fiscal 2011") and March 31, 2010 ("Fiscal 2010"), the Company manufactured and sold Lodrane 24® and Lodrane 24D® (the "Lodrane Extended Release Products"). On March 3, 2011, the U.S. Food and Drug Administration ("FDA") announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. 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 Lodrane Extended Release Products were responsible for 97% and 100% of the Company's revenues for Fiscal 2011 and Fiscal 2010, respectively.

ECR Pharmaceuticals ("ECR"), a wholly owned subsidiary of Hi-Tech Pharmacal, Inc. and 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 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 Products. The Company has received no further information from ECR with regards to the status of the Petition filed.

Elite also purchased from Mikah Pharma LLC, an approved Abbreviated New Drug Application ("ANDA") for Naltrexone 50mg tablets. Transfer of production of this product from the previous ANDA holder, Mikah Pharma to our manufacturing facilities is currently in process. Elite also completed a contract manufacturing agreement with Mikah Pharma for two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg.

The Company has a pipeline of additional generic drug candidates under active development, including, without limitation, ELI-154, a once-a-day oxycodone product and ELI-216, an abuse resistant oxycodone product which utilizes the Company's propriety formulation for abuse resistant products utilizing the pharmacological approach ("Elite's Abuse Resistant Technology"). On May 22, 2012, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,182,836, entitled "Abuse-Resistant Oral Dosage Forms and Method of Use Thereof with such patent providing further protection for the Elite's Abuse Resistant Technology.

Elite's facility in Northvale, New Jersey (the "Facility") operates under Good Manufacturing Practice ("GMP ") and is a United States Drug Enforcement Agency (" DEA ") registered facility for research, development and manufacturing.

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 ANDA's; (iii) development of additional generic pharmaceutical products; (iv) the development of the other products in our pipeline including the products pursuant to the Epic Strategic Alliance Agreement and other 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 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. Please refer to the Current Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 15, 2010 for further details on the Hydromorphone Agreement, with such filing being herein incorporated by reference.

On May 31, 2011, the Company received a letter from the FDA responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 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.

Please refer to the Current Reports on Form 8-K filed with the SEC on May 24, 2010, June 6, 2011 and January 27, 2012 for further details on Hydromorphone 8mg, with each of such filings being herein incorporated by reference.

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.

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 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 immediately following the next paragraph.

Current Reports on Form 8-K were filed on September 10, 2010 and February 4, 2011 in relation to the Phentermine ANDA, with such filings being herein incorporated by reference. Please also refer to Exhibit 10.7 of the Quarterly Report on Form 10-Q filed with the SEC on November 15, 2010, with such filing being herein incorporated by reference.

Licensing Agreement with Precision Dose Inc.

On September 10, 2010, Elite executed a License Agreement with Precision Dose to market and sell four Elite generic products, consisting of Hydromorphone, Naltrexone, Phentermine 37.5mg tablets ("Phentermine 37.5mg") and one additional generic products for which an ANDA has been filed but not yet approved by the FDA, through its wholly-owned subsidiary, TAGI Pharma, Inc. in the United States, Puerto Rico and Canada (the "Precision Dose License Agreement"). 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.

Current Reports on Form 8-K were filed with the SEC on September 10, 2010 and September 16, 2010 in relation to the Precision Dose License Agreement, with such filings being incorporated herein by this reference. Please also refer to exhibits 10.8 and 10.9 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filings being incorporated herein by this reference.

Research and Development

During each of the last two fiscal years, we have focused on research and development activities. We spent $1,735,689 during fiscal year ended March 31, 2012 (“Fiscal 2012”) and $1,385,211 during Fiscal 2011 on 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

On April 7, 2011, Elite commenced shipping phentermine HCl 37.5 mg tablets to TAGI Pharma. This triggered a milestone payment under the License, Manufacturing and Supply Agreement with Precision Dose. Phentermine tablets are now a commercial product being distributed by our partner, TAGI Pharma. Please refer to the Current Report on Form 8-K filed with the SEC on April 7, 2011 for more details, with such filing being incorporated herein by this reference.

On September 27, 2011, Elite made the initial shipment of Lodrane D® immediate release capsules to ECR. Lodrane D is an immediate release formulation of brompheniramine maleate and pseudoephedrine HCl. Elite will manufacture this product for ECR and will receive revenues for the manufacturing, packaging and laboratory stability study services for this product as well as royalties on sales. For further details, please refer to the Current Report on Form 8-K filed with the SEC on September 27, 2011, with such filing being herein incorporated by reference.

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.

On January 17, 2012, Elite commenced shipping Methadone 10mg tablets to ThePharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories, LLC. (together, "TPN") pursuant to a commercial manufacturing and supply agreement dated June 23, 2011 between Elite and TPN. Please refer to the Current Report on Form 8-K filed with the SEC on January 17, 2012 for more details, with such filing being herein incorporated by reference. For details on the commercial manufacturing and supply agreement dated June 23, 2011 between Elite and TPN, please refer to the immediately following section of this Annual Report on Form 10-K titled "Contract Manufacturing".

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. Please refer to the Current Report on Form 8-K filed with the SEC on March 13, 2012 for more details, with such filing being incorporated herein by this reference. For further details on the multi-product distribution agreement with Precision Dose Inc., please refer to the section above titled "Licensing Agreement with Precision Dose Inc.".

Contract Manufacturing

On June 1, 2011, Elite Pharmaceuticals Inc. ("Elite") executed a Manufacturing and Supply Agreement (the "Mikah Manufacturing and Supply Agreement") with Mikah to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg (the "Mikah Products"), 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 of America, its territories, possessions, and commonwealths in accordance with the requirements of the Mikah Manufacturing and Supply

Agreement; Elite will 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 the Mikah Products for commercial sale by Mikah or its designees in accordance with the terms of the Mikah Manufacturing and Supply Agreement. During the term of the Mikah Manufacturing and Supply Agreement and subject to the provisions therein, Mikah will purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Mikah Product as Mikah may order from time to time pursuant to the Manufacturing and Supply Agreement. Mikah will compensate Elite at an agreed upon transfer price for the manufacturing and packaging of the Products. 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 Mikah Product for the work associated with the technology transfer. The milestone payment will be made upon the successful manufacturing and testing of the exhibit batch. The Mikah Manufacturing and Supply Agreement has a term of five years and will automatically renew 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.

A Current Report on Form 8-K was filed on June 7, 2011 in relation to the Mikah Manufacturing and Supply Agreement, with such filing being herein incorporated by reference.

Transfer of the manufacturing site of the Mikah Products to Elite's Facility is in progress as of the date of this report.

In June 2011, Elite entered into a commercial manufacturing and supply agreement with ThePharmaNetwork, LLC and its wholly owned subsidiary, Ascend Laboratories LLC (together "TPN"). Under the terms of the agreement, Elite will perform manufacturing and packaging for TPN's Methadone Hydrochloride, 10mg tablets. The FDA has approved the manufacturing of Methadone 10mg at the Northvale Facility and commercial launch of this product is expected during this fiscal year. As noted above, the initial shipment to TPN of Methadone 10mg was made on January 17, 2012.

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.

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. Please refer to the Current Report on Form 8-K filed on March 22, 2012 in relation to the D&L Agreement, with such filings being herein incorporated by reference.

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Manufacturing Site Transfers in Progress

Elite is currently engaged in the transfer of the manufacturing site for the following generic product for which it purchased approved ANDA's during the fiscal year ended March 31, 2011: Naltrexone 50 mg tablets.

Please refer to the sections above titled "Elite's Purchase of a Generic Naltrexone Product" for further details on the transfer of the manufacturing site for Naltrexone 50 mg.

Discontinued Products

Elite manufactured two once-daily allergy products, Lodrane 24® and Lodrane 24D®, that were co-developed with its partner, ECR. Elite entered into development agreements for these two products with ECR in June 2001 whereby Elite agreed to commercially develop two products in exchange for development fees, certain payments, royalties and manufacturing rights. The products were being marketed by ECR which also has the responsibility for regulatory matters. In addition to receiving revenues for the manufacture of these products, Elite is to receive a royalty on in-market sales.

Lodrane 24®, was first commercially offered in November 2004 and Lodrane 24D® was first commercially offered in December, 2006. Elite's revenues for manufacturing these products and a royalty on sales for the years ended March 31, 2012 and 2011 aggregated $506,353 and, $3,917,721, respectively.

Since January, 2010, the Company has performed laboratory stability studies of Lodrane 24® and Lodrane 24D®, for ECR, on a contract basis. Elite's revenues from such contract laboratory services were $166,189 and $348,242 for Fiscal 2012 and Fiscal 2011, respectively.

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 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.

ECR initiated a formal approval process with the FDA in 2010 regarding the Lodrane Products and issued a press release on March 3, 2011 stating that they will continue to actively pursue approval for the Lodrane 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 Products. The Company has received no further information from ECR with regards to the status of the Petition filed.

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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.

ELI-154 and ELI-216

For ELI-154, Elite has developed a once-daily oxycodone formulation using its proprietary technology. An investigational new drug application, or IND, has been filed and Elite has completed two pharmacokinetic studies in healthy subjects that compared blood levels of oxycodone from dosing ELI-154 and the twice-a-day product that is on the market currently, OxyContin® marketed in the U.S. by Purdue Pharma LP. The Company believes that these studies confirmed that ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hour period and equivalent blood levels to the twice-a-day product at the end of 24 hours. Elite has successfully manufactured multiple batches on commercial scale equipment and it is looking for a partner who can complete the clinical studies required for Europe and who can sell and distribute the product in key European territories. An interested party was identified that would fund half of the clinical costs for Europe, however, Elite is not able to find a way to fund the remaining costs at this time.

