ELITE PHARMACEUTICALS INC /DE/
Form 10-K
June 29, 2011

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, 2011

¨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)

Delaware	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). The registrant is not yet subject to this requirement.	Yes ¨	No x
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K.	Yes ¨	No ¨

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, 2010, 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	5,559,405	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	243,363,531	June 24, 2011

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K (e.g., Part I, Part II, etc.) into which the document is incorporated: (1) Any annual report to security holders; (2) Any proxy or information statement; and (3) Any prospectus filed pursuant to Rule 424(b) or (c) under the Securities Act of 1933, as amended. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980).

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. Many of these risks and uncertainties are discussed in this report, particularly in the sections titled “Business”, “Risk Factors” and “Management’s Discussion and Analysis of Financial Conditions and Results of Operations”. When used in this Annual 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,” “an “estimate,” or “continue” or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. 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.

Any reference to “Elite”, the “Company”, “we”, “us”, “our” or the “Registrant” means Elite Pharmaceuticals Inc. an subsidiaries.

Table of Contents

PART I

ITEM 1 BUSINESS

General

Elite Pharmaceuticals, Inc. ("Elite Pharmaceuticals") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiaries, Elite Laboratories, Inc. ("Elite Labs") and Elite Research, Inc. ("Elite Research"), were incorporated on August 23, 1990 and December 20, 2002, respectively, under the laws of the State of Delaware.

On October 24, 1997, Elite Pharmaceuticals merged with and into our predecessor company, Prologica International, Inc. ("Prologica"), an inactive publicly held Pennsylvania corporation. At the same time, Elite Labs merged with a wholly-owned subsidiary of Prologica. Following these mergers, Elite Pharmaceuticals survived as the parent to its wholly-owned subsidiary, Elite Labs.

On September 30, 2002, pursuant to a termination agreement, dated as of September 30, 2002 (the "Elan Termination Agreement"), between us and Elan Corporation, plc and Elan International Services, Ltd. (together "Elan"), we acquired from Elan its 19.9% interest in Elite Research, Ltd. ("ERL"), a joint venture formed between Elite and Elan in which our initial interest was 80.1% of the outstanding capital stock (100% of the outstanding common stock). As a result of the termination of the joint venture, we owned 100% of ERL's capital stock. On December 31, 2002, ERL (a Bermuda Corporation) was merged into Elite Research, our wholly-owned subsidiary.

The address of our principal executive offices and our telephone and facsimile numbers at that address are:
Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, New Jersey 07647
Phone No.: (201) 750-2646
Facsimile No.: (201) 750-2755.

We file registration statements, periodic and current reports, proxy statements and other materials with the Securities and Exchange Commission (the "SEC"). You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.W., Washington, DC 20549, on official business days during the hours of 10:00 am to 3:00 pm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. You may also visit our website at www.elitepharma.com for information regarding the Company including information relating to our SEC filings.

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 one product, Phentermine 37.5mg tablets, currently being sold commercially.

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 Products"). On March 3, 2011, the U.S. Food and Drug Administration ("US-FDA") announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The Lodrane Products were included in the FDA list of 500 products. After this announcement by the US-FDA, the Company's customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products has ceased. 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.

The Lodrane Products were responsible for 97% and 100% of the Company's revenues for Fiscal 2011 and Fiscal 2010, respectively.

ECR (the owner and marketer of the Lodrane Products) has 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 US-FDA with relation to the Lodrane Products.

Elite also purchased from Mikah Pharma LLC, an approved Abbreviated New Drug Applications ("ANDAs") for Hydromorphone 8 mg and 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 and with ThePharmaNetwork for methadone 10 mg.

The Company has a pipeline of additional generic drug candidates under active development, including, without limitation, ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-a-day oxycodone product.

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 abbreviated new drug applications ("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 Abbreviated New Drug Application 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. A current report on form 8-K was filed on May 24, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

For further details on the Hydromorphone Agreement, please refer to Exhibit 10.4 to the Quarterly Report on Form 10-Q, filed with the SEC on November 15, 2010, and incorporated herein by reference.

On May 31, 2011, the Company received a letter from the US Food and Drug Administration (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 will delay the commercialization.

A current report on form 8-K was filed on June 6, 2011 in relation to this announcement, such filing being incorporated herein by this reference.

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

This product is included in the license and manufacturing agreements executed with Precision Dose Inc ("Precision Dose") and its wholly owned subsidiary, TAGI Pharma Inc ("TAGI") and dated September 10, 2010. A current report on form 8-K was filed on September 16, 2010, in relation to the signing of this agreement, such filing 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 Abbreviated New Drug Application number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto (the "ANDA"), that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in the 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. A current report on form 8-K was filed on August 27, 2010 in relation to this announcement, such filing being incorporated herein by this reference. Please also refer to exhibit 10.5 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

The transfer of production of Naltrexone Hydrochloride Tablets USP, 50mg ("Naltrexone 50mg Tablets") from Mikah to the Facility is currently in progress. Similar to Hydromorphone 8 mg, The Company also recorded an impairment of this product, Naltrexone 50 mg, in an amount equal to the entire purchase price of the acquisition since it could also be affected in the same manner as hydromorphone.

Elite's Purchase of a Generic Phentermine Product

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement (the "Phentermine Purchase Agreement") with Epic Pharma LLC (the "Seller") for the purpose of acquiring from the seller an Abbreviated New Drug Application for a generic phentermine product (the "Phentermine ANDA"), with such being filed with, but not yet approved by the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the Company announced the approval by the FDA of 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. Current reports on form 8-K were filed on September 10, 2010 and February 4, 2011 in relation to the Phentermine Purchase Agreement and the Phentermine ANDA, with such filings being incorporated herein by this reference. Please also refer to exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

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 current report on form 8-K was filed on September 16, 2010 in relation to signing of this agreement, such filing being incorporated herein by this reference

Licensing Agreement with Precision Dose Inc.

On September 10, 2010, Elite Pharmaceuticals Inc. ("Elite") executed a License Agreement with Precision Dose, Inc. ("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. 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 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 6 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. A current report on form 8-K

was filed on September 10, 2010 in relation to this announcement, such filing 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 $1,385,211 for the fiscal year ended March 31, 2011 ("Fiscal 2011") and $794,433 for the fiscal year ended March 31, 2010 ("Fiscal 2010") 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 Pharmaceuticals, Inc. announced that the company made the initial shipment of phentermine HCl 37.5 mg tablets to TAGI Pharma, a wholly owned subsidiary of Precision Dose. 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.

A Current Report on form 8-K was filed on April 7, 2011 in relation to this announcement, such filing being incorporated herein by this reference.

Contract Manufacturing

Subsequent to March 31, 2011 and prior to the date of filing of this Annual Report on Form 10-K, Elite entered into two separate contractual relationships for the contract manufacturing by Elite for three different generic products. As these contracts were executed after March 31, 2011, they had no effect on the results presented in this Annual Report on Form 10-K.

