

ELITE PHARMACEUTICALS INC /DE/  
Form 10-K  
July 07, 2010

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-K

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED – March 31, 2010

OR

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days. Yes  No

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

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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, a non-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, 2009, 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 | \$4,651,271            | September 30, 2009         |

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

| Title of Class                   | Shares Outstanding | As of Close of Business on |
|----------------------------------|--------------------|----------------------------|
| Common Stock - \$0.001 par value | 87,352,981         | June 30, 2010              |

#### 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. and its subsidiaries.

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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](http://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](http://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. 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 two products, Lodrane 24® and Lodrane 24D®, currently being sold commercially. We also have an approved generic methadone product developed with our partner, The PharmaNetwork. Elite is preparing for a commercial launch of this product. We are currently negotiating a sales and distribution agreement for this product. A sales and distribution agreement is a prerequisite for the launch of this product. Elite also purchased an approved generic to Dilaudid® (a product owned and sold by Purdue Pharma). The transfer of the process from the previous ANDA holder, Mikah Pharma, to our manufacturing facilities is currently in progress. 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 (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 Lodrane 24® and Lodrane 24D® products; (iii) set up and launch of the methadone generic and hydromorphone generic products; (iv) the development of the other products in our pipeline including the eight products pursuant to the Epic Strategic Alliance Agreement; (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 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.

### FDA Approval for generic Methadone tablets

On December 2, 2009, Elite and ThePharmaNetwork, LLC ("TPN") announced the approval of an Abbreviated New Drug Application ("ANDA") for methadone hydrochloride 10mg tablets by the U.S. Food and Drug Administration ("FDA"). Elite and TPN co-developed the product and the ANDA was filed under TPN's name.

A current report on form 8-K was filed on December 2, 2009 in relation to this announcement. The information included in that filing is incorporated herein by reference.

### Elite Purchased A Generic Hydromorphone HCl Product

On May 18, 2010, Elite executed an asset purchase agreement with Mikah Pharma LLC. Under that agreement we completed the acquisition from Mikah of an Abbreviated New Drug Application (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 is due to be paid to Mikah on June 15, 2010. The Company may, at its election, make this payment in cash or by issuing to Mikah 937,500 shares of the Company's common stock. Elite is transferring the process to the Facility in Northvale, NJ where it intends to manufacture the product. Elite will engage a third party to distribute and sell the product.

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.

## Research and Development

During each of the last two fiscal years, we have focused on research and development activities. We spent \$794,433 for the fiscal year ended March 31, 2010 and \$3,631,425 for the fiscal year ended March 31, 2009 on research and development activities. We have reduced our research and development spending this past year to conserve our cash, but we continue our development work for ELI-216 and ELI-154 and for a number of generic products.





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

Elite manufactures 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, 2010 and 2009 aggregated \$3,339,870 and, \$2,274,825, respectively.

#### Approved Products

Elite co-developed a generic methadone product that was approved in November 2009. Elite and its partner, The PharmaNetwork, are in discussions to complete a marketing and distribution arrangement for this product. Elite is also preparing for the manufacture of this product at the Facility. Elite intends to launch this product as soon as these steps have been completed.

Elite purchased a generic hydromorphone product (equivalent to 8 mg Dilaudid®) in May 2010. Elite is transferring this product to the Facility. Elite will also complete a sales and distribution agreement with a third party for the product. Elite expects to launch this product after these steps have been completed.

#### 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 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 our 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, or ART, 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 King Pharmaceuticals, have been approved by the FDA and are being marketed in the United States.

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 will pay a 1% royalty to Elan based on the product’s net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite’s net revenues from this product. (Elite’s net product revenues would include license fees, royalties, manufacturing profits and milestones) Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

#### Epic Strategic Alliance Agreement

On March 18, 2009, Elite and Epic Pharma, LLC and Epic Investments, LLC, a subsidiary of Epic Pharma LLC (collectively, “Epic”) entered into the Epic Strategic Alliance Agreement (amended on April 30, 2009, June 1, 2009 and July 28, 2009). 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 marketing partners 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.

### 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 King Pharmaceuticals, Sandoz (a Novartis company), Durect Corporation, Mylan Laboratories, Inc., Par Pharmaceuticals, Inc., Teva Pharmaceuticals Industries Ltd., Biovail Corporation, Ethypharm S.A., Eurand, Impax Laboratories, Inc., K-V Pharmaceutical Company and Penwest Pharmaceuticals Company. 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 King Pharmaceuticals, Pain Therapeutics (which has an agreement with Durect Corporation and King Pharmaceuticals), 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:

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- 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.

We contract manufacture two products for commercial sale by our customer, ECR Pharmaceuticals. We have recently experienced delays when passing imported raw materials through customs. We have also had a shipment for one of the imported raw materials rejected at customs under Federal Drug & Cosmetic Act (FD&CA) Sections 502(f)(1) and 801(a)(3). ECR Pharmaceuticals is responsible for regulatory matters related to these products. We have notified ECR Pharmaceuticals and they have initiated a discussion with the FDA. If rejection of this raw material at customs continues, it could prevent us from manufacturing these products.

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 an agreement with ECR which sells and distributes two products that we manufacture: Lodrane 24® and Lodrane 24D®. We receive revenues to manufacture these products and also receive royalties based on in-market sales of the products. These are our only products that are being sold commercially now and are the primary source of our revenue currently.

#### Employees

As of June 15, 2010, we had 16 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 \$8,056,874 and \$6,604,708, 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 \$400,000 which permits us to continue at our anticipated level of operations, including, but not limited to, the continued development of our pipeline products, through July 2011. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement, including the consummation of the third closing thereof, will provide additional funds to permit us to continue development of our product pipeline for more than 2 years. Beyond 2 years, we are anticipating that, with growth of Lodrane; the launch of the ANDA for the methadone product that was approved last year with our co-development partner, The PharmaNetwork; and the launch of the generic hydromorphone product that we purchased, 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.

Despite the successful completion of the initial and second closings of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate the third and 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 \$1.6875 million. Even if we were able to successfully complete the third and 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 and June 5, 2009, 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, 2010 we had cash and cash equivalents of approximately \$400,000. We believe that our existing cash and cash equivalents plus revenues from sale of our Lodrane 24® and Lodrane 24D® products will be sufficient to fund our anticipated operating expenses and capital requirements through July 2011. We will require additional funding in order to continue to operate thereafter. If the third and 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 consummate the third and 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 third and 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.

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 two of our generic products are still at an early stage of development. Other than Lodrane 24® and Lodrane 24D®, which are commercial drug products, and a generic drug product for which an ANDA was approved in 2009 and a generic drug product which Elite purchased in 2010, we will need to perform additional development work for the additional product candidates in our pipeline before we can seek the regulatory approvals necessary to begin commercial sales.

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

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

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

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



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

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

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

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

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

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

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



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

We have entered into several collaborations and licensing arrangements for the development of generic 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.

We have recently experienced delays when passing imported raw materials through customs. We have also had a shipment for one of the imported raw materials used to manufacture the products made for ECR Pharmaceuticals rejected at customs under Federal Drug & Cosmetic Act (FD&CA) Sections 502(f)(1) and 801(a)(3). ECR Pharmaceuticals is responsible for the regulatory matters related to these products. We have notified ECR Pharmaceuticals and they have initiated a discussion with the FDA. If rejection of this raw material at customs continues, it could prevent us from manufacturing these products.

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 involve an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could

be very expensive to us, damaging our financial position. The amount of our insurance coverage, which has been limited due to our limited financial resources, may be materially below the coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of March 31, 2010.

## 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, 2010, the closing sale price on the OTC Bulletin Board (“OTC-BB”) of our Common Stock fluctuated from a high of \$0.20 per share to a low of \$0.06 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.

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.

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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 third closing and the quarterly payment closings under the Epic Strategic Alliance Agreement, Elite will issue to Epic an aggregate of 1,750 shares of Series E Preferred Stock, convertible into an aggregate of approximately 61.8 million shares of Common Stock, based on a conversion price as of June 30, 2010, and warrants to purchase an additional 40 million shares of Common Stock. If Epic converts the shares of Series E Preferred Stock into shares of Common Stock and exercises the warrants for 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 D 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 (the “Facility”) 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 have entered into a lease for a portion of a one-story warehouse, located at 80 Oak Street, Norwood, New Jersey consisting of approximately 3,500 square feet of floor space, and used for the storage of pharmaceutical finished goods, raw materials, equipment and documents. We have exercised an option to rent the property through July 31, 2010. It is our intention to vacate these premises on or before the expiration of the lease.