ELI-216 utilizes Elite's patent-pending abuse-deterrent technology that is based on a pharmacological approach. ELI-216 is a combination of a narcotic agonist, oxycodone hydrochloride, in a sustained-release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, naltrexone hydrochloride, formulated to deter abuse of the drug. Both of these compounds, oxycodone hydrochloride and naltrexone hydrochloride, have been on the market for a number of years and sold separately in various dose strengths. Elite filed an IND for the product and has tested the product in a series of pharmacokinetic studies. In single-dose studies for ELI-216, it was demonstrated that no quantifiable blood levels of naltrexone hydrochloride were released at a limit of quantification ("LOQ") of7.5 pg/ml. As described below, when crushed, naltrexone hydrochloride was released at levels that would be expected to eliminate the euphoria from the crushed oxycodone hydrochloride. This data is consistent with the premise of Elite's abuse resistant technology, that essentially no naltrexone is released and absorbed when administered as intended. 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, have been approved by the FDA.

ELI-216 demonstrates a euphoria-blocking effect when the product is crushed. A study completed in 2007 was designed to determine the optimal ratio of oxycodone hydrochloride and the opioid antagonist, naltrexone hydrochloride, to significantly block the euphoric effect of the opioid if the product is abused by physically altering it (i.e., crushing). The study also helped determine the appropriate levels of naltrexone hydrochloride required to reduce

or eliminate the euphoria experienced by subjects who might take crushed product to achieve a “high”.

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. The issuance of this patent will further protect Elite’s proprietary formulation for abuse resistant products utilizing the pharmacological approach. The Company has additional patents pending for its technology. A Current Report on Form 8-K was filed with the SEC on May 22, 2012, with such filing being herein incorporated by reference.

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has chosen to develop these products itself but expects to license these products at a later date to a third party who could provide funding for the remaining clinical studies, including a Phase III study, and who could provide sales and distribution for the product. The drug delivery technology underlying ELI-154 was originally developed 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 ELI-154. Upon licensing or commercialization of ELI-154, Elite will pay a royalty to Elan pursuant to the Termination Agreement. If Elite were to sell the product itself, Elite would pay a 1% royalty to Elan based on the product's net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite's net revenues from this product. (Elite's net product revenues would include license fees, royalties, manufacturing profits and milestones) Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Epic Strategic Alliance Agreement

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a subsidiary of Epic Pharma LLC (collectively, "Epic") entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009). Epic is a pharmaceutical company that operates a business synergistic to that of Elite in the research and development, manufacturing and sales and marketing of oral immediate release and controlled-release drug products.

Use of Facility and Joint Development of Drug Products

Pursuant to the Epic Strategic Alliance Agreement, on June 3, 2009 (the "Initial Closing Date"), Elite and Epic conducted the initial closing (the "Initial Closing") of the transactions contemplated by the Epic Strategic Alliance Agreement, and Epic and its employees and consultants commenced use of a portion of Elite's facility located at 165 Ludlow Avenue, Northvale, New Jersey (the "Facility"), for the purpose of developing new generic drug products, all at Epic's sole cost and expense for a period of at least three years (the "Initial Term"), unless sooner terminated or extended pursuant to the Epic Strategic Alliance Agreement or by mutual agreement of Elite and Epic (the Initial Term, as shortened or extended, the "Term"). Although the Term has expired, cooperation under the Epic Strategic Alliance Agreement is ongoing. In addition to the use of the Facility, Epic uses Elite's machinery, equipment, systems, instruments and tools residing at the Facility (collectively the "Personal Property") in connection with its joint drug development project at the Facility. Under the Epic Strategic Alliance Agreement, Epic has the right, exercisable in its sole discretion, to extend the Initial Term for two periods of one year each by giving written notice to Elite of such extension within ninety days of the end of the Initial Term or any extension thereof. Any such extension will be on the same terms and conditions contained in the Epic Strategic Alliance Agreement. Elite will be responsible for (and Epic

will have no responsibility for) any maintenance, services, repairs and replacements in, to or of the Facility and the Personal Property, unless any such maintenance, service, repair or replacement is required as a result of the negligence or misconduct of Epic's employees or representatives, in which case Epic will be responsible for the costs and expenses associated therewith.

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During the Term, Epic will use and occupy a portion of the Facility and use the Personal Property for the purpose of developing (i) at least four controlled-release products (the "Identified CR Products") and (ii) at least four immediate-release products (the "Identified IR Products"), the identity of each have been agreed upon by Epic and Elite. If, during the Term, Epic determines, in its reasonable business judgment, that the further or continuing development of any Identified CR Product and/or Identified IR Product is no longer commercially feasible, Epic may, upon written notice to Elite, eliminate from development under the Epic Strategic Alliance Agreement such Identified CR Product and/or Identified IR Product, and replace such eliminated product with another controlled-release or immediate-release product, as applicable.

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

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

With respect to each Identified CR Product and Additional CR Product developed by Epic at the Facility: (i) Elite will issue and deliver to Epic a seven-year warrant to purchase up to 10,000,000 shares of Common Stock, at an exercise price of $0.0625, following the receipt by Elite from Epic of each written notice of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified CR Products and/or Additional CR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 40,000,000 shares of Common Stock (such warrants, the "CR Related Warrants"), and (ii) Elite will issue and deliver to Epic 7,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified CR Products and/or Additional CR Products, up to a maximum of an aggregate of 28,000,000 shares of Common Stock (such shares, the "CR Related Shares").

With respect to each Identified IR Product and Additional IR Product developed by Epic at the Facility, (i) Elite will issue and deliver to Epic a seven year warrant to purchase up to 4,000,000 shares of Common Stock, at an exercise price of $0.0625, following the receipt by Elite from Epic of each written notice of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for such Identified IR Products and/or

Additional IR Products, up to a maximum of four such warrants for the right to purchase up to an aggregate of 16,000,000 shares of Common Stock (such warrants, together with the CR Related Warrants, the "Milestone Warrants"), and (ii) Elite will issue and deliver to Epic 3,000,000 shares of Common Stock following the receipt by Elite from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified IR Products and/or Additional IR Products, up to a maximum of an aggregate of 12,000,000 shares of Common Stock (such shares, together with the CR Related Shares, the "Milestone Shares"). The Milestone Warrants may only be exercised by payment of the applicable cash exercise price. Elite will have no obligation to register with the United States Securities and Exchange Commission (the "SEC") or any state securities commission the resale of the Milestone Shares, Milestone Warrants or the shares of Common Stock issuable upon exercise of the Milestone Warrants.

Subject to the mutual agreement of Epic and Elite with respect to the selection of Additional CR Products and/or Additional IR Products pursuant to the Epic Strategic Alliance Agreement, Epic will have the sole right to make all decisions regarding all aspects of the Products, including, but not be limited to, (i) research and development, formulation, studies and validation of each Product, (ii) identifying, evaluating and obtaining ingredients for each Product, (iii) preparing and filing the ANDA for each Product with the FDA and addressing and handling all regulatory inquiries, audits and investigations pertaining to the ANDA, and (iv) the manufacture, marketing, supply and commercialization of each Product. In addition, Epic would be the sole and exclusive owner of all right, title and interest in and to each of the Products.

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

Under certain circumstances Epic will be entitled to terminate the Term early in the event that the Facility is totally damaged or destroyed such that the Facility is rendered wholly untenable. In addition, subject to certain exceptions, either Elite or Epic may terminate the Term at any time if the other party is in breach of any material obligations under Article V of the Epic Strategic Alliance Agreement and has not cured such breach within sixty days after receipt of written notice requesting cure of such breach.

Elite may also terminate the Term by written notice to Epic if (i) all conditions precedent that Elite is obligated to satisfy pursuant to Article II of the Epic Strategic Alliance Agreement on or prior to a Closing (as defined in the Epic Strategic Alliance Agreement) have been, or will have been, satisfied by Elite in accordance with the terms thereof and (ii) Epic does not consummate such Closing in accordance with Article II. Notwithstanding the foregoing, if Elite terminates the Epic Strategic Alliance Agreement as described in this paragraph, then any and all product fees to which it would otherwise be entitled will remain the obligation of Epic and must be paid to Elite in accordance with the terms of Epic Strategic Alliance Agreement.

Infusion of Additional Capital Necessary for Product Development

In order to provide Elite with the additional capital necessary for the product development and synergies presented by the strategic relationship with Epic, Epic agreed to invest $3.75 million in Elite through the purchase of Elite's Series E Preferred Stock and Common Stock warrants. At the Initial Closing, which occurred on June 3, 2009, in order to fund the continued development of Elite's drug products, Elite issued and sold to the Epic, in a private placement, pursuant to an exemption from registration under Section 4(2) of the Securities Act, 1,000 shares of its Series E Convertible Preferred Stock, par value $0.01 per share (the "Series E Preferred Stock"), at a price of $1,000 per share, each share convertible, at $0.05 per share (the "Conversion Price"), into 20,000 shares of Common Stock, par value $0.001 per share (the "Common Stock"). The Conversion Price is subject to adjustment for certain events, including, without

limitation, dividends, stock splits, combinations and the like. The Conversion Price is also subject to adjustment for (a) the sale of Common Stock or securities convertible into or exercisable for Common Stock, for which Epic's consent was not required under the terms of the Series E Convertible Preferred Stock in Epic's Articles of Incorporation, at a price less than the then applicable Conversion Price, (b) the issuance of Common Stock in lieu of cash in satisfaction of Elite's dividend obligations on outstanding shares of its Series B 8% Convertible Preferred Stock, par value $0.01 per share, Series C 8% Convertible Preferred Stock, par value $0.01 per share, and/or Series D 8% Convertible Preferred Stock, par value $0.01 per share (the "Series D Preferred Stock, and (c) the issuance of Common Stock as a result of any holder of Series D Preferred Stock exercising its right to require Elite to redeem all of such holder's shares of Series D Preferred Stock pursuant to the terms thereof. Epic also acquired a warrant to purchase 20,000,000 shares of Common Stock (the "Initial Warrant"), exercisable on or prior to June 3, 2016, at a per share exercise price of $0.0625 (the "Exercise Price"), subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The Exercise Price of the Initial Warrant will also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock, for which Epic's consent was not required under the Epic Strategic Alliance Agreement, at a price less than the then applicable Exercise Price of the Initial Warrant. Epic paid an aggregate purchase price of $1,000,000 for the shares of Series E Preferred Stock and the Initial Warrant issued and sold by Elite to the Epic at the Initial Closing, of which $250,000 was received by Elite, in the form of a cash deposit, on April 30, 2009, pursuant to the First Amendment. The remaining $750,000 of such aggregate purchase price was paid to Elite by Epic at the Initial Closing.