On June 1, 2011, Elite Pharmaceuticals Inc. ("Elite") executed a Manufacturing and Supply Agreement (the "Agreement") with Mikah Pharma, LLC ("Mikah") to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg (the "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 this Agreement; Elite shall 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 Products for commercial sale by Mikah or its designees in accordance with the terms of this Agreement. During the term of this Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this 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 Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch. The Manufacturing and Supply Agreement has a term of five (5) years and shall automatically renew for additional periods of one (1) year unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term.

9

Transfer of the manufacturing site to Elite's Facility is in progress as of the date of filing of this Annual Report on Form 10-K.

A Current Report on Form 8-K was filed on June 7, 2011 in relation to this announcement, such filing being herein incorporated by this reference.

On June 29, 2011, Elite Pharmaceuticals, Inc. announced that it 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 Company expects to commence commercial contract manufacturing and packaging operations pursuant to this agreement during 2011.

A Current Report on Form 8-K was filed on June 29, 2011 in relation to this announcement, such filing being herein incorporated by this reference.

Manufacturing Site Transfers in Progress

Elite is currently engaged in the transfer of the manufacturing site for the following two generic products for which it purchased approved ANDA's during the fiscal year ended March 31, 2011: Hydromorphone 8mg and Naltrexone 50mg tablets.

Please refer to the sections above titled "Elite's Purchase of a Generic Hydromorphone HCl Product" and "Elite's Purchase of a Generic Naltrexone Product" for further details on the transfer of the manufacturing site for Hydromorphone 8mg and Naltrexone 50mg, respectively.

Discontinued Products

Elite manufactured two once-daily allergy products, Lodrane 24® and Lodrane 24D®, that were co-developed with our partner, ECR Pharmaceuticals ("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 are being marketed by ECR which also has the responsibility for regulatory matters. In addition to receiving revenues for the manufacture of these products, Elite receives 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, 2011 and 2010 aggregated $3,917,721 and, $3,339,870, respectively.

Since January, 2010, the Company has performed laboratory stability studies of Lodrane24® and Lodrane 24D®, for ECR, on a contract basis. Elite's revenues from such contract laboratory services were $348,242 and $4,429 for Fiscal 2011 and Fiscal 2010, respectively.

On March 3, 2011, the U.S. Food and Drug Administration ("US-FDA") announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market. The Lodrane Products were included in the FDA list of 500 products. After this announcement by the US-FDA, the Company's customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products has ceased.

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.

ECR (the owner and marketer of the Lodrane Products) has 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 US-FDA with relation to the Lodrane Products.

Products Under Development

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. 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 we have discussions ongoing in Europe for the licensing of this product. We are 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.

ELI-216 utilizes Elite Pharmaceuticals' 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 has 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") of 7.5 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".

Elite met with the FDA for a Type C clinical guidance meeting regarding the NDA development program for ELI-216. Elite has incorporated the FDA's guidance into its developmental plan. Elite has obtained a special protocol assessment, or SPA, with the FDA for the ELI-216 Phase III protocol. Elite will conduct additional Phase I studies including, but not limited to, food effect, ascending dose and multi-dose studies.

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has currently 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.

Under the Epic Strategic Alliance Agreement (i) at least eight additional generic drug products will be developed by Epic at the Facility with the intent of filing abbreviated new drug applications for obtaining FDA approval of such generic drugs, (ii) Elite will be entitled to 15% of the profits generated from the sales of such additional generic drug products upon approval by the FDA, and (iii) Epic and Elite will share certain resources, technology and know-how in the development of drug products, which Elite believes will benefit the continued development of its current drug products.

For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under "Epic Strategic Alliance Agreement" in Item 7 of Part II of this Annual Report on Form 10-K, 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 seven United States patents of which two have been assigned for a fee to another pharmaceutical company. Elite's patents are:

PATENT	EXPIRATION DATE
U.S. patent 5,871,776	October 28, 2016
U.S. patent 5,902,632	July 31, 2017
U.S. patent 5,837,284 (assigned to Celgene Corporation)	November 17, 2018
U.S. patent 6,620,439	October 3, 2020
U.S. patent 6,635,284 (assigned to Celgene Corporation)	March 11, 2018
U.S. patent 6,926,909	April 4, 2023
U.S. patent 6,984,402	April 10, 2023

We have pending applications for four additional U.S. patents. The pending patent applications relate to two different controlled-release pharmaceutical products on which we are working. Three of these patents are for an opioid agonist and antagonist product that we are developing to be used with oxycodone and other opioids to minimize the abuse potential for the opioids. Another U.S. patent is for formulation of oral sustained-release opioids intended to improve the delivery of 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 on March 3, 2011, the U.S. Food and Drug Administration (“US-FDA”) announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with such list of 500 products including the Lodrane Products. After this announcement by the US-FDA, the Company’s customer for the Lodrane Products cancelled all outstanding orders and manufacturing of the Lodrane Products has ceased.

The Lodrane Products were responsible for approximately 97% of the Company’s gross revenues in Fiscal 2011 and while the timing of the announcement by the US-FDA at the end of Fiscal 2011 resulted in such having a minimal effect on the Company’s results for Fiscal 2011, the announcement has a material adverse effect on revenues for periods beginning after 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.

14

ECR (the owner and marketer of the Lodrane Products) has 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 US-FDA with relation to the Lodrane Products.

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 “Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight” at Item 1A.

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

ECR has 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 US-FDA with relation to the Lodrane Products.

The agreement with Precision Dose is currently the only commercially active contractual relationship from which the Company generates revenue.

Employees

As of June 15, 2011, we had 17 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 years, we incurred net losses of $13,582,159 and $8,056,874, respectively and losses from operations of $1,936,321 and $445,758, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

There is doubt as to our ability to continue as a going concern.

On June 21, 2010, we had cash reserves of approximately $1.8 million. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement will provide additional funds to permit us to continue development of our product pipeline. We are anticipating that, with the growth of the generic phentermine product, the contract manufacturing of methadone, Phendimetrazine and Isradipine, the launch of the generic hydromorphone and 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 will add a new revenue source for Elite. However, there can be no assurances as to the success of the development of such Epic products or the commercialization of such Epic products or the success or commercialization of other pipeline products of Elite.

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 $0.6875 million. Even if we were 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. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under “Epic Strategic Alliance Agreement” in Item 7 of Part II of this Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009, June 5, 2009 and July 1, 2010, which are incorporated herein by reference.

If we are unable to obtain additional financing needed for the expenditures for the development and commercialization of our drug products, it would impair our ability to continue to meet our business objectives.

We continue to require additional financing to ensure that we will be able to meet our expenditures to develop and commercialize our products. As of June 21, 2011 we had cash and cash equivalents of approximately $1.8 million. Elite must be able to commercialize other products or pipeline opportunities such as the generic hydromorphone and naltrexone products at that time or we will require additional funding in order to continue to operate. If the quarterly payment closings of the transactions contemplated by the Epic Strategic Alliance Agreement are not closed on a timely basis, or if another financing or strategic alternative providing sufficient resources to allow us to continue operations is not consummated upon exhaustion of our current capital, we will be required to cease operations and liquidate our assets. No assurance can be given that we will be able to commercialize the new opportunities or 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. Moreover, even if we consummate the quarterly payment closings under the Epic Strategic Alliance Agreement, or such other financing or strategic alternative, we may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain additional capital on favorable terms, if at all.