We entered into a lease for a portion of a one-story warehouse, located at 135 Ludlow Avenue, Northvale, New Jersey, consisting of approximately 15,000 square feet of floor space. The lease term begins 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. It is expected that approximately 3,500 square feet of this property will be constructed and qualified as suitable for use for storage of pharmaceutical finished goods, raw materials, equipment and documents on or before the expiration of the lease for the warehouse at 80 Oak Street, as noted above. 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.

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 Releasers") 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, "Losses") which the Elite Releasers 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 Releasers 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' Releasers") 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' Releasers 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 xx, 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.

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 reported by NYSE Amex until May 21, 2009 and the high and low bid information as reported by OTC Bulletin Board thereafter. Over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

| Quarter ended                      | Common Stock |          |
|------------------------------------|--------------|----------|
|                                    | High         | Low      |
| Fiscal Year ending March 31, 2010: |              |          |
| March 31, 2010                     | \$ 0.11      | \$ 0.02  |
| December 31, 2009                  | \$ 0.22      | \$ 0.22  |
| September 30, 2009                 | \$ 0.17      | \$ 0.17  |
| June 30, 2009                      | \$ 0.16      | \$ 0.016 |
| Fiscal Year ending March 31, 2009: |              |          |
| March 31, 2009                     | \$ 0.26      | \$ 0.03  |
| December 31, 2008                  | \$ 0.16      | \$ 0.05  |
| September 30, 2008                 | \$ 0.45      | \$ 0.06  |
| June 30, 2008                      | \$ 0.80      | \$ 0.48  |

On June 30, 2010, the last reported sale price of our Common Stock, as quoted by the OTC Bulletin Board, was \$0.07 per share

### Holders

As of June 30, 2010, there were approximately 201 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, 2010.

## 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, 2010.

| 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) | 3,287,000   | \$ 1.41   | 6,713,000   |
| Equity compensation plans not approved by security holders | —   | —   | 7,090,909(2)  |
| Total  | 3,362,000   | \$ 1.41   | 13,803,909  |

(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 regrant 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"). The Company intends to seek stockholder approval of the Equity Incentive Plan within 12 months of its date of adoption by the Board.

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 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]

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## 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 two products, Lodrane 24® and Lodrane 24D®, currently being sold commercially. We also have an approved generic methadone product developed with our partner, The PharmaNetwork. Elite is preparing for a commercial launch of this product. We are currently negotiating a sales and distribution agreement for this product. A sales and distribution agreement is a prerequisite for the launch of this product. Elite also purchased an approved generic to Dilaudid® (a pharmaceutical product sold by Purdue Pharma). We are transferring the process for this hydromorphone hydrochloric acid product from the previous ANDA holder, Mikah Pharma, to Elite. 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.

### Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite’s pain management products, (ii) manufacturing of Lodrane 24® and Lodrane 24D® products; (iii) set up and launch of the methadone generic and hydromorphone generic products; (iv) the development of the other products in Elite’s pipeline including development of the products pursuant to the Epic Strategic Alliance Agreement; (v) commercial exploitation of Elite’s products either by license and the collection of royalties, or through the manufacture of Elite’s formulations, and (vi) 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.



#### FDA Approval for generic Methadone tablets

On December 2, 2009, the Registrant and ThePharmaNetwork, LLC (“TPN”) announced the approval of an Abbreviated New Drug Application (“ANDA”) for methadone hydrochloride 10 mg tablets by the U.S. Food and Drug Administration (“FDA”). Elite and TPN co-developed the product and the ANDA was filed under TPN’s name.

A current report on form 8-K was filed on December 2, 2009 in relation to this announcement, such filing being incorporated herein by this reference.

#### Elite Purchased A Generic Hydromorphone HCl Product

On May 18, 2010, Elite Pharmaceuticals, Inc. executed an asset purchase agreement with Mikah Pharma LLC. Under that agreement completed the acquisition from the Mikah of an Abbreviated New Drug Application (Hydromorphone Hydrochloride Tablets USP, 8 mg) for aggregate consideration of \$225,000, comprised of an initial payment of \$150,000 paid to the Seller on May 18, 2010 and a second payment of \$75,000 to be made to the Seller on June 15, 2010 (the “Final Payment”). The Company has the option to make the Final Payment in either cash or shares of common stock of the Company with an aggregate value of \$75,000, based on the closing price of the Company’s common stock on May 18, 2010. Elite is transferring the process to its facility in Northvale, NJ where it intends to manufacture the product. Elite will engage a third party to distribute and sell the product.

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.

#### 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.





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 or before December 31, 2010, it is anticipated that Elite and Epic will conduct a third closing (the "Third Closing" and the date of such Third Closing, the "Third Closing Date"), provided that all conditions precedent to such Third Closing contained in the Epic Strategic Alliance Agreement have been satisfied or waived by the appropriate party on or before such Third Closing Date. At the Third Closing, if such closing is held, Epic will pay to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which shares will be convertible, as described above, into 20,000,000 shares of Common Stock, and a warrant (the "Third Warrant" and collectively with the Initial Warrant and the Second Warrant, the "Warrants") to purchase an additional 40,000,000 shares of Common Stock. The Third Warrant is to be exercisable until the date that is the seventh anniversary of the Third Closing Date and is to have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The per share exercise price of the Third Warrant is to also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock at a price less than the then applicable per share exercise price of the Third Warrant, for which the Epic's consent was not required under the Epic Strategic Alliance Agreement.

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 and, as agreed upon with Elite, will resume payments beginning with the quarter ending September 30, 2010.

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.

## 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 December 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.

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, 2010. The valuation of the Company's investment in Novel remains at \$3,329,322, an amount equal to the valuation as of March 31, 2009 with no impairment write downs.

#### 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 are more likely than not to be realized. We assess the recoverability of 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, 2010, our principal source of liquidity was approximately \$578,000 of cash and cash equivalents, or approximately twelve months of cash or cash equivalents available based on our current operations. Our strategic alliance with Epic may also generate (i) an additional \$1.6875 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.

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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, 2010, we expended approximately \$1.4 million in operating activities which we funded through the \$2.0 million in gross proceeds realized from the issuance of Series E Preferred Stock pursuant to the Epic Strategic Alliance Agreement and from cash on hand as of March 31, 2009. Our working capital at March 31, 2010 was negative \$2.3 million compared with working capital of \$0.8 million at March 31, 2009. Cash and cash equivalents at March 31, 2010 were \$0.6 million an increase of \$0.3 million from the \$0.3 million of cash and cash equivalents at March 31, 2009.

On June 3, 2009 and October 30, 2009, respectively, we consummated the Initial and Second Closings of the transactions contemplated by the Epic Strategic Alliance Agreement and received from Epic cash payments of \$1,000,000 (including \$250,000 previously paid to us as a good faith deposit) at the Initial Closing and \$1,000,000 at the Second Closing, in exchange for 1,000 shares of our Series E Preferred Stock, at each closing. 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. The Epic Strategic Alliance Agreement also contemplates one additional closing, which could generate an additional \$1.0 million in cash proceeds through Epic's purchase of additional shares of Series E Preferred Stock.

On November 12, 2009, the Company received \$62,500 from Epic in exchange for 62.5 shares of Series E Preferred Stock to be issued to Epic. 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, 2010, 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 and the interest payments due on September 1, 2009 and March 1, 2010, totaling \$120,775 and \$113,075, respectively were all paid from the Debt Service Reserve Fund, due to the Company not having sufficient available funds to make such payments when due. Nonpayment of the amounts when due constituted 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 and March 1, 2010. The Company is required to make two additional payments of \$18,846 each, on July 15, 2010 and August 15, 2010, in order to fully replenish the March 1, 2010 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, 2010 as compared to the Year Ended March 31, 2009

Elite's revenues for the year ended March 31, 2010 were \$3,344,298, an increase of \$1,069,473 over revenues for the prior year, and consisted of \$2,575,942 in manufacturing fees, \$763,928 in royalty fees and \$4,429 in contract lab service fees. Revenues for the year ended March 31, 2009 consisted of \$1,927,062 in manufacturing fees and \$347,763 in royalty fees. Manufacturing fees increased by approximately 34% and royalties increased by approximately 120% due to growth of product sales.