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

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

In addition, within ten business days following the last day of each calendar quarter, beginning with the first calendar quarter following the Initial Closing Date and continuing for each of the eleven calendar quarters thereafter, Epic will pay to Elite a sum of $62,500, for an aggregate purchase price over such period of $750,000, in exchange for an additional 62.5 shares of Series E Preferred Stock per quarter and 750 shares of Series E Preferred Stock, in the aggregate, over such period, which such shares will be convertible into 1,250,000 shares of Common Stock per quarter and 15,000,000 shares of Common Stock, in the aggregate, over such period, subject to adjustment. To date, Epic has made five payments.

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

Elite believes, which as to such belief there can be no assurances, the completion of the transactions contemplated by the Epic Strategic Alliance Agreement creates value for our stockholders by adding a new revenue source for Elite upon the commercialization of the Epic products developed at our facility, providing an experienced partner to assist in the development, manufacture and licensing of our pharmaceutical products, and contributing funding for the products. Importantly, Elite will continue the development of its pain products and, with the help of Epic, work towards securing licensing arrangements for such pain products.

Board of Directors Composition and Voting Rights

As of the Initial Closing Date and at all times thereafter, except as otherwise set forth in the Epic Strategic Alliance Agreement, Elite and its Board of Directors is required to take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the "Epic Directors") will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the period commencing on the Initial Closing Date and ending on the date immediately following the first anniversary of the Third Closing Date Epic owns less than (i) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by Epic at all of the then applicable Closings or (ii) following the conversion by Epic of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither Elite nor its Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be removed from office for cause unless such removal is directed or approved by (x) a majority of the independent members of the Board of Directors and (y) all of the non-affected Epic Director (s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the request of Epic, with or without cause. At such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that Epic will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a majority of the Board of Directors.

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

In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, Elite may conduct its operations

only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein.

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For additional information regarding the Epic Strategic Alliance Agreement, please see the disclosure in Item 1. “Business: Epic Strategic Alliance Agreement” in Part I and Item 10. “Directors, Executive Officers and Corporate Governance “Epic Strategic Alliance Agreement” in Part II, 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 are incorporated herein by reference.

Novel Labs Investment

At the end of 2006, Elite entered into a joint venture with VGS Pharma, LLC (“VGS”) and created Novel Laboratories, Inc. (“Novel”), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite owns approximately 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 eight United States patents of which two have been assigned for a fee to another pharmaceutical company. Elite’s patents are:

PATENT
U.S. patent 5,871,776
U.S. patent 5,902,632
U.S. patent 5,837,284 (assigned to Celgene Corporation)
U.S. patent 6,620,439
U.S. patent 6,635,284 (assigned to Celgene Corporation)
U.S. patent 6,926,909
U.S. patent 6,984,402
U.S. patent 8,182,836

We have pending applications for four 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.

A Current Report on Form 8-K was filed with the SEC on March 4, 2011 in relation to this announcement by the US-FDA, such filing being herein incorporated by reference.

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

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

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

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

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

ANDAs

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

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

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

Controlled Substances

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

GMP

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

Compliance with Environmental Laws

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

Competition

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

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

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

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

Sources and Availability of Raw Materials; Manufacturing

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

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

Please see the Risk Factor entitled "We are dependent on a small number of suppliers for our raw materials and any delay or unavailability of raw materials can materially adversely affect our ability to produce products" in Item 1A of this Annual Report on Form 10-K.

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.

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 June 29, 2012, we had 19 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

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. For the past two fiscal years, we incurred net losses of $15,058,274 and $13,582,159, respectively and losses from operations of $1,966,137 and $885,760, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

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

As of March 31, 2012, we had cash reserves of approximately $0.7 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”, the U.S. Food and Drug Administration’s (“FDA”) removed our Lodrane® extended release product line from the market in March 2011. The Lodrane® extended release products constituted approximately 97% of our revenues at the time of FDA’s directive. The FDA has also reclassified our Changes Being Effected in 30 Days supplements (“CBE-30”) filed in relation to the transfer of manufacturing of two approved generic products to the Facility to a “prior approval supplemental application”. Such reclassifications have resulted in significant delays in the commercialization of these two approved generic products, with accordingly significant delays in our being able to generate revenues, if any, from the manufacture and sale of such approved generic products.

To tide us over in the short term, our CEO, Jerry Treppel has provided Elite with a revolving bridge credit line of up to $500,000. 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, which ever occurs first. While we believe that the completion of all transactions contemplated by the Epic Strategic Alliance Agreement along with the Treppel bridge line will provide additional funds to permit us to continue development of our product pipeline, we will need to obtain additional funding through the sale of our equity or debt securities or otherwise. We are anticipating that, with the growth of the generic phentermine product, the contract manufacturing of methadone, Lodrane D® immediate release, Hydromorphone, Phendimetrazine and Isradipine, the eventual launch of the generic naltrexone products and other opportunities in our pipeline, Elite could be profitable. In addition, the commercialization of the Epic products developed under the Epic Strategic Alliance Agreement should add a new revenue source for Elite. However, there can be no assurances that we will be able to timely raise additional funds on acceptable terms, that the FDA will approve generic Naltrexone, the development of such Epic products will be successful or that such Epic products will be successfully commercialized or that other pipeline products of Elite will be successfully commercialized. For more detailed information about the Epic Strategic Alliance Agreement please see Item 1. “Description of Business; Epic Strategic Alliance Agreement.”

Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate quarterly payment closings pursuant to the terms and conditions of the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of $0.4375 million.

Even if we are able to successfully complete the quarterly payment closings of the Epic Strategic Alliance Agreement, we still may 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.

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 from the Epic Strategic Alliance Agreement or other sources 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, consummate the quarterly payment closings under the Epic Strategic Alliance Agreement on a timely basis, 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, 2012 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 a Notice of Default from the Trustee in relation to the NJEDA Bonds and we have requested a postponement of principal payments due on September 1st of 2010, 2011 and 2012, with an aggregate of all such postponed principal payments being added to the principal payments due on September 1, 2013. Resolution of our default under the NJED Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future. For more information on the NJEDA Bonds, see "Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources; NJEDA Bonds".

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

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

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

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

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

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

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

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

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

- ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;
- delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards;
- slower than expected rate of patient recruitment and enrollment; inability to adequately follow and monitor patients after treatment; difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- government or regulatory delays; and
- clinical trial costs that are greater than we currently anticipate.

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

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

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

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

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

- collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;
- collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial or abandon a product candidate;
- expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;

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

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

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

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

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

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

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

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

In April 2011, we ceased production of the Lodrane Extended Release Products, which are the subject of the agreements with ECR, pursuant to the FDA's announcement of its intention to remove approximately 500 cough/cold and allergy related products from the US market, including the Lodrane Extended Release Products. After this announcement by the FDA, the Company's customer for the Lodrane Extended Release Products cancelled all outstanding orders and manufacturing of the Lodrane Extended Release Products has ceased. The Lodrane Extended Release Products for which production has ceased were responsible for 97% of the Company's revenues during the fiscal year ended March 31, 2011. The cessation of production of the Lodrane Extended Release Products has had a material adverse effect on Elite's revenues for all periods beginning after March 31, 2011.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;

- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

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

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

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

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

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

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

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

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

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

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

At the end of 2006, Elite entered into a joint venture with VGS Pharma, LLC (“VGS”) and created Novel Laboratories, Inc. (“Novel”), a privately-held company specializing in pharmaceutical research, development, manufacturing, licensing, acquisition and marketing of specialty generic pharmaceuticals. Novel's business strategy is to focus on its core strength in identifying and timely executing niche business opportunities in the generic pharmaceutical area. Elite owns approximately 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, 2012, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.24 per share to a low of $0.07 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including, without limitation:

- Results of our clinical trials;
- Approval or disapproval of our ANDAs or NDAs;
- Announcements of innovations, new products or new patents by us or by our competitors;
- Governmental regulation;

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

Future sales of our Common Stock could lower the market price of our Common Stock.

Sales of substantial amounts of our shares in the public market could harm the market price of our Common Stock, even if our business is doing well. A significant number of shares of our Common Stock are eligible for sale in the public market under Rule 144, promulgated under the Securities Act of 1933, as amended (the "Securities Act").

In this regard, as of June 22, 2012, there were outstanding approximately 346.2 million shares of Common Stock, shares of preferred stock convertible into approximately 81.3 million shares of Common Stock and warrants to purchase an aggregate of approximately 152.6 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. Sales of these shares, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

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 are obligated to issue a significant number of additional shares of Common Stock pursuant to existing agreements, including the Epic Strategic Alliance Agreement and outstanding warrants and preferred stock,. Existing holders of our Common Stock will experience substantial dilution from the issuance of shares of Common Stock pursuant to these obligations By way of example, if we and Epic consummate the quarterly payment closings under the Epic Strategic Alliance Agreement, we will issue to Epic an aggregate of 437.5 shares of Series E Preferred Stock, convertible into an aggregate of approximately 18.0 million shares of Common Stock, based on a conversion price as of June 22, 2012. In addition, with respect to the products developed by Epic under the Epic Strategic Alliance Agreement, we may issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of our Common Stock upon the receipt by us from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at the Facility and (b) up to an aggregate of 40,000,000 additional shares of our Common Stock following the receipt by us from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and

immediate-release products developed by Epic at the Facility.

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

Any 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.