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.

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.

22

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.

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 five 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.

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:

- 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, recent changes in 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.

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.

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 involves 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 March 31, 2011.

RISKS RELATED TO OUR COMMON STOCK

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"), subject in some cases to volume and other limitations. These sales, 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.

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, 2011, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.10 per share to a low of $0.04 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:

- 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;
- Commercial success of the eight drug products of Epic identified under the Epic Strategic Alliance Agreement; and
- Our ability to consummate the third closing of the transactions contemplated by the Epic Strategic Alliance Agreement

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.

28

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.

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 warrants and shares to Epic under the Epic Strategic Alliance Agreement will cause existing holders of our Common Stock to experience substantial dilution.

If Elite and Epic consummate the quarterly payment closings under the Epic Strategic Alliance Agreement, Elite will issue to Epic an aggregate of 687.5 shares of Series E Preferred Stock, convertible into an aggregate of approximately 27 million shares of Common Stock, based on a conversion price as of June 30, 2011. If Epic converts the shares of Series E Preferred Stock into shares of Common Stock, the existing holders of our Common Stock will experience substantial dilution.

In addition, with respect to the products developed by Epic under the Epic Strategic Alliance Agreement, Elite may 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 the Facility and (b) up to an aggregate of 40,000,000 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 these events occur, the existing holders of our Common Stock will also experience substantial dilution upon the issuance of the additional shares of Common Stock and the shares of Common Stock underlying the warrants, if the warrants are exercised.

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 will have the ability to exert substantial influence over Elite.

Under the Epic Strategic Alliance Agreement, Elite agreed that it and its 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 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 (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 Elite's Board of Directors, the outcome of issues submitted to our stockholders for approval and the management and affairs of Elite.

In addition, the Series E Certificate 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 Certificate, 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 Certificate, 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 Certificate, Elite 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 Elite and may have the effect of preventing a change of control of Elite.

In addition, with respect to the products developed by Epic under the Epic Strategic Alliance Agreement, Elite may 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 the Facility and (b) up to an aggregate of 40,000,000 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 warrants and such additional shares of its Common Stock to Epic in accordance with the Epic Strategic Alliance Agreement, Epic may beneficially own in excess of 50% of the issued and outstanding Common Stock or other voting securities of Elite. 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 the Purchaser will be entitled to designate under the Alliance Agreement 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.

In addition, pursuant to the Epic Strategic Alliance Agreement and the Series E Certificate, 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 Certificate, Elite must obtain the prior written consent of Epic in order to take certain actions specifically enumerated therein. This right will terminate if Epic's ownership percentage of the capital

stock of Elite, on an as-converted basis, falls below 20% of Elite's capital stock, on an as-converted basis, as a result of transfers made by Epic.

Section 203 of the Delaware General Corporation Law may deter a third party from acquiring us.

Section 203 of the Delaware General Corporation Law prohibits a merger with a 15% shareholder within three years of the date such shareholder acquired 15%, unless the merger meets one of several exceptions. The exceptions include, for example, approval by the holders of two-thirds of the outstanding shares (not counting the 15% shareholder), or approval by the Board of Directors prior to the 15% shareholder acquiring its 15% ownership. This provision makes it difficult for a potential acquirer to force a merger with or takeover of us, and could thus limit the price that certain investors might be willing to pay in the future for shares of our Common Stock.

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. Please see the discussion entitled "Liquidity and Capital Resources" in Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations. 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".

During Fiscal 2011, on November 30, 2010, a lease which the Company entered into for a portion of a one-story warehouse, located at 80 Oak Street, Norwood, New Jersey ("80 Oak") consisting of approximately 3,500 square feet of floor space, and used for the storage of pharmaceutical finished goods, raw materials, equipment and documents expired.

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

ITEM 3. LEGAL PROCEEDINGS.

In the ordinary course of business we may be subject to litigation from time to time. Except as follows, there is no past, 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.

Midsummer Investments, Ltd., et al. v. Elite Pharmaceuticals, Inc.

On or about September 22, 2009, Midsummer Investments, Ltd. ("Midsummer") and Bushido Capital Master Fund, LP ("Bushido", and together with Midsummer, the "Plaintiffs") filed a complaint against Elite Pharmaceuticals, Inc., a Delaware corporation (the "Company"), in the United States District Court, Southern District of New York (Case No. 09 CIV 8074) (the "Action"). The Plaintiffs asserted claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (injunctive relief and damages), and attorneys' fees, arising out of a Securities Purchase Agreement, dated September 15, 2008, by and among the Company and certain purchasers of the Company's securities (including the Plaintiffs) and the Certificate of Designation of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, filed with the Secretary of State of the State of Delaware on September 15, 2009 (the "Series D Certificate"). Plaintiffs claimed that they were entitled to a reduced conversion price for their Series D 8% Convertible Preferred Stock, par value US$0.01 per share (the "Series D Preferred Stock"), as a result of the Strategic Alliance Agreement, dated March 18, 2009, as amended (the "Epic SAA"), by and among the Company, on the one hand, and Epic Pharma, LLC ("Epic") and Epic Investments, LLC ("Epic Investments", and together with Epic, the "Epic Parties"). With their complaint, the Plaintiffs concurrently filed a request for preliminary injunction. Pursuant to an order of the Court entered into on October 16, 2009, the Plaintiffs' request for a preliminary injunction was denied. Thereafter, Plaintiffs filed an amended complaint (the "Complaint"), asserting claims for breach of contract (injunctive relief and damages), anticipatory breach of contract (injunctive relief), conversion (damages) and attorneys' fees, seeking compensatory damages of $7,455,363.00, delivery of 1,000,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), a declaration that all future conversions of the Series D Preferred Stock, held by Plaintiffs is at a conversion price of $0.05, attorneys' fees, interest and costs.

The Company disputed the claims in the Complaint, believing the lawsuit to be without merit, and vigorously defended against them. The Company moved for summary judgment on the Complaint and the judge in the case did not issue an order on such motion. The Company proceeded with extensive, time-consuming and costly discovery. The court scheduled the trial to commence on June 28, 2010.

In order to avoid the delays, expense and risks inherent in litigation, after extensive negotiations, the Company entered into (i) a Stipulation of Settlement and Release, dated June 25, 2010 (the "Settlement Agreement"), with the Plaintiffs and the Epic Parties, (ii) an Amendment Agreement, dated June 25, 2010 (the "Series D Amendment Agreement"), with the Plaintiffs and (iii) an Amendment Agreement, dated June 25, 2010 (the "Series E Amendment Agreement") with the Epic Parties. As part of the Settlement Agreement, the Action will be dismissed with prejudice.