Research and development costs for the year ended March 31, 2010 were \$794,433, a decrease of \$2,836,992, or approximately 78%, from \$3,631,425 of such costs for the prior year. Decreases were attributed to decreases in salaries and wages, consulting fees associated with the development of products and lower active pharmaceutical ingredient ("API") costs for product development. Research and development costs are expected to increase, however, 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, 2010, were \$1,841,425, a decrease of \$305,470, or approximately 14% from \$2,146,895 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 offset by increases in legal fees related to the Midsummer et al litigation. This litigation was settled on June 25, 2010.

Non-cash compensation satisfied by the issuance of stock options and warrants decreased \$796,438 to \$125,004 for the year ended March 31, 2010 from \$921,442 for the year ended March 31, 2009. 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 \$286,822, or approximately 57%, from \$500,817 for the prior year to \$213,995. We acquired no new machinery and equipment in the current year and we implemented revised cost accounting standards, both of which contributed to the decrease.

Other income (expenses) for the year ended March 31, 2010 were \$(6,120,553) compared to other income (expenses) of \$(211,266) for the year ended March 31, 2009. 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 \$(4,076,050), derivative interest expense of \$(1,271,254) and discount in Series E issuance attributable to beneficial conversion features of \$(512,912). The derivative expenses result from a change in accounting principal required by the adoption of EITF 07-5 as of the beginning of the 2010 fiscal year. Accordingly, derivative income/(expenses) were not applicable to the 2009 fiscal year.

As a result of the foregoing, Elite's net loss for the year ended March 31, 2010 was \$8,056,874 compared to \$6,604,708 for the year ended March 31, 2009.

## Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), decreased to a working capital deficiency of \$2,274,572 as of March 31, 2010 from \$758,676 as of March 31, 2009, primarily due to net proceeds received as a result of our private placement of Series E Convertible Preferred Stock, offset by net cash used in operations and the reclassification of the NJEDA Bonds as a current liability.

We experienced negative cash flows from operations of \$1,364,748 for the year ended March 31, 2010, primarily due to our net loss from operations of \$8,056,874, combined with an increase in accounts receivable of \$395,245 and offset by non-cash expenses included in the net operating loss of \$6,905,623. The increased accounts receivable were collected, in full, during the 3 months immediately subsequent to close of the 2010 fiscal year.

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 is currently manufacturing 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, 2010 was \$2,575,942 and \$763,928, respectively. We expect future cash flows from manufacturing fees and royalties to provide additional cash to help fund our operations. However, no assurance can be given that we will generate any material revenues from the manufacturing fees and royalties earned on the Lodrane products.

## Off-balance sheet arrangements

None.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable to smaller reporting companies

## 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.

The Audit Committee of the Board of Directors of Elite Pharmaceuticals, Inc ("Company") regularly reviews the selection of the Company's independent registered public accounting firm.

### Engagement of Demetrius & Company as the Company's Independent Registered Public Accounting Firm

On January 14, 2010, after an extensive evaluation process the Audit Committee engaged Demetrius & Company, LLC ("Demetrius") as its new independent registered public accounting firm and dismissed Rosen Seymour Shapss Martin & Company LLP ("Rosen") as the Company's independent registered public accounting firm.

The reports of Rosen on the Company's consolidated financial statements for the fiscal year ended March 31, 2009 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no disagreements with Rosen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Rosen's satisfaction, would have caused Rosen to make reference to the subject matter of the disagreement in connection with its report. During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, there were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K.

During the fiscal year ended March 31, 2009, and in the subsequent interim period from April 1, 2009 through and including January 14, 2010, the Company did not consult Demetrius with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements.

#### Merger of Miller, Ellin & Company LLP into Rosen Seymour Shapss Martin & Company LLP

Effective January 1, 2009, the Company's independent accountant, Miller, Ellin & Company, LLP, merged its practice into the practice of Rosen Seymour Shapss Martin & Company LLP ("Rosen Seymour"). As a result of such merger, Rosen Seymour became the Company's new principal accountant. By letter, dated February 12, 2009, Rosen Seymour notified the Company that such merger is considered by the Securities and Exchange Commission to be a change in independent auditors.

Prior to the merger, the Company had not consulted with Rosen Seymour with respect to (i) the application of accounting principles to a specific transaction, either completed or proposed, (ii) the type of audit opinion that might be rendered on the Company's financial statements, or (iii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K).

#### 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, 2010, 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, 2010. 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, 2010, 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.

OTHER INFORMATION.

## PART III

## ITEM 10. DIRECTORS , EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

## Directors and Executive Officers

On June 8, 2009, at a Special Meeting of the Board of Directors, the Board took the following actions, in accordance with the terms of the Epic Strategic Alliance Agreement: (1) increased the size of the Board from five directors to seven directors and (2) appointed each of Ashok G. Nigalaye, Jeenarine Narine and Ram Potti as directors effective immediately following the resignation of one of the existing directors. In accordance with the Epic Strategic Alliance Agreement, Chris Dick voluntarily resigned as a member of the Board, effective as of June 24, 2009, and, effective immediately following such resignation, Messrs. Nigalaye, Narine and Potti were appointed as members of the Board, representing the three directors designated by Epic for appointment to the Board (such three directors, the “Epic Directors”), in accordance with the terms of the Epic Strategic Alliance Agreement.

Our current directors, executive officers and key employees, and such persons’ biographical information are set forth below:

| Name                     | Age | Title  |
|--------------------------|-----|--|
| Jerry Treppel            | 56  | Director, Chairman of the Board, Chief Executive Officer |
| Barry Dash, Ph. D        | 78  | Director   |
| Ashok G. Nigalaye, Ph. D | 58  | Director, Chief Scientific Officer                       |
| Jeenarine Narine         | 60  | Director   |
| Ram Potti                | 57  | Director   |
| Chris Dick               | 55  | Director, President, Chief Operating Officer             |
| Jeffrey Whitnell         | 54  | Director   |
| Carter J. Ward           | 46  | Chief Financial Officer, Secretary and Treasurer         |

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

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



he is qualified to serve as a director.

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

Dr. Ashok G. Nigalaye, Director since June 24, 2009, member of the Compensation Committee since October 23, 2009 and Chief Scientific Officer since September 15, 2009. Dr. Nigalaye was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since July 2008, Dr. Nigalaye has been the President and Chief Executive Officer of Epic Pharma LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement. From August 1993 to February 2008, Dr. Nigalaye served as Vice President of Scientific Affairs and Operations of Actavis Totowa LLC, a manufacturer of generic pharmaceuticals, where he was responsible for directing and organizing company activities relating to pharmaceutical drug manufacturing, regulatory affairs and research and development. Dr. Nigalaye currently serves as a director of GTI Inc., a privately held company. Dr. Nigalaye holds a B.S. in Pharmacy from the University of Bombay, an M.S. in Industrial Pharmacy from Long Island University, and a Ph.D. in Industrial Pharmacy from St. John's University. Dr. Nigalaye is also a licensed pharmacist in the State of New York. Dr. Nigalaye's extensive education in pharmaceutical sciences and experience as a director and officer of pharmaceutical companies led to the conclusion that he is qualified to serve as a director.

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

Ram Potti, Director since June 24, 2009, chairman of the Nominating Committee since October 23, 2009 and member of the Audit Committee since October 23, 2009. Mr. Potti was elected as a member of Elite's Board in June 2009 as one of three directors designated by Epic pursuant to the terms of the Epic Strategic Alliance Agreement. Since July 2008, Mr. Potti has been the Vice President of Business Development of Epic Pharma LLC, a manufacturer of generic pharmaceuticals and Elite's strategic partner pursuant to the Epic Strategic Alliance Agreement, in which capacity he handles the company's new ventures and products. Mr. Potti is also the founder and current President of RSMB Investments LLC, an investment company that specializes in startup ventures in the healthcare and technology sectors. In addition, from 2002 to 2006, Mr. Potti was the President and Chief Operating Officer of Trigen Laboratories, a company which he founded that manufactures generic pharmaceutical products. Mr. Potti holds a B.S. in Chemistry from the University of Kerala, St. Albert's College. Mr. Potti's experience in developing business and products for Epic Pharma LLC led to the conclusion that he is qualified to serve as a director.