Under the Epic Strategic Alliance Agreement, we agreed that we and our Board of Directors will take any and all action necessary so that (i) the size of the Board of Directors will be set and remain at seven directors, (ii) three individuals designated by Epic (the " Epic Directors ") will be appointed to the Board of Directors and (iii) the Epic Directors will be nominated at each annual or special meeting of stockholders at which an election of directors is held or pursuant to any written consent of the stockholders; provided, however, that if at any time following the initial closing of the Epic Strategic Alliance Agreement and ending on the later of (a) the date immediately following the first anniversary of the Initial Closing Date and (b) the Third Closing Date, Epic owns less than (1) a number of shares of Series E Preferred Stock equal to ninety percent of the aggregate number of shares of Series E Preferred Stock purchased by Epic or (2) following the conversion by Epic of the Series E Preferred Stock, a number of shares of Common Stock equal to ninety percent of the number of shares of Common Stock so converted, neither we nor our Board of Directors will be obligated to nominate Epic Directors or take any other action with respect to those actions described in (i), (ii) and/or (iii) above. No Epic Director may be removed from office for cause unless such removal is directed or approved by (A) a majority of the independent members of the Board of Directors and (B) all of the non-affected Epic Director(s). Any vacancies created by the resignation, removal or death of an Epic Director will be filled by the appointment of an additional Epic Director. Any Epic Director may be removed from office upon the

request of Epic, with or without cause. Epic, by virtue of having the right to designate the three Epic Directors, will have the ability to exert substantial influence over the election of the other members of our Board of Directors, the outcome of issues submitted to our stockholders for approval and the management and affairs of Elite. In accordance with these rights, three of our current directors are nominees of Epic.

In addition, the Series E Designation provides that on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), Epic, as a holder of Series E Preferred Stock, will be entitled to cast the number of votes equal to the number of shares of Common Stock into which the shares of Series E Preferred Stock held by Epic are convertible as of the record date for determining the stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Series E Designation, Epic will vote together with the holders of Common Stock, as a single class. In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, Elite has agreed that, between the date of the initial closing under the Epic Strategic Alliance Agreement and the date which is the earlier of (x) the date the Epic Directors constitute a majority of the Board of Directors and (y) ninety days following the fifth anniversary of the Initial Closing Date, except as Epic otherwise agrees in writing, we may conduct our operations only in the ordinary and usual course of business consistent with past practice. Further, pursuant to the Epic Strategic Alliance Agreement and the Series E Designation, we must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein. Accordingly, as a result of such concentration of ownership, Epic will have the ability to exert further influence over us and may have the effect of preventing a change of control of Elite. For more detailed information about the Epic Strategic Alliance Agreement please see “Description of 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. If we are required to issue such securities, Epic may beneficially own in excess of 50% of our issued and outstanding shares of Common Stock or other voting securities. Under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of our issued and outstanding Common Stock or other voting securities, the number of Epic Directors that Epic will be entitled to designate will be equal to a majority of the Board of Directors.

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 B Preferred Stock, Series C 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 5. MARKET FOR COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Market Information

Our Common Stock was traded on NYSE Amex (formerly, the American Stock Exchange) under the symbol "ELI" until May 21, 2009, at which time Elite's Common Stock began to be 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.

Common Stock

Quarter ended	High	Low
Fiscal Year ending March 31, 2012:		
March 31, 2012	$0.13	$0.09
December 31, 2011	$0.10	$0.07
September 30, 2011	$0.14	$0.07
June 30, 2011	$0.24	$0.07
Fiscal Year ending March 31, 2011:		
March 31, 2011	$0.08	$0.04
December 31, 2010	$0.07	$0.04
September 30, 2010	$0.07	$0.05
June 30, 2010	$0.10	$0.07

On June 21 2012, the last reported sale price of our Common Stock, as quoted by the OTC Bulletin Board, was $0.13 per share

Holders

As of June 22, 2012, there were, respectively, approximately 141, 0, 8 and 1 holders of record of our Common Stock, Series B Preferred Stock, Series C Preferred Stock and Series E 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

There were no sales of unregistered securities during the quarter ended March 31, 2012.

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, 2012.

Plan Category		Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	(1)	2,999,000	$ 1.53	7,001,000	
Equity compensation plans not approved by security holders		—	—	1,123,152	(2)
Total		2,999,000	$ 1.53	8,124,152	

(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 of 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.

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.

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Liquidity and Capital Resources

Going concern considerations

As of March 31, 2012, the Company had a working capital deficit of $3.1 million, losses from operations totaling $2.0 million for the fiscal year ended March 31, 2012, other expenses totaling $13.6 million for the fiscal year ended March 31, 2012 and a net loss of $15.1 million for the fiscal year ended March 31, 2012. Please note that the Company's other income/(expenses) are significantly influenced by the fluctuations in the fair value of outstanding preferred share and warrant derivatives, and that such fair values strongly correlate to and vary inversely with the market share price of the Company's Common Stock.

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

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

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

As of March 31, 2012, we had cash reserves of $0.7 million. The completion of all transactions contemplated by the Epic Strategic Alliance agreement is expected to provide additional funds to permit us to continue development our product pipeline. Despite the successful completion of the initial, second and third closings of the Epic Strategic Alliance Agreement, and the first five of a total of twelve quarterly payments of $62,500 each, there can be no assurances that we will be able to consummate the remaining seven quarterly payments due under the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of $0.4375 million. Even if we were to receive the remaining quarterly payments due pursuant to the Epic Strategic Alliance Agreement, 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.

Furthermore, with regards to our product pipeline, please note that significant delays in the commercialization of Naltrexone 50 mg are expected as a result of the a notification received from the FDA reclassifying to a Prior

Approval Supplement, the Company's Changes Being Effected in 30 Days Supplement ("CBE-30") related to a change the manufacturing and packaging site of Naltrexone 50 mg.

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

For the fiscal year ended March 31, 2012, we sustained a negative cash flow from operations of approximately $0.4 million, compared with a positive cash flow from operations of approximately $1.6 million achieved during the prior fiscal year. Our working capital deficit at March 31, 2012 was approximately $3.2 million compared with working capital deficit of approximately $1.5 million at March 31, 2011. Please note that the working capital deficits include the entire principal amount due in relation to the NJEDA Bonds. This amount, totaling $3.4 million, is classified as a current liability due to the Notice of Default received from the Trustee in relation to the NJEDA Bonds. Please see "NJEDA Bonds" below.

Cash and cash equivalents at March 31, 2012, were approximately $0.7 million, a decrease of approximately $1.2 million from the approximately $1.9 million at March 31, 2011.

As of March 31, 2012, our principal source of liquidity was approximately $0.7 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.

Treppel $500,000 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. 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. 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 , which Form 8-K and exhibit 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 December 31, 2011, all of the proceeds were utilized by the Company for such stated purposes.

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

Company’s facility.

Bond issue costs of $354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,132 for the fiscal year March 31, 2012.

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

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

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

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

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

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

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

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

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

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

Our revenues for the year ended March 31, 2012 were $2,424,118 a decrease of $1,841,845 or approximately 43% from revenues for the comparable period of the prior year, and consisted of $1,120,050 in manufacturing fees, $655,857 in lab and product development fees and $648,211 in royalties and license fees. Revenues for the year ended March 31, 2011, consisted of $3,086,183 in manufacturing fees, $348,242 in lab and product development fees, and $831,538 in royalties and license fees. Manufacturing fees decreased by approximately 64% due to the removal from the market of the Lodrane® Extended Release Products, pursuant to a directive from the FDA issued in March 2011. Lab and product development fees increased by approximately 88% due to product development fees earned from the Hi-Tech Development Agreement and the Mikah Development Agreement, and fees earned from Elite's Development and License Agreement with a private Hong Kong-based company, offset by decreased lab stability study revenues relating the discontinuance of the Lodrane® Extended Release Products. Royalties and license fees decreased by 22% due to the removal from the market of the Lodrane® Extended Release Products as of August 30, 2011, offset by milestone payments received pursuant to the Precision Dose Agreement and related to the April 2011 launch of Phentermine 37.5 mg tablets and the March 2012 launch of Hydromorphone 8mg tablets. In-market sales of the Lodrane® Extended Release Products were only permitted for five of the twelve months in the year ended March 31, as compared to a full year of sales occurring during the comparable period of the prior year.

Research and development costs for the year ended March 31, 2012 were $1,735,689, an increase of $350,478 or approximately 25% from $1,385,211 of such costs for the comparable period of the prior year. The increase was primarily due to the shifting of personnel and operational resources from commercial manufacturing to product development as a result of the discontinuance of the Lodrane® Extended Release Products.

General and administrative expenses for the year ended March 31, 2012, were $1,410,192, an increase of $534,178, or approximately 61% from $876,014 of general and administrative expenses for the comparable period of the prior year. The increase was primarily due to overhead costs related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products, increased real estate taxes at the Northvale Facility and increased legal fees related to the conversion of Series B, C, D and E Preferred Shares to

Common Shares, and the preparation of the preliminary and final proxy statements which were filed during Fiscal 2012.

Depreciation and amortization for the year ended March 31, 2012 was $206,248, an increase of $32,884, or approximately 19%, from $173,364 for the comparable period of the prior year. The increase was primarily due to depreciation expense related to excess capacity at the Northvale Facility which has resulted from the discontinuance of the Lodrane® Extended Release Products.

Non-cash compensation through the issuance of stock options and warrants for the year ended March 31, 2012 was $24,453, a decrease of $17,563, or approximately 42% from $42,016 for the comparable period of the prior year. The decrease was due to the timing of the amortization schedule established at the time of issuance of the related stock options and warrants.

As a result of the foregoing, our loss from operations for the year ended March 31, 2012 was $1,966,138, compared to a loss from operations of $885,760 for the year ended March 31, 2011.

Other expenses for the year ended March 31, 2012 were a net expense of $13,576,088, an increase in other net expenses of $578,277 from the net other expense of $12,997,812 for the comparable period of the prior year. The increase in other expenses was due to derivative expenses relating to changes in the fair value of our preferred shares and outstanding warrants during the year ended March 31, 2012 totaling $12,672,032, as compared to a net derivative expense of $11,714,374 for the comparable period of the prior year. Please note that derivative income/(expenses) are most significantly determined by the closing price of the Company's Common Stock as of the end of each annual or quarterly reporting period, and also as of the date on which shares of the Company's convertible preferred stock are converted into common stock, with incomes being generated by decreases in such closing prices and expenses being incurred by increases in such closing prices. The closing price of the Company's Common Stock as of March 31, 2012 was $0.090, as compared to a closing price of $0.078 as of March 31, 2011. Closing prices on the various dates on which shares of convertible preferred stock were converted to common stock ranged from $0.07 to $0.24 during the year ended March 31, 2012. These variances in the closing price of the Company's Common Stock as compared with the closing price at the end of the immediately preceding fiscal year end were significant factors in the derivative income recorded during the year ended March 31, 2012.