Series D Amendment Agreement

Pursuant to the Series D Amendment Agreement, the Company and Plaintiffs agreed to amend the Series D Certificate. The holders of at least 50.1%, in the aggregate, of the Company's outstanding Series B Preferred 8% Convertible Preferred Stock, par value US$0.01 per share, Series C 8% Convertible Preferred Stock, par value US$0.01 per share, and Series D Preferred Stock, voting as one class, consented to the filing of the Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock (the "Amended Series D Certificate") with the Secretary of State of the State of Delaware. On June 29, 2010, pursuant to the authority of its Board of Directors, the Company filed with the Secretary of State of the State of Delaware the Amended Series D Certificate.

Pursuant to the terms of the Amended Series D Certificate, the terms of the Series D Preferred Stock have been amended as follows:

- Dividends: The Series D Preferred Stock will continue to accrue dividends at the rate of 8% per annum on their stated value of US$1,000 per share, payable quarterly on January 1, April 1, July 1 and October 1 and such rate shall not increase to 15% per annum as previously provided prior to giving effect to the Series D Amendment Agreement. In addition to being payable in cash and shares of Common Stock, as provided in the Series D Certificate, such dividends may also be paid in shares of Series D Preferred Stock (the "Dividend Payment Preferred Stock") or a combination of cash, Common Stock and Dividend Payment Preferred Stock. Dividend Payment Preferred Stock will have the same rights, privileges and preferences as the Series D Preferred Stock, except that such Dividend Payment Preferred Stock will not be entitled to, nor accrue, any dividends pursuant to the Amended Series D Certificate.

- Conversion Price: The conversion price of the Series D Preferred Stock shall be reduced from US$0.20 per share to US$0.07 per share (subject to adjustment as provided in the Amended Series D Certificate).

- Automatic Monthly Conversion: On each Monthly Conversion Date (as defined below), a number of shares of Series D Preferred Stock equal to each holder's pro-rata portion (based on the shares of Series D Preferred Stock held by each Holder on June 25, 2010) of the Monthly Conversion Amount (as defined below) will automatically convert into shares of Common Stock at the then-effective conversion price (each such conversion, a "Monthly Conversion"). Notwithstanding the foregoing, the Company will not be permitted to effect a Monthly Conversion on a Monthly Conversion Date unless (i) the Common Stock shall be listed or quoted for trading on a trading market, (ii) there is a sufficient number of authorized shares of Common Stock for issuance of all Common Stock to be issued upon such Monthly Conversion, (iii) as to any holder of Series D Preferred Stock, the issuance of the shares will not cause a breach of the beneficial ownership limitations set forth in the Amended Series D Certificate, (iv) if requested by a holder of Series D Preferred Stock and a customary Rule 144 representation letter relating to all shares of Common Stock to be issued upon each Monthly Conversion is provided by such holder after request from the Company, the shares of Common Stock issued upon such Monthly Conversion are delivered electronically through the Depository Trust Company or another established clearing corporation performing similar functions ("DTC"), may be resold by such holder pursuant to an exemption under the Securities Act and are otherwise free of restrictive legends and trading restrictions on such Holder, (v) there has been no public announcement of a pending or proposed Fundamental Transaction or Change of Control Transaction (as such terms are defined in the Amended Series D Certificate) that has not been consummated, (vi) the applicable holder of Series D Preferred Stock is not in possession of any information provided to such holder by the Company that constitutes material non-public information, and (vii) the average VWAP (as defined in the Amended Series D Certificate) for the 20 trading days immediately prior to the applicable Monthly Conversion Date equals or exceeds the then-effective conversion price of the Series D Preferred Stock. Shares of the Series D Preferred Stock issued to the holders of Series D Preferred Stock as Dividend Payment Preferred Stock shall be the last shares of Series D Preferred Stock to be subject to Monthly Conversion. As used herein, the following terms have the following meanings: (i) "Monthly Conversion Date" means the first day of each month, commencing on August 1, 2010, and terminating on the date the Series D Preferred Stock is no longer outstanding; (ii) "Monthly Conversion Amount" means an aggregate Stated Value of Series D Preferred Stock among all Holders that is equal to 25% of aggregate dollar trading volume of the Common Stock during the 20 trading days immediately prior to the applicable Monthly Conversion Date (such 20 trading day period, the "Measurement Period"), increasing to 35% of the aggregate dollar trading volume during the Measurement Period if the average VWAP during such Measurement Period equals or exceeds $0.12 (subject to adjustment for forward and reverse stock splits and the like that occur after June 25, 2010) and further increasing to 50% of the aggregate dollar trading volume during such Measurement Period if the average VWAP during such Measurement Period equals or exceeds $0.16 (subject to adjustment for forward and reverse stock splits and the like that occur after June 25, 2010).

- Change of Control Transaction: Epic and its affiliates were expressly excluded from any event which would otherwise constitute a "Change of Control Transaction" due to the acquisition in excess of 40% of the Company's voting securities.

Pursuant to the Series D Amendment Agreement, the exercise price of the Warrants (the "Series D Warrants") to purchase shares of Common Stock issued to the holders of Series D Preferred Stock pursuant to the Securities Purchase Agreement, dated as of September 15, 2008, by and among the Company and the purchasers of Series D Preferred Stock will be reduced from $0.25 per share to US$0.125. In addition, the exercise price of the Series D Warrants may be reduced as follows:

(i) by 20%, if on September 15, 2011, the holder of such Warrant still beneficially owns more than 50% of the Series D Preferred Stock beneficially owned by such holder as of June 25, 2010 ("Base Ownership"); and

(ii) by 20%, if (a) on September 15, 2011, such holder then beneficially owns more than 25% of the Base Ownership and 50% or less of the Base Ownership and (b) on September 15, 2012, such holder then beneficially owns more

than 25% of the Base Ownership.

Notwithstanding the foregoing, (x) in no event will the exercise price of the Series D Warrants be reduced more than once as a result of the amendments to such Series D Warrants, and (y) in the event that on September 15, 2011 or, if the condition of clause (ii)(a) above is met, on September 15, 2012, the Holder beneficially owns 25% or less of the Base Ownership, then no adjustment shall occur pursuant to the Series D Warrants, as amended by the Series D Amendment Agreement. Additionally, there will be no corresponding increase in the number of shares of Common Stock issuable upon exercise of the Warrants solely as a result of the foregoing adjustments.

To the extent such issuance does not cause the breach of the beneficial ownership limitations set forth in the Amended Series D Certificate (any excess shares will be issued to the affected holder of Series D Preferred Stock upon written notice from such holder when such holder's beneficial ownership is below 9.9% to the extent that such issuance does not cause such holder to exceed such amount), the Company agreed to issue certain shares of Common Stock to the Plaintiffs and their respective affiliates in satisfaction of the Company's obligation to pay certain previously accrued but unpaid dividends through March 31, 2010 owing to the Plaintiffs and their respective affiliates.