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

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

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

Each director holds office until the next annual meeting of stockholders or until such director's death, resignation or removal. There are no family relationships between any of our directors and executive officers.

#### Committees of the Board

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

#### Audit Committee

During the fiscal year ended March 31, 2010, the members of the Audit Committee were Barry Dash, Robert J. Levenson (Chairman of the Audit Committee) and Melvin Van Woert until October 23, 2009 and Jeffrey Whitnell (Chairman of the Audit Committee), Ram Potti and Dr. Barry Dash, thereafter. We deem the members of our Audit Committee to be independent and Mr. Levenson to be qualified as an audit committee financial expert.



## Nominating Committee

During the fiscal year ended March 31, 2010, the members of the Nominating Committee were Melvin Van Woert (Chairman of the Nominating Committee), Robert J. Levenson and Dr. Barry Dash until October 23, 2009 and Ram Potti (Chairman of the Nominating Committee), Dr. Barry Dash and Jeenarine Narine, thereafter. The Nominating Committee makes recommendations to the Board of Directors with respect to Director nominees. There were no material changes to the procedures by which security holders may recommend nominees to our Board of Directors since the filing of our last Annual Report on Form 10-K.

## Compensation Committee

During the fiscal year ended March 31, 2010, the members of the Compensation Committee were Barry Dash (Chairman of the Compensation Committee), Robert J. Levenson and Melvin Van Woert until October 23, 2009, and Dr. Barry Dash (Chairman of the Compensation Committee), Dr. Ashok Nigalaye and Jeffrey Whitnell, thereafter.

## Code of Conduct

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

## Section 16(a) Beneficial Ownership Reporting Compliance

To our knowledge, there was no person who, at any time during the fiscal year ended March 31, 2010, was a director, officer or beneficial owner of more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act, who failed to file on a timely basis a report required by Section 16(a) of the Exchange Act during or with respect to such fiscal year, except as follows.

In addition, Dr. Dash and Mr. Treppel each failed to file one report required by Section 16(a) of the Exchange Act for transactions since March 31, 2009 to report (a) in the case of Dr. Dash, the conversion of 20 shares of Series C Preferred Stock into 12,243 shares of Common Stock and the Company's issuance to him of warrant to purchase up to 12,243 shares of Common Stock on June 3, 2009 and (b) in the case of Mr. Treppel, the conversion by Wheaton of 75 shares of Series D Preferred Stock into 375,000 shares of Common Stock and the Company's issuance to Wheaton of a warrant to purchase up to 375,000 shares of Common Stock on June 3, 2009.

## ITEM 11. EXECUTIVE COMPENSATION.

### COMPENSATION DISCUSSION AND ANALYSIS

#### SUMMARY

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

#### Compensation Linked to Attainment of Performance Goals

Our plan to obtain and retain highly skilled employees is to provide significant incentive compensation opportunities and market competitive salaries. The plan was intended to link individual employee objectives with overall company

strategies and results, and to reward executive officers and significant employees for their individual contributions to those strategies and results. We use compensation and performance data from comparable companies in the pharmaceutical industry to establish market competitive compensation and performance standards for our employees. Furthermore, we believe that equity awards serve to align the interests of our executives with those of our stockholders. As such, equity is a key component of our compensation program.

## Role of the Compensation Committee and its Advisors

The Company formed the Compensation Committee in June 2007. Since the formation of the Compensation Committee all elements of the executives' compensation are determined by the Compensation Committee, which is comprised of a two independent non-employee directors, and one director who is also the Company's Chief Scientific Officer. However, the Compensation Committee's decisions concerning the compensation of the Company's Chief Executive Officer are subject to ratification by the independent directors of the Board of Directors. As of March 31, 2010, the members of the Compensation Committee were Barry Dash, Ashok Nigalaye and Jeffrey Whitnell. The Committee operates pursuant to a charter. Under the Compensation Committee charter, the Compensation Committee has authority to retain compensation consultants, outside counsel, and other advisors that the committee deems appropriate, in its sole discretion, to assist it in discharging its duties, and to approve the terms of retention and fees to be paid to such consultants

## NAMED EXECUTIVE OFFICERS AND KEY EMPLOYEES

The named executive officers and key employees for the fiscal year ending March 31, 2010 are Jerry Treppel, Chief Executive Officer since September 15, 2009; Chris C. Dick, President, Chief Operating Officer for the full year and acting Chief Executive Officer until September 15, 2009; Carter J. Ward, Chief Financial Officer, Secretary and Treasurer since July 1, 2009. These individuals are referred to collectively in this Annual Report on Form 10-K as the "Named Executive Officers."

## OUR EXECUTIVE COMPENSATION PROGRAM

### Overview

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

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

## ELEMENTS OF OUR EXECUTIVE COMPENSATION PROGRAM

### Base Salary

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

### Bonuses



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

## Stock Options

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

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

## Retirement and Deferred Compensation Benefits

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

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

## Post-Termination / Change of Control Compensation

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

## Perquisites

As described in more detail below, the perquisites provided to certain of the Named Executive Officers consist of car allowances and life insurance premiums. These perquisites represent a small fraction of the total compensation of each such Named Executive Officer. The value of the perquisites we provide are taxable to the Named Executive Officers and the incremental cost to us of providing these perquisites is reflected in the Summary Compensation Table. The Board of Directors believes that the perquisites provided are reasonable and appropriate. For more information on perquisites provided to the Named Executive Officers, please see the "All Other Compensation" column of the Summary Compensation Table on page 54 of this Annual Report on Form 10-K and "Agreements with Named Executive Officers" below.

## Agreements with Named Executive Officers

### Mr. Chris C. Dick

On November 13, 2006, we entered into an employment agreement and, on November 10, 2008, an amendment to the employment agreement, with Mr. Dick, as our Executive Vice President of Corporate Development and Chief Operating Officer (as amended, the "First Dick Agreement"). The First Dick Agreement was for an initial term that ended on November 13, 2009, without renewal. As provided in the First Dick Agreement, we have the right to terminate Mr. Dick's employment due to disability as defined in a long-term disability insurance policy reasonably satisfactory to him or, in the absence of such policy, due to Mr. Dick's inability for 120 days in any 12 month period to substantially perform his duties as a result of a physical or mental illness.



The First Dick Agreement provides for an initial base annual salary of \$250,000, a guaranteed bonus of \$25,000 payable within 30 calendar days of the end of each fiscal year during the term and a \$700 per month automobile allowance. The First Dick Agreement provides for payment of a discretionary bonus following the end of each fiscal year of up to 50% of Mr. Dick's then annual base salary. The amount, if any, of the discretionary bonus will be determined by the Board of Directors or the Compensation Committee. The discretionary bonus, if paid to Mr. Dick will be based on the achievement of goals discussed with the executive in good faith and within a reasonable time following the commencement of each fiscal year and may be paid in cash or shares of our Common Stock valued at the average of the closing price per share during the five trading days immediately preceding the date of issuance of the shares. For the year ended March 31, 2010 Mr. Dick is to receive a \$25,000 bonus.

The First Dick Agreement provides for the grant under the Stock Option Plan of fully-vested options to purchase 250,000 shares of Common Stock at an exercise price of \$2.25 per share. The Dick Agreement also provides for the grant of options to purchase up to 300,000 shares of Common Stock, at an exercise price of \$2.25 per share, which vest in two 150,000 share tranches upon the closing of an exclusive product license for the United States national market, the entire European Union Market or the Japan market or a product sale transaction of all our ownership rights in the United States (only once for each product) for our first drug developed by us for which FDA approval will be sought under a NDA (including a 505(b) (2) application) for a Non-Generic Opioid Product as to the first tranche and as to our second Non-Generic Opioid Product for the second tranche.