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

Material Changes in Financial Condition

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

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. 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 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, 2012, 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, 2012. 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, 2012, 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 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On June 20, 2012, we requested that the Commission withdraw the registration statement on Form S-1 that we had filed on March 1, 2012 related to the transactions contemplated by the Securities Purchase Agreement with Socius CG II, Ltd. After discussions with the Commission, we determined that the Socius transaction as structured in the Socius

Agreement could not be implemented. Accordingly, we will not be proceeding with the Socius financing.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following sets forth biographical information about each of our directors and executive officers:

Name	Age	Position	Director / Officer Since
Jerry Treppel[1]	58	Chairman and Chief Executive Officer	November 2008
Barry Dash, Ph. D.	80	Director	April 2005
Chris Dick[2]	57	President, Chief Operating Officer and Director	October 2009[3]
Ashok G. Nigalaye, Ph.D.	60	Chief Scientific Officer and Director	June 2009[4]
Jeenarine Narine	62	Director	June 2009
Ram Potti	59	Director	June 2009
Jeffrey Whitnell	56	Director	October 2009
Carter J. Ward	48	Chief Financial Officer, Secretary and Treasurer	July 2009

(1) Mr. Treppel also served as Chairman of the Board since November 6, 2008 and CEO since September 15, 2009.

(2) Mr. Dick also serves as our Chief Operating Officer and, President.

(3) Mr. Dick previously served on our Board of Directors from October 2008 to June 2009, and was re-nominated and re-elected to the Board at the 2009 Stockholder meeting held on October 23, 2009.

(4) Dr. Nigalaye has served as a Director since June 2009 and as Chief Scientific Officer since September 2009.

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

Jerry Treppel has served as a Director since October 28, 2008, Chairman of the Board since November 6, 2008 and Chief Executive Officer since September 15, 2009. Mr. Treppel served as the managing member of Wheaten Capital Management LLC, a capital management company focusing on investment in the health care sector from 2003 to 2009. In October 2008, Mr. Treppel was appointed managing director of Ledgemont Capital Group LLC, a boutique merchant bank that provides access to capital and corporate advisory services to public and private companies. Over the past 20 years, Mr. Treppel was an equity research analyst focusing on the specialty pharmaceuticals and generic drug sectors at several investment banking firms including Banc of America Securities, Warburg Dillon Read LLC (now UBS), and Kidder, Peabody & Co. He previously served as a healthcare services analyst at various firms, including Merrill Lynch & Co. He also held administrative positions in the healthcare services industry early in his career. From 2003 to 2009, Mr. Treppel served as a member of the board of directors of Akorn, Incorporated (NASDAQ: AKRX), a specialty pharmaceutical company engaged in the development, manufacturing and marketing of branded and multi-source pharmaceutical products and vaccines. Mr. Treppel also served as the Chair of Akorn's Nominating and Corporate Governance Committee and as a member of its Audit Committee and Compensation

Committee. Mr. Treppel holds a BA in Biology from Rutgers College in New Brunswick, N.J., an MHA in Health Administration from Washington University in St. Louis, Mo., and an MBA in Finance from New York University. Mr. Treppel has been a Chartered Financial Analyst (CFA) since 1988. Mr. Treppel's knowledge of the pharmaceutical industry as well as his education credentials and his experience as a member of the board of directors of Akorn, Incorporated led to the conclusion that he is qualified to serve as a director.

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

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

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

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

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

Ram Potti has served as a Director since June 24, 2009, chairman of the Nominating Committee since October 23, 2009 and member of the Audit Committee since October 23, 2009. Mr. Potti 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. Potti has been the Vice President 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 handles the company's new ventures and products. From July 2008 to December 2010, Mr. Potti served as Epic Pharma's Vice President of Business Development. Mr. Potti is also the founder and current President of RSMB Investments LLC, an investment company that specializes in startup ventures in the healthcare and technology sectors. In addition, from 2002 to 2006, Mr. Potti was the President and Chief Operating Officer of Trigen Laboratories, a company which he founded that manufactures generic pharmaceutical products. Mr. Potti holds a B.S. in Chemistry from the University of Kerala, St. Albert's College. Mr. Potti's experience in developing business and products for Epic Pharma LLC 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.

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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, 2012, 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 2012. Specifically, as follows:

Name	Late Filings	No. of Transactions
Ashok Nigalaye	4	7
Ram Potti	4	7
Jeenarine Narine	4	7
Epic Investments LLC	4	7
Epic Pharma LLC	4	7

Committees of the Board

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

Audit Committee

During Fiscal 2012, 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).

Nominating Committee

During Fiscal 2012, the members of the Nominating Committee were Ram Potti (Chairman of the Nominating Committee), 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.

Compensation Committee

During Fiscal 2012, 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, 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, 2012, the members of the Compensation Committee were Barry Dash, Ashok Nigalaye and Jeffrey Whitnell. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants.

Named Executive Officers and Key Employees

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

- Jerry Treppel, Chief Executive Officer for the full year

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

These individuals are referred to collectively in this Annual Report on Form 10-K as the "Named Executive Officers".

Our executive compensation program

Overview

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

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

Elements of our executive compensation program

Base Salary

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

Bonuses

The Board of Directors may authorize us to give discretionary bonuses, payable in cash or shares of Common Stock, to the Named Executive Officers and other key employees. Such bonuses are designed to motivate the Named

Executive Officers and other employees to achieve specified corporate, business unit and/or individual, strategic, operational and other performance objectives.

Stock Options

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

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

Retirement and Deferred Compensation Benefits

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

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

Post-Termination/Change of Control Compensation

We do not presently provide the Named Executive Officers with any plan or arrangement in connection with any termination, including, without limitation, through retirement, resignation, severance or constructive termination (including a change in responsibilities) of such Named Executive Officer's employment with the Company. We also do no presently provide the Named Executive Officers any plan or arrangement in connection with a change in control of the Company.

Perquisites

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

Agreements with Named Executive Officers

Jerry Treppel

On December 1, 2008, Elite entered into a compensation agreement with Mr. Treppel (the "*First Treppel Agreement*") providing for the terms under which Mr. Treppel will serve as the non-executive Chairman of the Board. Pursuant to the First Treppel Agreement, Mr. Treppel will serve as the non-executive Chairman of the Board until immediately prior to the next annual meeting of the Company's stockholders; provided, however, that following such annual meeting, and each subsequent annual meeting of the Company's stockholders, if the Board elects Mr. Treppel as the

non-executive Chairman of the Board, the term of the First Treppel Agreement will be extended through the earlier of (a) the date of the next subsequent annual meeting of the Company's stockholders and (b) the date upon which Mr. Treppel no longer serves as the non-executive Chairman.

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

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

Under the First Treppel Agreement, Elite has also agreed to indemnify Mr. Treppel to the fullest extent permitted by law in accordance with the By-Laws of Elite against (a) reasonable expenses, including attorneys' fees, incurred by him in connection with any threatened, pending, or completed civil, criminal, administrative, investigative, or arbitrative action, suit, or proceeding (and any appeal therein) seeking to hold him liable for actions taken in his capacity as Chairman of the Board, and (b) reasonable payments made by him in satisfaction of any judgment, money decree, fine (including assessment of excise tax with respect to an employee benefit plan), penalty or settlement for which he may have become liable in any such action, suit or proceeding, provided that any such expenses or payments are not the result of Mr. Treppel's gross negligence, willful misconduct or reckless actions.

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

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

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

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

Chris C. Dick

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

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

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

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

Carter J. Ward

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

Hedging Policy

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

Options Exercises and Stock Vested

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

Pension Benefits

We do not provide pension benefits to the Named Executive Officers

Nonqualified Deferred Compensation

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

Potential Payments Upon Termination or Change of Control

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

Compensation of named executive officers

Summary Compensation Table

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

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

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

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

(3) Represents total salaries due to Mr. Dick pursuant to the Dick Employment. Of the total salary amount, $175,000 was paid in cash as salary in accordance with the Company's payroll practices, and $25,000 is to be paid via the issuance of Common Shares in lieu of cash. A total of 419,443 shares of Common Stock were issued to Mr. Dick in payment of salaries due to him for Fiscal 2011. A total of 175,501 shares of Common Stock were issued to, and 61,606 shares of Common Stock are due and owing to, Mr. Dick in payment of salaries due to him for Fiscal 2012.

(4) Represents amounts paid for auto allowance

(5) Represents total salaries due to Mr. Ward pursuant to the Ward Employment. Of the total salary amount, $125,000 was paid in cash as salary in accordance with the Company's payroll practices, and $25,000 is to be paid via the issuance of Common Shares in lieu of cash. A total of 419,443 shares of Common Stock were issued to Mr. Ward in payment of salaries due to him for Fiscal 2011. A total of 175,501 shares of Common Stock were issued to, and 61,606 shares of Common Stock are due and owing to, Mr. Ward in payment of salaries due to him for Fiscal 2012.

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

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock option awards held by Named Executive Officers as of March 31, 2012:

Name	Number of securities underlying unexercised options Exercisable (#)	Number of securities underlying unexercised options Unexercisable (#)	Equity Incentive Plan Awards: Number of securities underlying unexercised unearned options (#)	Options Exercise Price ($)	Option Expiration Date
Chris Dick					
	10,000 (1)	—	—	2.34	10/31/2012
	10,000 (1)	—	—	2.34	10/31/2012
	10,000 (1)	—	—	2.34	10/31/2012
	10,000 (2)	—	—	2.21	6/13/2013
	10,000 (2)	—	—	2.21	6/13/2013
	10,000 (2)	—	—	2.21	6/13/2013
	40,000 (3)	—	—	2.80	7/14/2015
	250,000 (4)	—	—	2.25	11/13/2016
	—	—	150,000 (5)	2.25	11/13/2016
	—	—	150,000 (5)	2.25	11/13/2016
	—	—	200,000 (7)	2.25	11/13/2016
	133,333 (8)	—	66,667 (8)	0.10	1/17/2020
Jerry Treppel					
	60,000 (9)	—	—	0.06	12/1/2018
	60,000 (10)	—	—	0.06	12/1/2018
	60,000 (11)	—	—	0.06	12/1/2018
Carter J. Ward					
	133,333 (8)	—	66,667 (8)	0.10	1/17/2020

(1) Options vested on November 1, 2003, 2004 and 2005, respectively.