Series E Amendment Agreement

Pursuant to the Series E Amendment Agreement, the Company agreed to amend the Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock, filed with Secretary of State of the State of Delaware on June 3, 2009 (the "Series E Certificate"). The Epic Parties, constituting all holders of Series E Preferred Stock, consented to the filing of the Amended Certificate of Designations of the Series E Convertible Preferred Stock (the "Amended Series E Certificate") with the Secretary of State of the State of Delaware. On June 29, 2010, pursuant to the authority of its Board of Directors, Company filed with the Secretary of State of the State of Delaware the Amended Series E Certificate. Pursuant to the terms of the Amended Series E Certificate, the conversion price of the Series E Preferred Stock will be adjusted downward to reflect, on a pro rata basis, the reduction in the conversion price of the Series D Preferred Stock as the result of the Series D Amendment Agreement, to the extent shares of Series D Preferred Stock are converted at the reduced conversion price set forth in the Amended Series D Certificate.

Pursuant to the Series E Amendment Agreement, the Epic SAA was amended so that the purchase of the 750 Additional Shares of Series E Preferred Stock described therein for an aggregate purchase price of $750,000 would occur in 12 installments of 62.5 shares (for a purchase price of $62,500) (i) on or prior to November 1, 2009 (which has been satisfied) and (ii) within 10 business days following the last day of each calendar quarter, beginning with the first calendar quarter ending on September 30, 2010 and continuing for each of the 10 calendar quarters thereafter.

In addition, under the Series E Amendment Agreement, the third closing date is scheduled to occur on or before December 31, 2010, subject to certain conditions set forth in the Epic SAA (as amended by the Series E Amendment Agreement).

Under each of the Series D Amendment Agreement and the Series E Amendment Agreement, the Company agreed that at its next meeting of shareholders it will seek shareholder approval to amend its certificate of incorporation to increase the number of authorized but unissued shares of Common Stock to at least 760,000,000.

Settlement Agreement

Pursuant to the Settlement Agreement, Elite and the Epic Parties, individually and on behalf of each of their respective officers, directors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Elite Releasors") agreed to release and discharge each of the Plaintiffs, BCMF Trustees LLC, an affiliate of Bushido ("BCMF"), their respective owners, officers, directors, investors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Plaintiffs' Releasees") from any and all actions, causes of action, claims, liens, suits, debts, accounts, liabilities, expenses, attorneys' fees, agreements, promises, charges, complaints and demands (collectively, "Loses") which the Elite Releasors have or may have against the Plaintiffs' Releasees that could have been asserted in the Action or any other court action, based upon any conduct up to and including the date of the Settlement Agreement. Notwithstanding the foregoing, the Elite Releasors will not release any claim of breach of the terms of the Settlement Agreement, breach of the terms of the Series D Amendment Agreement, or any cause of action arising from future conduct by the Plaintiffs' Releasees.

Pursuant to the Settlement Agreement, the Plaintiffs and BCMF, individually and on behalf of each of their respective owners, officers, directors, investors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Plaintiffs' Releasors") agreed to release and discharge Elite and the Epic Parties and each of their respective officers, directors, agents, representatives, successors, affiliated entities, subsidiaries, heirs, employees, administrators and assigns (the "Elite Releasees"), from any and all Losses which the Plaintiffs' Releasors have or may have against the Elite Releasees that could have been asserted in the Action or any other court action, based upon any conduct up to and including the date of the Settlement

Agreement. Notwithstanding the foregoing, the Plaintiffs' Releasors did not release any claim of breach of the terms of the Settlement Agreement, breach of the terms of the Series D Amendment Agreement or any cause of action arising from future conduct by the Elite Releasees.

In addition, concurrently with the execution of the Settlement Agreement, legal counsel for both the Company and the Plaintiffs executed a Stipulation of Discontinuance of the Action, which such counsel will file once all conditions precedent to the effectiveness of the Settlement Agreement have been satisfied.

The foregoing description of the Amended Series D Certificate, Amended Series E Certificate, Settlement Agreement, Series D Amendment Agreement and Series E Amendment Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of such documents which are filed herewith and incorporated herein by reference.

On July 1, 2010, the Company filed with the SEC a Current Report on Form 8-K announcing the settlement of the litigation with the Plaintiffs, with such filing being incorporated by reference herein.

ThePharmaNetwork Inc. v. Elite Pharmaceuticals Inc.

On March 17, 2011, Elite Pharmaceuticals, Inc. (the "Company") issued a press release announcing the settlement of a lawsuit filed in the Superior Court of New Jersey, Chancery Division: Bergen County entitled ThePharmaNetwork, LLC v. Elite Pharmaceuticals, Inc. (Index No. C-272-10) (the "Action").

The Action was commenced on or about August 27, 2010 by ThePharmaNetwork, LLC ("TPN"). TPN alleged that the Company breached certain obligations in connection with a Product Collaboration Agreement (the "Collaboration Agreement"), made as of November 10, 2006, pursuant to which the Company and TPN agreed to collaborate in the development, commercialization, manufacturing and distribution of a generic pharmaceutical product, which the parties subsequently agreed would be methadone hydrochloride in a 10 mg. tablet (the "Product"). In the lawsuit, the Company asserted counterclaims against TPN arising out of the Collaboration Agreement, and sought damages of no less than $1,125,000 from TPN. Both parties denied the other side's allegations.

In order to fully and finally resolve the disputed claims arising in the Action, the Company and TPN have entered into a settlement agreement, dated March 11, 2011 (the "Settlement Agreement"), pursuant to which the Action, including all of TPN's claims and the Company's counterclaims, will be dismissed with prejudice.

Pursuant to the Settlement Agreement, the parties have agreed to terminate the Collaboration Agreement.

In addition, in consideration of the Company's agreement to terminate the Collaboration Agreement and to relinquish to TPN all rights and interest in the Abbreviated New Drug Application ("ANDA") for the Product approved by the U.S. Food and Drug Administration (FDA), TPN made a cash payment of $500,000 to Elite.

As part of the Settlement Agreement, TPN also acknowledges that the Company may develop a generic product containing methadone of any strength (including the filing of an abbreviated new drug application relating to such product) and that nothing in the Settlement Agreement restricts the Company from developing, commercializing, manufacturing and distributing any pharmaceutical product similar to, or which may compete with, the Product or the ANDA filed in connection with the Product.

The Settlement Agreement also contained a mutual release pursuant to which the Company and TPN agreed to release and discharge each other and their respective affiliates from all claims arising before the date of the Settlement Agreement.

Please refer to the Current Report on Form 8-K filed with the SEC on March 17, 2011, such filing being herein incorporated by reference, for further details on this settlement of litigation.

ITEM 4. REMOVED AND RESERVED.

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 sales 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, 2011:		
March 31, 2011	$ 0.09	$ 0.04
December 31, 2010	$ 0.07	$ 0.04
September 30, 2010	$ 0.08	$ 0.05
June 30, 2010	$ 0.10	$ 0.07
Fiscal Year ending March 31, 2010:		
March 31, 2010	$ 0.12	$ 0.08
December 31, 2009	$ 0.25	$ 0.06
September 30, 2009	$ 0.09	$ 0.06
June 30, 2009	$ 0.20	$ 0.05

On June 24 2011, the last reported sale price of our Common Stock, as quoted by the OTC Bulletin Board, was $ 0.175 per share

Holders

As of June 30, 2011, there were approximately 188 holders of record of our Common 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, 2011.