The First Dick Agreement also provides for the grant of options to purchase up to 200,000 shares of Common Stock at an exercise price of \$2.25 per share (the "Dick Milestone Options") with the Dick Milestone Options to vest (A) as to not more than 125,000 shares and 75,000 shares, respectively, upon the commencement of the first Phase III clinical trial relating to the first and then the second Non-Generic Opioid Product developed by us; (B) 50,000 shares upon the closing of each product license or product sale transaction (on a product by product basis and only once for each product) other than Non-Generic Opioid Products for which options were granted above; (C) 10,000 shares upon the filing by us (in our name) with the FDA of either an ANDA or an NDA, for a product not covered by a previous FDA application; (D) 40,000 shares upon the approval by the FDA of any ANDA or NDA (filed in our name) for a product not previously approved by the FDA; (E) 25,000 shares upon the filing of an application for a U.S. patent by us (in our name); and (F) 25,000 shares upon the granting by the PTO of a patent to us filed in our name or an approval of an ANDA or NDA; provided, however, that the foregoing options terminate upon the executive's termination of employment except that options under (D) and (F) nevertheless vest if the filing was made during the initial term but prior to termination of Mr. Dick's employment by us without cause and the approval was made within 540 days of the filing of the ANDA, NDA or patent application.

We also agreed that if all 200,000 Dick Milestone Options have fully vested during the initial term of the Dick Agreement, we will grant under the Stock Option Plan to Mr. Dick at the end of the first current fiscal year in which the following event occurs fully vested additional options to purchase the following shares at the fair market value on the date of grant (the "Additional Dick Milestone Options"): (a) to the extent not previously vested with respect to his comparable Dick Milestone Options: (i) up to 125,000 shares upon the commencement of the first Phase III clinical trial relating to the first Non-Generic Opioid Product developed by us; and (ii) up to an additional 125,000 shares as to such trial relating to the second Non-Generic Opioid Product developed by us, (b) 50,000 shares upon the closing of each product license for the United States national market or product sale transaction of all ownership rights (on a product by product basis and only once for each product); (c) 10,000 shares upon the filing by us (in our name) with the FDA of either an ANDA or NDA for a product not covered by a previous FDA application for each drug product of us, other than the Non-Generic Opioid Products for which any Opioid Option was granted under the Dick Agreement; (d) 40,000 shares upon the approval by the FDA of any ANDA, NDA or 505(b)(2) application filed in our name for a product not previously approved by the FDA; (e) 25,000 shares in the event of the filing of an application of an additional U.S. patent by us (filed in our name); and (f) 25,000 shares in the event of the granting by the PTO of the foregoing additional patent applications to us (filed in our name).

The First Dick Agreement allows us at our discretion to grant to Mr. Dick additional options under the Stock Option Plan and provides Mr. Dick the right to register at our expense for reoffering shares issued upon exercise of the options under the Securities Act in certain registration statements filed by us with respect to offerings of securities by us.

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The First Dick Agreement provides that in the event we terminate Mr. Dick's employment for Cause (as defined in the Dick Agreement) or Mr. Dick terminates employment without Good Reason (as defined in the Dick Agreement), he is to receive salary through date of termination, reimbursement for expenses incurred prior to termination, all unvested options will terminate as of the date of termination and vested options will be governed by the terms of the Stock Option Plan and the related option agreement. In the event of a termination due to death, disability or by us without cause or by Mr. Dick for Good Reason, we are to pay him or his estate subject to his compliance with certain covenants, including non-competition, non-solicitation, confidentiality and assignment of intellectual property, his base salary for the longer of the balance of the initial term or one year from date of termination, continue health insurance coverage for 12 months from termination and his vested options are to be exercisable for 90 days from date of termination.

In the event the employment of Mr. Dick is terminated by us following a Change of Control (as defined below) of Elite, Mr. Dick will be entitled to the amounts payable as a result of termination by us without cause plus a lump sum payment of \$500,000 and all unvested options shall immediately vest and along with unexercised vested options be exercisable within 90 days from the date of termination. "Change of Control" is defined as the acquisition of Elite pursuant to a merger or consolidation which results in the reduction to less than 50% of the shares outstanding upon consummation of the holders of its outstanding shares immediately prior thereto or sale of substantially all our assets or capital stock to another person, or the acquisition by a person or a related group in a single transaction or a series of related transaction of more than 50% of the combined voting power of Elite's outstanding voting securities.

The First Dick Agreement provides for a one-year non-competition covenant and a two-year non-solicitation covenant following termination of employment.

The First Dick Agreement provides for reimbursement of expenses (including business, travel and entertainment) reasonably incurred in the performance of his duties, provided, however that reimbursement of expenses in excess of \$2,000 per month are subject to the approval of our chief executive officer. Mr. Dick is entitled to participate in such employee benefit and welfare plans and programs, which may be offered to our senior executives including life insurance, health and accident insurance, medical plans and programs and profit sharing and retirement plans.

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

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

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

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

Mr. Jerry Treppel

In a Current Report on Form 8-K filed with the SEC on November 6, 2008, which is incorporated herein by reference, the Company disclosed that Jerry I. Treppel, a member of the Company's Board of Directors, was appointed as the Chairman of the Board. On December 1, 2008, Elite entered into a compensation agreement with Mr. Treppel (the

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

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

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

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

Either party may terminate the First Treppel Agreement, effective immediately upon the giving of written notice to the other party.

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

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

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

#### Mr. Carter J. Ward

In a Current Report on Form 8-K filed with the SEC on July 8, 2009, which is incorporated herein by reference, the Company disclosed that Carter J. Ward was appointed Chief Financial Officer on July 1, 2009, and that the Company entered into a letter agreement with Mr. Ward (the "First Ward Agreement") wherein Mr. Ward became an at-will employee as the Company's Chief Financial Officer. Under the terms of the First Ward Agreement, Mr. Ward will dedicate at least two business days per week toward fulfilling his responsibilities as Chief Financial Officer and will receive an annual base salary of \$60,000, payable in accordance with the Company's payroll practices. Mr. Ward is entitled to generally the same benefits offered to other employees of the Company, subject to applicable eligibility requirements and may become eligible for cash and/or equity based awards that may be granted by the Company in the future, with any such awards being granted in the discretion of the Company and its Chief Executive Officer.

On November 12, 2009, the Company entered into an employment agreement replacing the First Ward Agreement (the "Second Ward Agreement"). Pursuant to the terms of the Second Ward Agreement, Mr. Ward will continue as an



at-will employee of the Company as its Chief Financial Officer. Mr. Ward will receive a base salary of \$150,000, with \$125,000 of such amount being paid in accordance with the Company's payroll practices and \$25,000 of such amount being paid by the issuance of restricted shares of Common Stock, in lieu of cash. The Common Stock component of Mr. Ward's compensation is to be paid on a quarterly basis, with the number of shares issued equal to the quotient of the quarterly amount due of \$6,250 divided by the average daily closing price of the Company's Common Stock for the quarter just ended.

### Hedging Policy

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

### Option Exercises and Stock Vested

No options have been exercised by our Named Executive Officers during the fiscal year ended March 31, 2010.

### Pension Benefits

We do not provide pension benefits to the Named Executive Officers.