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

(3) Options vested on July 14, 2005.

(4) Options vested on November 3, 2006.

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

(6) Reserved

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

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

(9) Options vested on December 1, 2009

(10) Options vested on December 1, 2010

(11) Options vest on December 1, 2011

DIRECTOR COMPENSATION

The following table sets forth information concerning director compensation for the year ended March 31, 2012:

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

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

(2) Represents directors fees earned during the quarter ended March 31, 2012 for which 49,285 shares of Common Stock is due and owing to each Director. As of the date of this Annual Report on Form 10-K, such shares have not yet been issued.

Director Fee Compensation

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

Director Equity Compensation

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

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

Other

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

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

The following table sets forth certain information, as of June 22, 2012 (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 22, 2012, we had 346,216,612 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 1,750 shares of Series E Preferred Stock outstanding as of Jun 22, 2012 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). The 1,450 shares of Series C Preferred Stock outstanding as of June 22, 2012 are nonvoting. As of June 22, 2012, none of the individuals listed below beneficially owned any shares of Series C Preferred Stock or Series E Preferred Stock, except for the following (as further described in the footnotes to the table): (a) 1,750 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 22, 2012. Except as otherwise indicated, the stockholders listed in the table have sole voting and investment powers with respect to the shares indicated.

Name and Address Of Beneficial Owner of Common Stock	Amount and Nature of Beneficial Ownership***		Percent (%) of Class Beneficially Owned	
Chris Dick, President and Chief Operating Officer	1,260,672	(1)		**
Barry Dash, Director	790,238	(2)		**
Jerry Treppel, Chairman of the Board and Chief Executive Officer	4,096,498	(3)		**
Ashok G. Nigalaye, Chief Scientific Officer and Director *	205,011,455	(4)	48	%
Jeenarine Narine, Director *	205,011,455	(4)	48	%
Ram Potti, Director *	204,603,506	(4)	48	%
Jeffrey Whitnell	621,872	(5)		**
Carter J. Ward, Chief Financial Officer	2,732,353	(6)		**
Epic Investments LLC 227-15 North Conduit Ave. Laurelton, NY 11413	204,322,588	(4)	48	%
Epic Pharma LLC 227-15 North Conduit Ave. Laurelton, NY 11413	204,322,588	(4)	48	%
All Directors and Officers as a group	210,052,206	(7)	50	%

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

(1) Includes vested options to purchase 483,333 shares of Common Stock, 715,733 shares of Common Stock and 61,606 shares of Common Stock due and owing to Mr. Dick as of March 31, 2012, for salaries earned for the quarter then ended, pursuant to the employment agreement between the Company and Mr. Dick dated November 13, 2009 (the "Dick Agreement"). In addition, Mr. Dick has been granted options to purchase 566,667 shares of Common Stock under the Company's 2004 Equity Incentive Plan which were not vested as on June 22, 2012 and accordingly not included as part of Mr. Dick's beneficial ownership. 500,000 of these non-vested options, having exercise prices that range from $2.21 per share to $2.34 per share, will vest upon the occurrence of certain events and 66,667 of the non-vested options, having an exercise price of $0.10 per share, are scheduled to vest on January 18, 2013.

(2) Includes options to purchase 120,000 shares of Common Stock, warrants to purchase 12,434 shares of Common Stock, 608,519 shares of Common Stock and 49,285 shares of Common Stock due and owing to Dr. Dash as of March 31, 2012 for Director's fees earned by Dr. Dash for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

(3) Includes 419,059 shares of restricted Common Stock, 1,432,082 shares of unrestricted Common Stock, warrants to purchase up to 1,991,430 shares of Common Stock, an option to purchase up to 180,000 shares of Common Stock, and 73,927 shares of Common Stock due and owing to Mr. Treppel as of March 31, 2012 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.

(4) Includes 1,750 shares of Series E Preferred Stock convertible into 71,688,118 shares of Common Stock, 25,112,722 shares of Common Stock and warrants to purchase 107,519,998 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 and Mr. Narine each own 639,582 shares of Common Stock and each have 49,285 shares of Common Stock due and owing to them as of March 31, 2012 for Director's fees earned by each of them 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 231,633 shares of Common Stock and has 49,285 shares of Common Stock due and owing to him as of March 31, 2012 for Director's fees earned for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

(5) Includes 572,587 shares of Common Stock and 49,285 shares of Common Stock due and owing to Mr. Whitnell as of March 31, 2012 for Director's fees earned by Mr. Whitnell for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees.

(6) Includes vested options to purchase 133,333 shares of Common Stock, warrants to purchase 666,667 shares of Common Stock, 1,870,747 shares of Common Stock and 61,606 shares of Common Stock due and owing to Mr. Ward as of March 31, 2012, for salaries earned for the quarter then ended, pursuant to the employment agreement between the Company and Mr. Ward dated November 13, 2009 (the "Ward Agreement"). In addition, Mr. Ward has been granted options to purchase 66,667 shares of Common Stock under the Company's 2004 Equity Incentive Plan which were not vested as on June 22, 2012 and accordingly not included as part of Mr. Ward's beneficial ownership. These non-vested options, having an exercise price of $0.10 per share, are scheduled to vest on January 18, 2013.

(7) Includes 1,750 shares of Series E Preferred Stock convertible into 71,688,118 shares of Common Stock, warrants to purchase 110,190,529 shares of Common Stock, vested options to purchase 916,667 shares of Common Stock, 26,811,578 shares of Common Stock and 443,564 shares of Common Stock due and owing to the Chairman, Directors and Officers as of March 31, 2012, for Chairman Fees, Directors Fees and salaries earned for the quarter then ended, pursuant to the Company's policy regarding payment of Directors' fees, the Dick Agreement and the Ward Agreement, as applicable.

In addition, there are options to purchase up to 633,333 Common Shares that are not vested as of June 22, 2012, and are accordingly not included as part of the aggregate beneficial ownership of the Company's Directors and Officers.

2,085,640 shares of Common Stock issued to the Chairman and Directors in payment of Chairman and Director Fees pursuant to the Company's policy regarding payment of Chairman and Directors Fees, 852,384 shares of Common Stock issued pursuant to employment contracts with Officers, 3,112.5 shares of Series E Preferred Stock convertible into 126,674,934 shares of Common Stock, Warrants to purchase 121,271,942 shares of Common Stock, Options to purchase 1,416,668 shares of Common Stock, 979,799 shares of Common Stock, 1,505,601 of Common Shares due and owing to the Chairman and Directors as of December 31, 2011 for Chairman's and Director's Fees earned during the 12 month period ending on such date pursuant to the Company's policy regarding payment of Chairman and Director's Fees, and 579,078 shares of Common Stock due and owing to Officers as of December 31, 2011 for salaries earned during the 12 month period ended on such date pursuant to the employment contracts of each Officer. In addition, there are options to purchase 133,332 shares of Common Stock which have been granted to Officers of the Company but which were not vested as on February 21, 2012, and accordingly not included in the beneficial ownership amounts. These options are scheduled to vest on January 18, 2013.

Changes in Control

The following information is provided with respect to any arrangements known to the Company the operation of which may at a subsequent date result in a change of control of the Company.

As of June 29, 2012, Epic held a beneficial interest in an aggregate of 204,322,588 shares of Common Stock, as further described in footnote 4 of the above table listing the amount and nature of beneficial ownership. Further, the 1,750 shares of Series E Preferred Stock in which Epic has a beneficial interest as of June 29, 2012 are entitled to vote 71,688,118 shares of Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting).

In addition, in connection with subsequent closings of the transactions contemplated by the Epic Strategic Alliance Agreement, Epic could acquire an additional 437.5 shares of Series E Preferred Stock. Further, with respect to the products developed by Epic at the Facility under the Epic Strategic Alliance Agreement, the Company would also be obligated to issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of its Common Stock upon the receipt by Elite from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at Elite's facility and (b) up to an aggregate of 36,000,000 additional shares of its Common Stock following the receipt by Elite from Epic of written notices of Epic's receipt from the FDA of approval for certain controlled-release and immediate-release products developed by Epic at the Facility.

If Elite is required to issue such additional securities to Epic in accordance with the Epic Strategic Alliance Agreement, Epic could beneficially own in excess of 50% of the issued and outstanding Common Stock or other voting securities of the Company. Further, under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that Epic will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a majority of the Board of Directors.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Certain Related Person Transactions

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

On March 18, 2009, the Company entered into the Epic Strategic Alliance Agreement with Epic Pharma, LLC and Epic Investments, LLC, a subsidiary controlled by Epic Pharma LLC, as disclosed in 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.

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

With regards to synergies related to raw materials usage, the strategic alliance allowed the Company to purchase such raw materials from Epic, at the Epic acquisition cost, without markup. In all cases, the acquisition cost of Epic was lower than those costs available to the Company, mainly as a result of efficiencies of scale generated by significantly larger volumes purchased by Epic during the course of their normal operations. During the fiscal years ended 3/31/2012 and 3/31/2011, an aggregate amount of $15,552 and $232,305, respectively, in such materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma's acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC's acquisition cost.

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

During the fiscal year ended 3/31/2012, an aggregate amount of $133,003 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company. During the fiscal year ended 3/31/2011, an aggregate amount of $73,440 was paid to Epic as reimbursement for costs associated with facility maintenance, engineering and regulatory resources utilized by the Company.