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, 2011.

Plan Category		Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	(1)	3,057,000	$ 1.51	4,622,500	
Equity compensation plans not approved by security holders		—	—	—	(2)
Total		3,057,000	$ 1.51	4,622,500	

(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 the Company, and its Parent and Subsidiaries (if any), by offering them an opportunity to participate in the Company's 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 the Company's Compensation Committee (the "Compensation Committee"). Under the Equity Incentive Plan, the Company is 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, the Company is also 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 the Company 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.

The Company is also 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 to smaller reporting companies]

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 under the caption "Risk Factors" and "Special Note Regarding Forward Looking Statements" above. The following discussion is intended to assist the reader in understanding and evaluating our financial position.

Overview

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

Elite has one product, Phentermine 37.5mg tablets, currently being sold commercially. The Company also has a pipeline of additional generic drug candidates under active development and the Company is developing ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-a-day oxycodone product. Elite's facility in Northvale, New Jersey operates under Good Manufacturing Practice ("GMP") and is a United States Drug Enforcement Agency ("DEA") registered facility for research, development and manufacturing.

During Fiscal 2011, the Company was also engaged in the commercial manufacture and sale of Lodrane 24® and Lodrane 24D®, with such products constituting approximately 98% of the Company's gross revenues. On March 3, 2011, the US-FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. Market. This list included the Lodrane® Products. Shortly after this announcement by the US-FDA, the Company's customer for the Lodrane® Products cancelled all outstanding orders, citing the US-FDA's directive as the basis for such cancellations. Manufacturing by the Company of the Lodrane® Products has accordingly ceased.

While the announcement by the US-FDA had a minimal effect on the Company's results for Fiscal 2011, the Company's inability to manufacture the Lodrane Products®, has a material and adverse effect on its revenues for periods beginning subsequent to March 31, 2011.

ECR (the owner and marketer of the Lodrane Products) has 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 US-FDA with relation to the Lodrane Products.

Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite's pain management products, (ii) manufacturing of Phentermine and Hydromorphone products; (iii) the development of the other products in Elite's pipeline including development of the products pursuant to the Epic Strategic Alliance Agreement and other partners; (iv) commercial exploitation of Elite's products either by license and the collection of royalties, or through the manufacture of Elite's formulations, and (v) development of new products and the expansion of Elite's 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 ("NDA") under Section 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 as well as generic drug products (which require abbreviated new drug applications ("ANDA")).

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

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), pursuant to which Elite commenced a strategic relationship with Epic, a pharmaceutical company that operates a business synergistic to that of Elite in the research and development, manufacturing, sales and marketing of oral immediate 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"). In addition to the use of the Facility, Epic will use 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.

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.

43

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 Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock, at a price less than the then applicable Conversion Price, (b) the issuance of Common Stock in lieu of cash in satisfaction of Elite's dividend obligations on outstanding shares of its Series B 8% Convertible Preferred Stock, par value $0.01 per share, Series C 8% Convertible Preferred Stock, par value $0.01 per share, and/or Series D 8% Convertible Preferred Stock, par value $0.01 per share (the "Series D Preferred Stock"), and (c) the issuance of Common Stock as a result of any holder of Series D Preferred Stock exercising its right to require Elite to redeem all of such holder's shares of Series D Preferred Stock pursuant to the terms thereof. Epic also acquired a warrant to purchase 20,000,000 shares of Common Stock (the "Initial Warrant"), exercisable on or prior to June 3, 2016, at a per share exercise price of $0.0625 (the "Exercise Price"), subject to adjustments for certain events, including,

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

On October 30, 2009, Elite completed the second closing of the Strategic Alliance Agreement with Epic. Epic paid to Elite a sum of $1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, and a warrant to purchase an additional 40,000,000 shares of Common Stock. The warrant is 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.

On March 31, 2011, Elite completed the third 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 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. Epic made the first payment for the quarter ending September 30, 2009.

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.

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 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 Lock-Up Period (as defined above) the Purchaser 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 the Purchaser at all of the then applicable Closings or (ii) following the conversion by the Purchaser 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 the Purchaser, with or without cause. At such time as the Purchaser owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that the Purchaser 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 Certificate 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 Certificate, 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 Certificate, 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 Certificate, Elite must obtain the prior written consent of Epic in order to take the actions specifically enumerated therein.

For information regarding composition of the Board and voting rights in connection with the Epic Strategic Alliance Agreement, refer to the "Risk Factors" under Item 1A, of this Annual Report on Form 10-K and 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.

46

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'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.

Since its inception, Novel has filed at least 11 Abbreviated New Drug Applications with the US Food and Drug Administration. The first ANDA approval for Novel was received in Dec 2008 and at least three additional ANDA approvals were received in 2009. Four of the Novel ANDAs have been granted first-to-file status.

In addition, Novel has acquired three ANDAs to supplement its own in-house product development and marketing strategy. Novel has publicly said that it has identified over 50 drug products which are in various stages of development that it plans to commercialize in the coming years.

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 was 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, 2011. The valuation of the Company's investment in Novel remains at $3,329,322, an amount equal to the valuation as of March 31, 2010 with no impairment write downs.

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 Abbreviated New Drug Application for Hydromorphone Hydrochloride Tablets USP, 8 mg, for aggregate consideration of $225,000, comprised of an initial payment of $150,000, which was made on May 18, 2010. A second payment of $75,000 was due to be paid to Mikah on June 15, 2010, with the Company having the option to make this payment in cash or by issuing to Mikah 937,500 shares of the Company's common stock. The Company elected and did issue 937,500 shares of Common Stock during the quarter ended December 31, 2010, in full payment of the $75,000 due to Mikah pursuant to the asset purchase agreement dated May 18, 2010. A current report on form 8-K was filed on May 24, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

For further details on the Hydromorphone Agreement, please refer to Exhibit 10.4 to the Quarterly Report on Form 10-Q, filed with the SEC on November 15, 2010, and incorporated herein by reference.

On May 31, 2011, the Company received a letter from the US Food and Drug Administration (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 will delay the commercialization. A current report on form 8-K was filed on June 6, 2011 in relation to this announcement, such filing being incorporated herein by this reference.

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

This product is included in the license and manufacturing agreements executed with Precision Dose Inc ("Precision Dose") and its wholly owned subsidiary, TAGI Pharma Inc ("TAGI") and dated September 10, 2010. A current report on form 8-K was filed on September 16, 2010, in relation to the signing of this agreement, such filing 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 Abbreviated New Drug Application number 75-274 (Naltrexone Hydrochloride Tablets USP, 50 mg), and all amendments thereto (the "ANDA"), that have to date been filed with the FDA seeking authorization and approval to manufacture, package, ship and sell the products described in the 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. A current report on form 8-K was filed on August 27, 2010 in relation to this announcement, such filing being incorporated herein by this reference. Please also refer to exhibit 10.5 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

The transfer of production of Naltrexone Hydrochloride Tablets USP, 50mg ("Naltrexone 50mg Tablets") from Mikah to the Facility is currently in progress. Such transfer of production, however, will include the filing of a CBE 30 supplement which is similar in relevant aspects to the CBE 30 supplement filed for the site transfer of the manufacture of Hydromorphone 8mg. It is possible that FDA's response to a CBE 30 supplement filed for transfer of the manufacturing site of Naltrexone 50mg, may be similar to its response to the CBE 30 supplement filed for the transfer of the manufacturing site of Hydromorphone 8mg. Accordingly, Elite has recorded an impairment, equal to the full historical cost of the Naltrexone 50mg ANDA.