### Nonqualified Deferred Compensation

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

### Potential Payments Upon Termination or Change of Control

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

## COMPENSATION OF NAMED EXECUTIVE OFFICERS

## Summary Compensation Table

| Name<br>and principal position                          | Fiscal<br>Year | Salary<br>(\$) | Bonus<br>(\$) | Option<br>Awards<br>(\$) | All<br>Other<br>Compensation<br>(\$) | Total<br>(\$) |
|---|----------------|----------------|---------------|--------------------------|--------------------------------------|---------------|
| Jerry Treppel   | 2010(1)        | —              | —             | —                        | 27,500(2)                            | 27,500        |
| Chairman of the Board<br>and<br>Chief Executive Officer | 2009(1)        | —              | —             | —                        | 18,646(3)                            | 18,646        |
| Chris Dick  | 2010(1)        | 218,817(4)     | —             | 18,690(7)                | 8,400(6)                             | 245,907       |
| President and<br>Chief Operating Officer                | 2009(1)        | 218,750        | 25,000(5)     | —                        | 8,400(6)                             | 252,150       |
| Carter J. Ward  | 2010(1)        | 105,000(8)     | 500(9)        | 18,690(10)               | —                                    | 124,190       |
| Chief Financial Officer,<br>Secretary and Treasurer     | 2009(1)        | —              | —             | —                        | —                                    | —             |

- (1) Represents the fiscal years ended March 31, 2010 and 2009
- (2) Represents compensation due to Mr. Treppel for his service as Chairman of the Board. \$12,500 of the total amount results from cash compensation due pursuant to the First Treppel Agreement and \$15,000 of the total amount results from compensation due for Mr. Treppel's service as Chairman of the Board. Mr. Treppel receives no salary or additional compensation for his service as Chief Executive Officer
- (3) Represents Directors fees totaling \$8,750 earned while Mr. Treppel was a director of the Company and \$9,896 of compensation due to Mr. Treppel for his service as Chairman of the Board pursuant to the First Treppel Agreement. Mr. Treppel was appointed Chief Executive Officer on September 15, 2009 and accordingly did not serve in such position during the fiscal year ended March 31, 2009.
- (4) Represents salaries paid to Mr. Dick pursuant to the First Dick Agreement for the period April 2009 to November 2009, and pursuant to the Second Dick Agreement thereafter. Of the total salary amount, \$208,400 was paid in cash as salary in accordance with the Company's payroll practices, and \$10,417 which will be paid via the issuance of common shares in lieu of cash, pursuant to the Second Dick Agreement. The shares to be issued in relation to this amount have not been issued as of the date of filing of this annual report on Form 10-K
- (5) Represent guaranteed bonuses due to Mr. Dick pursuant to the First Dick Agreement
- (6) Represents amounts paid for auto allowance
- (7) Represents the value of incentive stock options granted to Mr. Dick under the Elite Pharmaceutical Inc. 2004 Stock Option Plan on January 18, 2010. Mr. Dick was granted options to purchase 200,000 shares of the Company's Common Stock at 10 cents per share. The options vest in equal increments of one-third of the total grant each on January 18, 2011, 2012 and 2013, respectively. The options expire on January 17, 2020. The options were valued using the Black Scholes Method. Please refer to note 12 of the financial statements for further details on the valuation assumptions, with such note so referenced deemed part of the disclosure provided pursuant to this Item.



- (8) Represents salaries paid to Mr. Ward pursuant to the First Ward Agreement for the period July 2009 to October 2009, and pursuant to the Second Ward Agreement thereafter. Of the total salary amount, \$94,583 was paid in cash as salary in accordance with the Company's payroll practices and \$10,417 will be paid via the issuance of common shares in lieu of cash, pursuant to the Second Ward Agreement. The shares to be issued in relation to this amount have not been issued as of the date of filing of this annual report on Form 10-K
- (9) Represents a discretionary bonus awarded to Mr. Ward by the Chief Executive Officer in December 2009.
- (10) Represents the value of incentive stock options granted to Mr. Ward under the Elite Pharmaceutical Inc. 2004 Stock Option Plan on January 18, 2010. Mr. Ward was granted options to purchase 200,000 shares of the Company's Common Stock at 10 cents per share. The options vest in equal increments of one-third of the total grant each on January 18, 2011, 2012 and 2013, respectively. The options expire on January 17, 2020. The options were valued using the Black Scholes Method. Please refer to note 12 of the financial statements for further details on the valuation assumptions, with such note so referenced deemed part of the disclosure provided pursuant to this Item.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock option awards held by Named Executive Officers as of March 31, 2010:

| Name           | OPTION AWARDS   |   |   |                             |                        |
|----------------|---|---|---|-----------------------------|------------------------|
|                | Number of securities underlying unexercised options (#) exercisable | Number of securities underlying unexercised options (#) unexercisable | Equity incentive plan awards: Number of securities underlying unexercised options (#) | Options exercise price (\$) | Option expiration date |
| Chris Dick     | 10,000(1)   | —   | —   | 2.34                        | 10/31/12               |
|                | 10,000(1)   | —   | —   | 2.34                        | 10/31/12               |
|                | 10,000(1)   | —   | —   | 2.34                        | 10/31/12               |
|                | 10,000(2)   | —   | —   | 2.21                        | 6/13/13                |
|                | 10,000(2)   | —   | —   | 2.21                        | 6/13/13                |
|                | 10,000(2)   | —   | —   | 2.21                        | 6/13/13                |
|                | 40,000(3)   | —   | —   | 2.80                        | 7/14/15                |
|                | 250,000(4)  | —   | —   | 2.25                        | 11/13/16               |
|                | —   | —   | 150,000(5)  | 2.25                        | 11/13/16               |
|                | —   | —   | 150,000(6)  | 2.25                        | 11/13/16               |
| Jerry Treppel  | 60,000(9)   | —   | —   | 0.06                        | 12/1/18                |
|                | —   | 60,000(10)  | —   | 0.06                        | 12/1/18                |
|                | —   | 60,000(11)  | —   | 0.06                        | 12/1/18                |
| Carter J. Ward | —   | —   | 200,000(8)  | 0.10                        | 1/17/20                |



- (1) Options vested on November 1, 2003, 2004 and 2005, respectively
- (2) Options vested on June 13, 2004, 2005 and 2006, respectively
- (3) Options vested on July 14, 2005
- (4) Options vested on November 3, 2006
- (5) These options vest upon the closing of an exclusive product license for the first of the United States national market, the entire European Union market or the Japan market or product sale transaction of all of our ownership rights in the United States (only once for each individual product) for our first Non-Generic Opioid Product.
- (6) These options vest upon the closing of an exclusive product license for the United States national market, the entire European Union market or the Japan market or product sale transaction of all of our ownership rights in the United States (only once for each individual product) for our second Non-Generic Opioid Product.
- (7) These options vest as follows: upon the commencement of the first Phase III clinical trial relating to the first "Non-Generic Opioid Product" developed by the Company as to 125,000 options and relating to the second "Non-Generic Opioid Product" developed by the Company as to 75,000 options.
- (8) Options vest in annual increments on January 18, 2011, 2012 and 2013, with each increment equal to one-third of the total options granted.
- (9) Options vested on December 1, 2009
- (10) Options vest on December 1, 2010
- (11) Options vest on December 1, 2011

## DIRECTOR COMPENSATION

The following table sets forth information concerning director compensation for the year ended March 31, 2010:

| Name             | Fees earned or paid in cash (\$) | Stock awards (\$) | Option awards (\$) | Non-equity incentive plan compensation earnings (\$) | Nonqualified deferred compensation earnings (\$) | All other compensation (\$) | Total (\$) |
|------------------|----------------------------------|-------------------|--------------------|--|--|-----------------------------|------------|
| Ashok Nigalaye   | 4,750(1)                         | —                 | —                  | —  | —  | 10,000(2)                   | 14,750     |
| Ram Potti        | 4,750(1)                         | —                 | —                  | —  | —  | 10,000(2)                   | 14,750     |
| Jeenarine Narine | 4,750(1)                         | —                 | —                  | —  | —  | 10,000(2)                   | 14,750     |
| Barry Dash       | 19,500(1)                        | —                 | —                  | —  | —  | 10,000(2)                   | 29,500     |
| Jeffrey Whitnell | —                                | —                 | —                  | —  | —  | 10,000(2)                   | 10,000     |
| Robert Levenson  | 21,500(1)                        | —                 | —                  | —  | —  | —                           | 21,500     |
| Melvin van Woert | 19,500(1)                        | —                 | —                  | —  | —  | —                           | 19,500     |

(1) Represents directors fees earned pursuant to the Company's policy with regards to directors fees in effect until October 23, 2009.