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

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

The Company also purchased an ANDA for Phentermine 37.5mg tablets from Epic Pharma LLC for a cost of $450,000. Please refer to Exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010 for further details on this ANDA purchase.

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

During the fiscal year ended March 31, 2011, the Company also performed method development services for Epic Pharma LLC, for which it was paid $25,000, sold retired equipment to Epic for $30,000 and sold excess raw materials to Epic for a total of $2,903.

On June 12, 2012, we entered into a bridge loan agreement with Jerry Treppel, our Chairman and CEO, pursuant to which, we have the right, in our sole discretion, to a line of credit in the maximum principal amount of up to $500,000 at any one time. For more information, please see “Treppel $500,000 Bridge Revolving Credit Line” in Item 7, “Management’s Discussion and Analysis of Financial Condition and Results Of Operation; Liquidity and Capital Resources”.

Director Independence

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Company's independent registered public accounting firm is Demetrius and Company 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 2011 and Fiscal 2012.

	Fiscal 2012	Fiscal 2011
Audit Fees	76,250	78,250
Audit-Related Fees	3,000	—
Tax Fees	—	—
All Other Fees	475	1,175

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.

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 2012 and 2011.

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 No.	Description
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.*
3.2(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	Socius Warrant to Purchase Common Stock, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
4.2	Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.*
4.3	Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, 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.*
4.4	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.*
4.5	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.*
4.6	Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.*
4.7	Warrant to purchase 50,000 shares of Common Stock issued to Jason Lyons incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.*
4.8	Form of Warrant to purchase shares of Common Stock issued to designees of lender with respect to financing of an equipment loan incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.*
4.9	Form of Short Term Warrant to purchase shares of Common Stock issued to purchasers in the private placement which initially closed on October 6, 2004 (the "Series A Financing"), incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.*
4.10	Form of Long Term Warrant to purchase shares of Common Stock issued to purchasers in the Series A Financing, incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.*
4.11	Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series A Financing, incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.*

4.12	Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.*
4.13	Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.*
4.14	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.*
4.15	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.*
4.16	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.*
4.17	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.*
4.18	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.*
4.19	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.*
4.20	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.*
4.21	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.*
4.22	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.*

4.23	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.*
4.24	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.*
4.25	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.*
4.26	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.*
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	Amended and Restated Employment Agreement dated as of September 2, 2005 between Bernard Berk and the Company, incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
10.5	Option Agreement between Bernard Berk and the Company dated as of July 23, 2003 incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q for three months ended June 30, 2003 (the "June 30, 2003 10Q Report").
10.6	Option Agreement between Bernard Berk and the Company dated as of July 23, 2003, incorporated by reference to Exhibit 10.8 to the June 30, 2003 10Q Report.
10.7	Amendment, dated as of September 2, 2005, by and between, the Company and Bernard Berk, to the Stock Option Agreement, dated as of July 23, 2003, incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
10.8	Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.

10.9	Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
10.10	Engagement letter dated February 26, 1998, between Gittelman & Co. P.C. and the Company incorporated by reference to Exhibit 10.10 to the Form 10-K for the period ended March 31, 2004 filed with the SEC on June 29, 2004.
10.11	Product Development and Commercialization Agreement, dated as of June 21, 2005, between the Company and IntelliPharmaceutics, 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).
10.12	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).
10.13	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.
10.14	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.
10.15	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.
10.16	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.
10.17	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.
10.18	Form of Warrant Exercise Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 14, 2005 and filed with the SEC on December 20, 2005.
10.19	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 December 14, 2005 and filed with the SEC on December 20, 2005.

10.20	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.
10.21	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 March 15, 2006 and filed with the SEC on March 16, 2006.
10.22	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.
10.23	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.
10.24	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.
10.25	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.
10.26	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.
10.27	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).
10.28	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.
10.29	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.
10.30	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.
10.31	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.

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10.32	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.
10.33	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.
10.34	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.
10.35	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.
10.36	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.
10.37	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.
10.38	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.
10.39	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.
10.40	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.
10.41	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.
10.42	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.
10.43	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.

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10.44	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.
10.45	Consulting Agreement, dated as of October 20, 2008, by and between the Company and Parallex 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.
10.46	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.
10.47	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.
10.48	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.
10.49	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.
10.50	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.
10.51	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.
10.52	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.
10.53	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.
10.54	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.
10.55	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.

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10.56	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.
10.57	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.
10.58	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.
10.59	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
10.60	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
10.61	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
10.62	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.
10.63	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).
10.64	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).

10.65	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).
10.66	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).
10.67	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).
10.68	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).
10.69	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.
10.70	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).
10.71	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).
10.72	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.

10.73	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.
10.74	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.
10.75	Form of Lock-Up Agreement (included as Exhibit D to the Securities Purchase Agreement with Socius mentioned in 10.2 above), incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on January 5, 2012.
10.76	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.
10.77	Development And License Agreement between the Company and a Hong Kong-based client dated March 16, 2012.** Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
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, 2012 and 2011, 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**

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* 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.

*** As contemplated by SEC Release No. 33-8212, 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.

**** 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.

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 29, 2012

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

Dated: June 29, 2012

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.

Signature	Title	Date
/s/ Jerry Treppel	Chairman, Chief Executive Officer	June 29, 2012
/s/ Chris Dick	President, Chief Operating Officer, Director	June 29, 2012
/s/ Carter J. Ward	Chief Financial Officer, Treasurer, Secretary	June 29, 2012
/s/ Barry Dash	Director	June 29, 2012
/s/ Jeenarine Narine	Director	June 29, 2012
/s/ Ashok Nigalaye	Director	June 29, 2012
/s/ Ram Potti	Director	June 29, 2012
/s/ Jeffrey Whitnell	Director	June 29, 2012

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2012 AND 2011

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Report of Independent Registered Public Accounting Firm

To The Board of Directors and

Shareholders of Elite Pharmaceuticals, Inc. & Subsidiaries

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiaries ("the Company") as of March 31, 2012 and 2011 and the related consolidated statements of operations, stockholders' deficit and cash flows for each of the years in the two-year period ended March 31, 2012. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2012 and 2011 and the results of their operations and their cash flows for each of the years in the two year period ended March 31, 2012 in conformity with accounting principles generally accepted in the United States of America.

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

/s/Demetrius & Company, L.L.C.

Wayne, New Jersey

June 29, 2012

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2012 and 2011

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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2012 and 2011

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

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY

FOR THE YEAR ENDED MARCH 31, 2011

	Common Stock		Additional Paid-In	Treasury Stock		Accumulated	Stockholders'
	Shares	Amount	Capital	Shares	Amount	Deficit	Deficit
Balance at Mar 31, 2010	83,950,168	$83,950	$90,903,896	100,000	$(306,841)	$(101,278,870)	$(10,597,865)
Net Income						(13,582,159)	(13,582,159)
Common shares issued in lieu of cash in payment of preferred share derivative interest expense	21,241,590	21,242	1,261,999				1,283,240
Common shares issued pursuant to the conversion of Series D Convertible Preferred Derivatives	70,649,154	70,649	4,394,935				4,465,584
Non-cash compensation through the issuance of stock options			42,017				42,017
Common shares issued pursuant to ANDA purchase agreement dated 5/18/2010	937,500	938	74,062				75,000
Common shares issued in lieu of cash in payment of consulting expenses	343,425	343	13,394				13,737
Common shares issued in payment of Director's Fees	2,493,589	2,494	97,249				99,743
Common shares issued in payment of employee salaries	930,231	930	36,280				37,210

Proceeds received in exchange for beneficial conversion features embedded in Series E Preferred Shares			292,213				292,213
Balance at Mar 31, 2011	180,545,657	$180,546	$97,116,044	100,000	$(306,841)	$(114,861,029)	$(17,871,280)

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS (DEFICIT) EQUITY

FOR THE YEAR ENDED MARCH 31, 2012

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

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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(page 1 of 2)

	Years Ended March 31,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Loss from continuing operations	$(15,058,274)	$(13,582,159)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	484,151	483,473
Change in fair value of warrant derivative liability	1,444,075	1,297,997
Change in fair value of preferred shares derivative liability	11,227,957	10,416,375
Discount in Series E issuance attributable to embedded beneficial ownership feature	250,000	292,213
Preferred shares derivative interest satisfied by the issuance of common stock	636,179	1,283,240
Legal and consulting expenses satisfied by the issuance of common stock	—	13,737
Salaries and Directors Fees satisfied by the issuance of common stock	213,230	136,953
Non-cash compensation satisfied by the issuance of common stock, options and warrants	24,452	42,017
Non-cash rent expense	11,090	48,064
Impairment of Intangible Assets	—	440,000
Non-cash lease accretion	1,276	20,682
Changes in assets and liabilities:		
Accounts and interest receivable	174,820	(166,706)
Inventories	311,480	754,931
Prepaid expenses and other current assets	5,767	(1,962)
Security deposit	13,464	(13,725)
Accounts payable, accrued expenses and other current liabilities	(133,749)	87,686
NET CASH (USED IN) PROVIDED BY OPERATING ACTIVITIES	(394,082)	1,552,815
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(201,777)	(178,169)
Cost of leasehold improvements	(421,556)	(343,631)
Proceeds from sale of retired equipment	—	30,000
Costs incurred for intellectual property assets	(45,292)	(866,150)
Withdrawals from restricted cash, net	10,835	3,416
NET CASH (USED IN) INVESTING ACTIVITIES	(657,790)	(1,354,533)
CASH FLOWS FROM FINANCING ACTIVITIES		
Other loan payments	(13,411)	(13,106)
Costs associated with raising capital	(342,169)	—
Proceeds from issuance of Series E Convertible Preferred Stock and Warrants	250,000	1,062,500
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	**(105,580)**	1,049,394
NET CHANGE IN CASH AND CASH EQUIVALENTS	(1,157,451)	1,247,676

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

Schedule continues on next page

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(page 2 of 2)

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

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2012 AND 2011

NOTE 1 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

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

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of Elite Pharmaceuticals, Inc. and its wholly-owned subsidiary, Elite Laboratories, Inc. ("Elite Labs") (collectively the "Company") for the years ended March 31, 2012 ("Fiscal Year 2012") and 2011 ("Fiscal Year 2011"). Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2012, the financial statements of all wholly-owned entities are consolidated and all significant intercompany accounts are eliminated upon consolidation.