Elite's Purchase of a Generic Phentermine Product

On September 10, 2010, Elite, together with its subsidiary, Elite Laboratories, Inc., executed a Purchase Agreement (the "Phentermine Purchase Agreement") with Epic Pharma LLC (the "Seller") for the purpose of acquiring from the seller an Abbreviated New Drug Application for a generic phentermine product (the "Phentermine ANDA"), with such being filed with, but not yet approved by the FDA at the time the Phentermine Purchase Agreement was executed. On February 4, 2011, the Company announced the approval by the FDA of the Phentermine ANDA. As per the terms and conditions of the Phentermine Purchase Agreement, the acquisition of the Phentermine ANDA will close on the later of 60 days from the date of the Purchase Agreement or upon receipt of FDA approval of the Phentermine ANDA. Upon the closing, Elite will pay a portion of the purchase price. The remainder of the purchase price will be paid in quarterly installments over a period of three years, beginning at the end of the first full quarter following the closing. Current reports on form 8-K were filed on September 10, 2010 and February 4, 2011 in relation to the Phentermine Purchase Agreement and the Phentermine ANDA, with such filings being incorporated herein by this reference. Please also refer to exhibit 10.7 of the Quarterly Report on Form 10-Q filed with SEC on November 15, 2010, such filing being incorporated herein by this reference.

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 current report on form 8-K was filed on September 16, 2010 in relation to signing of this agreement, such filing being incorporated herein by this reference

Licensing Agreement with Precision Dose Inc.

On September 10, 2010, Elite Pharmaceuticals Inc. ("Elite") executed a License Agreement with Precision Dose, Inc. ("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. 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 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 6 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. A current report on form 8-K was filed on September 10, 2010 in relation to this announcement, such filing 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.

49

Manufacturing and Supply Agreement with Mikah Pharma LLC

On June 1, 2011, Elite Pharmaceuticals Inc. ("Elite") executed a Manufacturing and Supply Agreement (the "Agreement") with Mikah Pharma, LLC ("Mikah") to undertake and perform certain services relating to two generic products: Isradipine Capsules USP, 2.5 mg and 5 mg and Phendimetrazine Tartrate Tablets USP, 35 mg (the "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 this Agreement; Elite shall 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 Products for commercial sale by Mikah or its designees in accordance with the terms of this Agreement. During the term of this Agreement and subject to the provisions herein, Mikah shall purchase from Elite and Elite agrees to manufacture and supply solely and exclusively to Mikah, such Product as Mikah may order from time to time pursuant to this 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 Product for the work associated with the Technology transfer. The milestone payment shall be made upon the successful manufacturing and testing of the exhibit batch.

The Manufacturing and Supply Agreement has a term of five (5) years and shall automatically renew for additional periods of one (1) year unless Mikah provides written notice of termination to Elite at least six (6) months prior to the expiration of the Term or any Renewal Term.

A current report on Form 8-K was filed on June 6, 2011, with such filing being herein incorporated by reference. Please also refer to exhibit 10.70 to this annual report on Form 10-K.

Critical Accounting Policies and Estimates

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Liquidity and Capital Resources

As of March 31, 2011, our principal source of liquidity was approximately $1.8 million of cash and cash equivalents. Our strategic alliance with Epic may also generate (i) an additional $0.6875 million in cash proceeds to us through Epic's purchase of additional shares of Series E Preferred Stock over the course of additional closings pursuant to the terms and conditions of the Epic Strategic Alliance Agreement and (ii) profit sharing in the revenue from commercialized products which were developed at Elite's Facility pursuant to the Epic Strategic Alliance Agreement. However, no assurance can be given that we will consummate such additional closings of the transactions contemplated by, or successfully commercialize the products developed under, the Epic Strategic Alliance Agreement. If adequate funds are not available to us as we need them, it would raise substantial doubt about our ability to continue as a going concern.

From time to time we will consider potential strategic transactions including acquisitions, strategic alliances, joint ventures and licensing arrangements with other pharmaceutical companies. There can be no assurance that any such transaction will be available or consummated in the future.

For the year ended March 31, 2011, operating activities provided the Company with $1.5 million in cash, with an additional $1.0 million in cash being provided by net financing activities. The cash provided by net financing activities was primarily from $1.0625 million in gross proceeds realized from the issuance of Series E Preferred Stock pursuant to the Epic Strategic Alliance Agreement. The Company expended $1.4 million in investing activities, with such amount mostly consisting of $0.9 million in costs incurred for intellectual property assets, $0.3 million in leasehold improvements and $0.2 million for the purchase of manufacturing equipment. Cash and cash equivalents at March 31, 2011 were $1.8 million, an increase of $1.2 million from the $0.6 million of cash and cash equivalents on hand at March 31, 2010.

The Company's working capital at March 31, 2011 was negative $1.5 million, compared with a working capital at March 31, 2010 of negative $2.3 million.

On March 31, 2011, we consummated the Third Closing of the transactions contemplated by the Epic Strategic Alliance Agreement and received from Epic cash payments of $1,000,000 in exchange for 1,000 shares of our Series E Preferred Stock. These funds provide us with the additional capital necessary for the development of both the product and the business synergies contemplated by the Epic Strategic Alliance Agreement.

On September 29, 2010, the Company issued 62.5 shares of Series E Preferred Stock, in exchange for $62,500 which was received from Epic on November 12, 2009. The Epic Strategic Alliance Agreement also contemplates an additional 11 payments of $62,500, over the next three years, which could generate an additional $687,500 in cash proceeds through Epic's purchase of additional shares of Series E Preferred Stock.

The Company had outstanding, as of March 31, 2011, bonds in the aggregate principal amount of $3,385,000 consisting of $3,140,000 of 6.5% tax exempt bonds with an outside maturity of September 1, 2030 and $245,000 of 9.0% bonds with an outside maturity of September 1, 2012 (together, the "NJEDA Bonds"). The NJEDA Bonds are secured by a first lien on the Facility in Northvale, New Jersey. Pursuant to the terms of the NJEDA Bonds, a restricted cash account has been established for the payment of bond principal and interest, in the event that the Company does not make such payments when due. Bond proceeds were utilized for the redemption of previously issued tax exempt bonds issued by the Authority in September 1999 and to refinance equipment financing, as well as provide approximately $1,000,000 of capital for the purchase of additional equipment for the manufacture and development at the Facility of pharmaceutical products and the maintenance of a $388,990 debt service reserve (the "Debt Service Reserve Fund") to be held in the restricted cash account established with the Trustee for the NJEDA Bonds. All proceeds from the NJEDA Bonds, other than the amount used to establish the Debt Service Reserve Fund, were expended within the year ended March 31, 2007.