(2) Represents directors fees earned pursuant to the Company's policy with regards to directors fees in effect since October 23, 2009. In accordance with such policy, all directors are to be paid via the issuance of common stock of the Company in lieu of cash



## Fee Compensation

As of January 1, 2008 and until October 23, 2009, the Company's policy regarding director fees was as follows: (i) Directors who are employees or consultants of the Company (and/or any of its subsidiaries) receive no additional remuneration for serving as directors or members of committees of the Board; (ii) all Directors are entitled to reimbursement for out-of-pocket expenses incurred by them in connection with their attendance at the Board or committee meetings; (iii) Directors who are not employees or consultants of the Company (and/or any of its subsidiaries) receive \$15,000 annual retainer fee for their service on the Board and all committees; (iv) Directors who are not employees or consultants of the Company (and/or any of its subsidiaries) receive a per board meeting fee of \$1,000 for each board meeting and a per committee meeting fee of \$1,000 for each committee meeting attended by such Director; provided that the chairperson of the committee conducting such meeting shall (in place of the \$1,000 meeting fee) receive a per committee meeting fee of \$1,500 for each committee meeting attended; and (v) for purposes of the compensation schedule set forth above, (x) a meeting shall only constitute a meeting of the Board or a committee entitling a participant to a meeting fee if such meeting extends to at least sixty (60) minutes (including the time of any reconvened portion of a meeting after an adjournment), (y) a meeting shall include all meetings attended in-person (whether at the Company's offices or at any other location) or via telephone conference, and (z) only one fee may be payable to Director and/or committee member per calendar day. Except as described in this section, non-employee Directors do not receive any additional compensation for their services on the Board of Directors, except for Mr. Treppel, who receives \$25,000 per year for serving as Chairman of the Board in lieu of the fees described above, pursuant to First Treppel Agreement.

As of October 23, 2009, the Company's policy regarding director fees was as follows: ((i) Directors who are employees or consultants of the Company (and/or any of its subsidiaries), except for Mr. Jerry Treppel, Chief Executive Officer and Dr. Ashok Nigalaye, Chief Scientific Officer, receive no additional remuneration for serving as directors or members of committees of the Board; (ii) all Directors are entitled to reimbursement for out-of-pocket expenses incurred by them in connection with their attendance at the Board or committee meetings; (iii) Directors who are not employees or consultants of the Company (and/or any of its subsidiaries) receive \$20,000 annual retainer fee, payable on a quarterly basis, in arrears, for their service on the Board and all committees; (iv) The Chairman of the Board receives a \$30,000 annual retainer fee, payable on a quarterly basis, in arrears; (v) Directors and the Chairman do not receive any additional compensation for attendance at or chairing of any meetings. (vi) Mr. Jerry Treppel receives no additional compensation, above the annual retainer fee due to the Chairman of the Board, for his services as Chief Executive Officer (vii) Dr. Ashok Nigalaye receives no additional compensation, above the annual retainer fee due to Directors, for his services as Chief Scientific Officer. (viii) All Director and Chairman fees are paid via the issuance of common stock of the Company, in lieu of cash, as described below.

## Equity Compensation

As of October 23, 2009, Members of the Board of Directors and the Chairman are paid their annual retainer fees via the issuance of restricted shares of Common Stock of the Company, in lieu of cash. The number of shares to be issued to each Director and the Chairman is equal to the quotient of the quarterly amount due to each Director and the Chairman, respectively, divided by the average daily closing price of the Company's stock for the quarter just ended.

Members of the Board of Directors during the fiscal years ended March 31, 2010 and March 31, 2009 did not receive any options or equity compensation for serving as directors other than the grant of grant of 180,000 options to the Chairman of the Board in December 2008 and shares of Common Stock earned in lieu of cash in relation to Director and Chairman fees due since October 23, 2009.

## Other

The Company has entered into indemnification agreements with each of its directors to indemnify them to the fullest extent permitted under Delaware General Corporation Law.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information, as of June 30, 2010 (except as otherwise indicated), regarding beneficial ownership of our Common Stock by (i) each person who is known by us to own beneficially more than 5% of the Common Stock, (ii) each of our directors and nominees for director, (iii) each of the Named Executive Officers (as defined below) and (iv) all our directors and executive officers as a group. On June 30, 2010, we had 87,352,981 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 2,000 shares of Series E Preferred Stock outstanding as of June 30, 2010 are entitled to vote, on an as-converted basis, with the Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting). The 895.5590 shares of Series B Preferred Stock, 5,418 shares of Series C Preferred Stock and 9,008.4410 shares of Series D Preferred Stock outstanding as of June 30, 2010 are nonvoting. As of June 30, 2010, none of the individuals listed below beneficially owned any shares of Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock or Series E Preferred Stock, except for the following (as further described in the footnotes to the table): (a) 2,062.5 shares of Series E Preferred Stock were beneficially owned by Messrs. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, including 62.5 shares of Series Preferred Shares which are fully paid but not yet issued, (c) 3,956 shares of Series D Preferred Stock were beneficially owned by Midsummer Capital LLC, (d) 2,064.4410 shares of Series D Preferred Stock were beneficially owned collectively by Bushido Capital Master Fund LP and BCMF Trustees LLC. There are currently no shares of Series A Preferred Stock outstanding.

As used in the table below and elsewhere in this Annual Report on Form 10-K, the term beneficial ownership with respect to a security consists of sole or shared voting power, including the power to vote or direct the vote, and/or sole or shared investment power, including the power to dispose or direct the disposition, with respect to the security through any contract, arrangement, understanding, relationship, or otherwise, including a right to acquire such power(s) during the 60 days immediately following June 30, 2010. Except as otherwise indicated, the stockholders listed in the table have sole voting and investment powers with respect to the shares indicated.

| Name and Address of Beneficial Owner of Common Stock                      | Amount and Nature of Beneficial Ownership*** | Percent (%) of Class Beneficially Owned |
|---|--|---|
| Chris Dick, President and Chief Operating Officer*                        | 985,647(1)                                   | **                                      |
| Barry Dash, Director*   | 274,240(2)                                   | **                                      |
| Jerry Treppel, Chairman of the Board and Chief Executive Officer*         | 2,159,557(3)                                 | **                                      |
| Ashok G. Nigalaye, Chief Scientific Officer and Director *                | 158,123,783(4)                               | 36.9                                    |
| Jeenarine Narine, Director *  | 158,123,783(4)                               | 36.9                                    |
| Ram Potti, Director *   | 158,123,783(4)                               | 36.9                                    |
| Jeffrey Whitnell *  | 96,584(5)                                    | **                                      |
| Carter J. Ward, Chief Financial Officer *                                 | 100,360(6)                                   | **                                      |
| Epic Pharma, LLC<br>227-15 North Conduit Ave.<br>Laurelton, NY 11413      | 158,027,199(4)                               | 36.9                                    |
| Trellus Management Company<br>Adam Usdan<br>350 Madison Avenue, 9th Floor | 23,391,777(9)                                | 5.5                                     |

New York, New York 10017

|                              |               |      |
|------------------------------|---------------|------|
| Midsummer Capital LLC        | 68,556,721(7) | 16.0 |
| Scott D. Kaufman             |               |      |
| 295 Madison Ave., 38th Floor |               |      |
| New York, NY 10017           |               |      |

|                             |               |     |
|-----------------------------|---------------|-----|
| Bushido Capital Partners    | 14,328,847(8) | 8.6 |
| Ronald S. Dagar             |               |     |
| 145 E. 57th St., 11th Floor |               |     |
| New York, NY 10022          |               |     |

|  |                 |      |
|--|-----------------|------|
| All Directors and Officers as a group*** | 161,932,339(10) | 37.8 |
|--|-----------------|------|

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\* The address is c/o Elite Pharmaceuticals Inc., 165 Ludlow Avenue, Northvale, NJ 07647.

\*\* Less than 1%

\*\*\* As of June 30, 2010

(1) Includes options to purchase 850,000 shares of Common Stock, warrants held by Mr. Dick and Hedy Rogers as joint tenants to purchase 10,479 shares of Common Stock, 24,808 shares of Common Stock and 100,360 shares of Common Stock to be issued to Mr. Dick for the five months ended March 31, 2010, in accordance with the terms and conditions of the Second Dick Agreement. In addition, Mr. Dick has been granted options to purchase 200,000 shares of Common Stock under the Company's 2004 Equity Incentive Plan. These options vest in equal annual increments over a three year period, with the first vesting to occur on January 18, 2011. As of June 30, 2010, none of the options granted were vested and accordingly they are not included as part of Mr. Dick's beneficial ownership.