NATURE OF BUSINESS

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

CASH AND CASH EQUIVALENTS

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

INVENTORIES

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

LONG-LIVED ASSETS

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

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

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

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

RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense as incurred.

CONCENTRATION OF CREDIT RISK

The Company maintains cash balances, which, at times, may exceed the amounts insured by the Federal Deposit Insurance Corp. Uninsured balances at March 31, 2012 are $668,407. Management does not believe that there is any significant risk of losses.

The Company in the normal course of business extends credit to its customers based on contract terms and performs ongoing credit evaluations. An allowance for doubtful accounts due to uncertainty of collection is established based on historical collection experience. Amounts are written off when payment is not received after exhaustive collection efforts. During Fiscal 2011 and Fiscal 2012 the Company generated all its revenues from four companies. The termination of the contracts with either of such four companies will result in the loss of a significant amount of revenues currently being earned.

USE OF ESTIMATES

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

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

INCOME TAXES

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

GAAP prescribes a recognition threshold and measurement attribute for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. GAAP requires that the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. No adjustments related to uncertain tax positions were recognized during the years ended March 31, 2012 and March 31, 2011.

The Company recognizes interest and penalties related to uncertain tax positions as a reduction of the income tax benefit. No interest and penalties related to uncertain tax positions were accrued as of March 31, 2012 and March 31, 2011.

The Company operates in multiple tax jurisdictions within the United States of America. Although we do not believe that we are currently under examination in any of our major tax jurisdictions, we remain subject to examination in all of our tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2012, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal, 2008 and forward, and State, 2004 and forward. The Company does not expect to have a material change to unrecognized tax positions within the next twelve months.

EARNINGS PER COMMON SHARE

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

REVENUE RECOGNITION

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

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

Revenues derived from providing research and development services under contracts with other pharmaceutical companies are recognized when earned. These contracts provide for non-refundable upfront and milestone payments. Because no discrete earnings event has occurred when the upfront payment is received, that amount is deferred until the achievement of a defined milestone. Each nonrefundable milestone payment is recognized as revenue when the performance criteria for that milestone have been met. Under each contract, the milestones are defined, substantive effort is required to achieve the milestone, the amount of the non-refundable milestone payment is reasonable, commensurate with the effort expended, and achievement of the milestone is reasonably assured.

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

TREASURY STOCK

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

FAIR VALUE OF FINANCIAL INSTRUMENTS

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

STOCK-BASED COMPENSATION

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

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

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

The compensation expense recognized for the years ended March 31, 2012 and 2011 was $24,453 and $42,016, respectively.

FAIR VALUE MEASUREMENTS

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

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

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

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

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

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial position or results of operations upon adoption.

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

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

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

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

NOTE 2 MANAGEMENT'S LIQUIDITY PLANS

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

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

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

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

NOTE 3 INVENTORIES

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

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

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

The Inventory Valuation Reserve as of March 31, 2011, consists of raw materials with an aggregate cost of $918,355 having no commercial value due to the FDA's decision to remove Lodrane from the market and the FDA's recent reclassification of the Company's application to transfer the manufacturing site of Hydromorphone to its facilities from CBE-30 to Prior Approval, as well as $35,762 in expired raw materials which have not yet been destroyed and $93,339 in mark-to-market adjustments required to fairly state the Company's raw materials inventory at the lower of cost or market, with current replacement cost being the standard upon which the market value is determined.

Please refer to the Current Reports on Form 8-K filed with the SEC on March 4, 2011 and June 6, 2011 for details on the FDA's decision to remove Lodrane from the market and the FDA's reclassification of the Company's application for transfer of manufacturing site, respectively, with such filings being herein incorporated by reference.

NOTE 4 - PROPERTY AND EQUIPMENT

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

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

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

Depreciation and amortization expense amounted to $484,156 and $483,473 for the years ended March 31, 2012 and 2011, respectively.

NOTE 5 - INTANGIBLE ASSETS

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

As of March 31, 2012 and 2011, the following costs were recorded as intangible assets on the Company's balance sheet:

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

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

The costs incurred in patent applications totaling $45,292 and $51,152 for the 2012 and 2011 fiscal years, were all related to our abuse resistant and extended release opioid product lines. The Company is continuing its efforts to achieve approval of such patents. Additional costs incurred in relation to such patent applications will be capitalized as intangible assets, with amortization of such costs to commence upon approval of the patents.

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

The ANDA acquisition costs of $890,000 incurred during the 2011 fiscal year, are related to our acquisition of the ANDA's for Hydromorphone 8mg, Naltrexone 50mg and Phentermine 37.5mg tablets. For further details on these acquisitions, please refer to the current reports on Form 8-K filed with the SEC on May 24, 2010 for the Hydromorphone ANDA acquisition and September 1, 2010 for the Naltrexone and Phentermine ANDA acquisitions, such filings being herein incorporated by this reference. In addition, please refer to exhibits 10.4, 10.5 and 10.7 of the quarterly report on Form 10-Q filed with the SEC on November 15, 2010 for the purchase agreements for Hydromorphone, Naltrexone, and Phentermine, respectively, such filings being herein incorporated by this reference.

The Company has successfully transferred production of the Phentermine 37.5mg product to its facilities and has commenced commercial production of this product. Please refer to the current report on Form 8-K, filed with the SEC on April 7, 2011, such filing being herein incorporated by reference.

On May 31, 2011, the Company received a letter from the FDA responding to a Changes Being Effected in 30 Days ("CBE 30") supplement filed by the Company with the agency to change the manufacturing and packaging location of the Hydromorphone Hydrochloride Tablets USP, 8mg ANDA purchased from Mikah Pharma. The letter from the FDA informed the Company that the agency has reclassified the application as a prior approval supplemental application which will delay the commercialization of the product. The delay imposed by such reclassification was a significant detrimental factor to the value of the Hydromorphone AND. In accordance with GAAP, the Company recorded an impairment equal to the full historical cost, with such impairment being included in the financial statements issued for Fiscal 2011.

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

The Company has also recorded an impairment equal to the full historical cost of the Naltrexone 50mg ANDA, as the reason given by the FDA for the reclassification of the Company's application filed with the FDA for Hydromorphone

may also apply to a similar application filed by the Company with the FDA for the transfer of manufacturing and packaging for Naltrexone 50mg. Formal notification of the FDA's reclassification of the Company's CBE 30 application to a prior approval supplement was received by the company on December 14, 2011.

NOTE 6 INVESTMENT IN NOVEL LABORATORIES INC.

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

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

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

We also know from public information that Perrigo Company acquired rights in 2010 for an undisclosed amount to an additional Novel ANDA approved in 2010 for the product HalfLytely®. Novel believes this is a first to file ANDA. Perrigo expects to be in a position to launch a generic version of this product later this year and they expect to have 180 days of generic exclusivity. Novel will manufacture the product exclusively for Perrigo. Annual sales for the branded product were approximately $80 million according to Wolters Kluwer.

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

- A significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee
- A significant adverse change in the regulatory, economic, or technological environment of the investee
- A significant adverse change in the general market condition of either the geographic area or the industry in which the investee operates
- A bona fide offer to purchase (whether solicited or unsolicited), an offer by the investee to sell, or a completed auction process for the same or similar security for an amount less than the cost of the investment

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

A review and assessment of all documents available, public announcements by Novel and communications with the management of Novel does not indicate the existence of impairment indicators. Accordingly, the Company determined that no impairment is required in the valuation of its investment in Novel as of March 31, 2012. The valuation of the Company's investment in Novel remains at $3,329,322, an amount equal to the valuation as of March 31, 2011 with no impairment write downs.

NOTE 7 - NJEDA BONDS

On September 2, 1999, the Company completed the issuance of tax exempt bonds by the New Jersey Economic Development Authority ("NJEDA" or the "Authority"). The aggregate proceeds from the issuance of the fifteen year term bonds were $3,000,000. Interest on the bonds accrues at 7.75% per annum. A portion of the proceeds were used by the Company to refinance its land and building, and the remaining proceeds were intended to be used for the purchase of manufacturing equipment and building improvements.

On August 31, 2005, the Company successfully completed a refinancing of a prior 1999 bond issue through the issuance of new tax-exempt bonds (the "Bonds"). The refinancing involved borrowing $4,155,000, evidenced by a 6.5% Series A Note in the principal amount of $3,660,000 maturing on September 1, 2030 and a 9% Series B Note in the principal amount of $495,000 maturing on September 1, 2012. The net proceeds, after payment of issuance costs, were used (i) to redeem the outstanding tax-exempt Bonds originally issued by the Authority on September 2, 1999, (ii) refinance other equipment financing and (iii) for the purchase of certain equipment to be used in the manufacture of pharmaceutical products. As of December 31, 2011, all of the proceeds were utilized by the Company for such stated purposes.

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

Bond issue costs of $354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond issuance costs amounted to $14,132 for the fiscal year March 31, 2012.

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

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

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

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

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

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

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

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

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

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

	2012	2011
Refinanced NJEDA Bonds	$3,385,000	$3,385,000
Current portion	(3,385,000)	(3,385,000
Long term portion, net of current maturities	$—	$—

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

YEAR ENDING MARCH 31,	AMOUNT
2013	$730,000
2014	185,000
2015	195,000
2016	210,000
2017	220,000
Thereafter	1,845,000
	$3,385,000

NOTE 8 - LOANS PAYABLE AND LONG TERM DEBT

Loans payable and long term debt consisted of the following:

	March 31, 2012		March 31, 2011	
	Current	Long-Term	Current	Long-Term
Note payable to First Niagara Bank in 60 monthly installments of $1,180, including interest at the rate of 9.00% per annum; Final payment in September 2012 ; Secured by vehicle purchased with proceeds of loan	$6,923	$—	$13,105	$6,717
Capital lease payable to Shimadzu Financial Services; 24 payments of $594; Final payment due in March 2014	6,393	6,295		