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 principal payment due on September 1, 2009, totaling $210,000, the interest payment due on September 1, 2009, totaling and interest payments due on March 1, 2010, September 1, 2010 and March 1, 2011 totaling $113,075 each, were all paid from the Debt Service Reserve Fund, due to the Company not having sufficient available funds to make such payments when due.

The Company did not have sufficient funds available to make the principal payments due on September 1, 2010, totaling $200,000, and requested the Trustee to withdraw the funds from the debt services reserve held in the restricted cash account and to utilize such funds to make the principal payment due. The Company's request was denied by the Trustee. Accordingly, the principal payment due on September 1, 2010 was not paid.

Non-payment of the amounts when due, even if such payment is made from the Debt Service Reserve Fund, constitute an Event of Default under the NJEDA Bonds and the loan document executed with NJEDA Bonds. Pursuant to the terms of the NJEDA Bonds, the Company is required to replenish any amounts withdrawn from the Debt Service Reserve Fund 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 Fund 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 September 1, 2009 March 1, 2010 and September 1, 2010. The Company is required to make two additional payments of $19,529 each, on July 15, 2011 and August 15, 2011, in order to fully replenish the March 1, 2011 withdrawal from the debt service reserve.

The Company has received Notice of Default from the Trustee of the NJEDA Bonds in relation to the withdrawals from the Debt Service Reserve Fund and nonpayment of the Company's obligation when due. The Company 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 NJEDA Bonds and our request for postponement of principal payments will have a significant effect on our ability to operate in the future.

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.

The Trustee's remedies on default include declaring the NJEDA Bonds due and payable and exercising rights against the collateral provided to secure the NJEDA Bonds.

Results of Operations:

Year Ended March 31, 2011 as compared to the Year Ended March 31, 2010

Elite's revenues for the year ended March 31, 2011 were $4,265,963, an increase of $921,664 over revenues for the prior year, and consisted of $3,086,183 in manufacturing fees, $831,538 in royalty fees and $348,242 in contract lab service fees. Revenues for the year ended March 31, 2010 consisted of $2,575,942 in manufacturing fees, $763,928 in royalty fees and $4,429 in contract lab service fees. Manufacturing fees increased by approximately 20% and royalties increased by approximately 9% due to growth of product sales.

Research and development costs for the year ended March 31, 2011 were $1,385,211, an increase of $590,778, or approximately 74%, from $794,433 of such costs for the prior year. Increases in research and development costs were mainly attributable to charges recorded as a result of the FDA's reclassification of the Company's application for transferring of the site of manufacture of Hydromorphone 8mg, costs related to the transfer of production of new products acquired by the Company during the year and an increase in research and development activities. Research and development costs are expected to increase, in future periods, once Phase III and other clinical trials for ELI-216 are initiated.

General and administrative expenses for the year ended March 31, 2011, were $876,012, a decrease of $965,413, or approximately 52% from $1,841,425 of general and administrative expenses for the prior year. The decrease was primarily attributable to decreases in salaries and fringe benefits from Elite's force reduction and management's continued cost reduction efforts.

Non-cash compensation satisfied by the issuance of stock options and warrants decreased $82,987 to $42,017 for the year ended March 31, 2011 from $125,004 for the year ended March 31, 2010. Decreases were the result of previously issued options becoming vested and forfeitures as a result of the reduction in workforce.

Depreciation and amortization decreased by $40,592, or approximately 19%, from $213,955 for the prior year to $173,363. While depreciation expense for the year ended March 31, 2011 decreased from the prior year, please note that during the year ended March 31, 2011, we acquired equipment costing approximately $180k and invested approximately $340k in leasehold improvements. Neither the equipment nor the leasehold improvements were placed in service during the year ended March 31, 2011, but we anticipate both to be placed in service during the year immediately subsequent to March 31, 2011. Accordingly, depreciation expenses in future years are expected to increase. Other income (expenses) for the year ended March 31, 2011 were $(13,125,979) compared to (expenses) of $(6,120,553) for the year ended March 31, 2010. The decrease in other income (expenses) was due to derivative expenses related to changes in the fair value of our preferred shares and outstanding warrants of $(11,714,372), derivative interest expense of $(1,259,480) and discount in Series E issuance attributable to beneficial conversion features of ($292,213), impairment of intangible assets of ($440,000), offset by sales of New Jersey Net Operating Losses of $311,835 and proceeds received pursuant to the settlement of litigation with The Pharma Network totaling $500,000.

As a result of the foregoing, Elite's net loss for the year ended March 31, 2011 was $13,582,159 compared to a net loss of $8,056,874 for the year ended March 31, 2010.

Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), increased to a working capital deficiency of $1,521,959 as of March 31, 2011 from a working capital deficiency of $2,274,572 as of March 31, 2010, primarily due to net proceeds received as a result of our private placement of Series E Convertible Preferred Stock, and by net cash provided by operations.

We experienced positive cash flows from operations of $1,552,815 for the year ended March 31, 2011, primarily due to our net loss of $13,582,159, offset by non-cash expenses totaling $14,474,751, included in the net loss, combined with a decrease in inventory of $754,931.

On November 15, 2004 and on December 18, 2006, Elite's partner, ECR, launched Lodrane 24® and Lodrane 24D®, respectively. Under its agreement with ECR, Elite manufactured, through April 2011, commercial batches of Lodrane 24® and Lodrane 24D® in exchange for manufacturing margins and royalties on product revenues. Manufacturing revenues and royalty income earned for the year ended March 31, 2011 was $3,086,183 and $831,538, respectively. In addition, the Company earned $348,242 from contract lab services related to the Lodrane Products. Gross revenues earned in relation to the Lodrane Products equaled 98% of the Company's revenues for the year ended March 31, 2011.

On March 3, 2011, the US-FDA announced its intention to remove approximately 500 cough/cold and allergy related products from the U.S. market, with Lodrane 24® and Lodrane 24D® being included in such list. According to the press release issued by the US-FDA, manufacturers must stop manufacturing the affected products within 90 days of March 3, 2011 and distribution of the affected products must stop within 180 days of March 3, 2011. Elite's customer for Lodrane 24® and Lodrane 24D® cancelled all outstanding orders, other than those orders for which manufacturing had commenced, citing the announcement by the US-FDA and advising that existing stocks of Lodrane 24® and Lodrane 24D® were sufficient and that additional quantities could not be sold prior to the 180 day distribution deadline announced by the US-FDA.

While the timing of the announcement by the US-FDA resulted in such having a minimal effect on the Company's results for the year ended March 31, 2011, the Company's inability to manufacture Lodrane 24® and Lodrane 24D® has a material and adverse effect on its revenues for period beginning after March 31, 2011.

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

ECR (the owner and marketer of the Lodrane Products) has 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 US-FDA with relation to the Lodrane Products.

Off-balance sheet arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable to smaller reporting companies

54

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, 2011, 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 pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report.

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2011. 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, 2011, 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 year 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B.