(2) Includes options to purchase 120,000 shares of Common Stock, warrants to purchase 21,544 shares of Common Stock, 36,112 shares of Common Stock and 96,584 shares of Common Stock to be issued to Mr. Dash in payment of Director Fees earned and owing as of March 31, 2010, pursuant to the Company's policy regarding payment of Director's Fees..

(3) Includes 396,569 shares of restricted Common Stock, 190,000 shares of unrestricted common stock, warrants to purchase up to 1,257,113 of Common Stock, an option to purchase up to 180,000 shares of Common Stock and 144,875 shares of Common Stock to be issued to Mr. Treppel in payment of Chairman of the Board Fees earned and owing as of March 31, 2010, pursuant to the Company's policy regarding payment of the Chairman's Fees.

(4) Based on information in the Schedule 13D filed jointly on June 12, 2009 by Epic Pharma, LLC ("Epic Pharma"), Epic Investments, LLC ("Epic Investments"), Ashok G. Nigalaye, Jeenarine Narine and Ram Potti and the individual Forms 3 filed on June 12, 2009 by each of Epic Pharma and Messrs. Nigalaye, Narine and Potti. Represents 2,000 shares of Series E Preferred Stock convertible into 73,237,821 shares of Common Stock, warrants to purchase 80,000,000 shares of Common Stock held by Epic Investments, LLC, a Delaware limited liability company and 62.5 shares of Series E Preferred Stock convertible into 2,289,377 shares of Common Stock and warrants to purchase 2,500,000 shares of Common Stock which have been paid in full by, but not yet issued to Epic Investments, LLC, a Delaware limited liability company. Messrs. Nigalaye, Narine and Potti are executive officers and equity owners of Epic Pharma, LLC, a Delaware limited liability company, and Epic Investments, LLC, a Delaware limited liability company. Epic Pharma, LLC is an equity owner of Epic Investments, LLC. Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti share voting and investment control over, and are indirect beneficial owners of, the shares. The interest of Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti in the shares is limited, and each disclaims beneficial ownership of such shares except to the extent of its pecuniary interest in Epic Investments, LLC. In addition to beneficial interests related to Epic Investments, Messrs. Nigalaye, Narine and Potti each are due 96,584 shares of Common Stock in payment of Director's Fees earned and owing as of March 31, 2010, pursuant to the Company's policy regarding payment of Director's Fees.

(5) Included 96,584 shares of Common Stock to be issued to Mr. Whitnell in payment of Director Fees earned and owing as of March 31, 2010, pursuant to the Company's policy regarding payment of Director's Fees..

(6) Consists of 100,360 shares of Common Stock to be issued to Mr. Ward for the five months ended March 31, 2010, in accordance with the terms and conditions of the Second Ward Agreement. In addition, Mr. Ward has been granted options to purchase 200,000 shares of Common Stock under the Company's 2004 Equity Incentive Plan. These options vest in equal annual increments over a three year period, with the first vesting to occur on January 18, 2011. As of June 30, 2010, none of the options granted were vested and accordingly they are not included as part of Mr. Ward's beneficial ownership.

(7) Includes 3,956 shares of Series D Preferred Stock convertible into an aggregate of 56,514,286 shares of Common Stock, 543,143 shares of common stock to be issued pursuant to the Settlement Agreement and 6,663,040 shares of Common Stock issued to Midsummer in lieu of cash for payment of Series D Preferred Share dividends earned and owed during the period from October 1, 2008 to June 30, 2010 and warrants to purchase up to 4,836,252 shares of Common Stock held by Midsummer Investment, Ltd. ("Midsummer"). Notwithstanding the inclusion of the beneficial ownership calculation, pursuant to the terms of our Certificate of Designation of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock (the "Series D Certificate") and the aforementioned warrants, the number of shares of Common Stock into which the Series D Preferred Stock are convertible and the warrants are exercisable is limited to the extent that, after giving effect to such conversion or exercise, Midsummer (together with its affiliates, and any other person or entity acting as a group together with Midsummer or any of its affiliates) would beneficially own in excess of 4.99% of the number of shares of Common Stock outstanding, provided, however, that such beneficial ownership limitation may be increased at the election of Midsummer to a percentage not in excess of 9.99% upon at least 61 days' prior notice to the Company.

(8) Includes 2,064,441 shares of Series D Preferred Stock convertible into an aggregate of 29,492,000 shares of Common Stock 277,992 shares of common stock to be issued pursuant to the Settlement Agreement and 3,242,180 shares of Common Stock issued to Bushido in lieu of cash for payment of Series D Preferred Share dividends earned and owed during the period from October 1, 2008 to June 30, 2010 and warrants to purchase up to 3,906,642 shares of Common Stock held collectively by Bushido Capital Master Fund LP and BCMF Trustees LLC (together, "Bushido"). Notwithstanding the inclusion of the beneficial ownership calculation, pursuant to the terms of the Series D Certificate and the aforementioned warrants, the number of shares of Common Stock into which the Series D Preferred Stock are convertible and the warrants are exercisable is limited to the extent that, after giving effect to such conversion or exercise, Midsummer (together with its affiliates, and any other person or entity acting as a group together with Bushido or any of its affiliates) would beneficially own in excess of 4.99% of the number of shares of Common Stock outstanding, provided, however, that such beneficial ownership limitation may be increased at the election of Bushido to a percentage not in excess of 9.99% upon at least 61 days' prior notice to the Company.

(9) Based on information provided by Trellus Management Company, LLC ("TMC"), Trellus Partners L.P ("TPLP"), Trellus Partners II L.P. ("TPLP II") and Trellus Offshore Fund Limited ("TOF"), and Adam Usdan ("Usdan" and, together with TMC, TPLP, TPLP II and TOF, , the "Trellus Entities") in the Schedule 13D filed jointly by the Trellus Entities with the SEC on February 16, 2010, Includes an aggregate of 23,391,777 shares of Common Stock held collectively by Trellus Partners L.P ("TPLP"), Trellus Partners II L.P. ("TPLP II") and Trellus Offshore Fund Limited ("TOF") (the "Trellus Entities") and warrants to purchase up to 4,703,063 shares of Common Stock held collectively by the Trellus Entities. TMC is the investment adviser to TPLP, TPLP II, and TOF. Mr. Usdan is the controlling principal and chief investment officer of TMC. Mr. Usdan and TMC share voting power and dispositive power over the shares. Pursuant to the terms of the warrants, the number of shares of Common Stock into which the warrants are exercisable is limited to that number of shares of Common Stock which would result in the Trellus Entities, together with their affiliates, having aggregate beneficial ownership of not more than 4.99% of the total number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon any exercise of the warrants, provided, however, that such beneficial ownership limitation may be increased at the election of the

Trellus Entities to 9.99% upon at least 61 days' prior notice to the Company.

(10) Includes 396,569 shares of restricted Common Stock, 250,920 shares of unrestricted Common Stock, 828,515 shares of Common Stock to be issued in aggregate to the Directors and Officers in payment of Chairman fees, Director fees and salaries earned and owing pursuant to the Company's policy regarding payment of Chairman's fees, Director fees and pursuant to the Second Dick Agreement and the Second Ward Agreement, 2,000 shares of Series E Preferred Stock convertible into 73,237,821 shares of Common Stock warrants to purchase 81,469,136 shares of Common Stock, options to purchase 970,000 shares of Common Stock, and 62.5 shares of Series E Preferred Stock convertible into 2,289,377 shares of Common Stock and warrants to purchase 2,500,000 shares of Common Stock which have been paid in full by, but not yet issued to Epic Investments, LLC, a Delaware limited liability company.

### Changes in Control

Set forth below are any arrangement known to the Company the operation of which may at a subsequent date result in a change of control of the Company. As of June 30, 2010, Epic held 2,000 shares of Series E Preferred Stock convertible into 73,237,821 shares of Common Stock, a warrant to purchase up to 80,000,000 shares of Common Stock and has fully paid and is to be issued 62.5 shares of Series E Preferred Stock, convertible into 2,289,377 shares of Common Stock and warrants to purchase up to 2,500,000 shares of Common Stock, representing its beneficial ownership of approximately 36.9% of the Company's outstanding Common Stock as of such date (calculated in accordance with Rule 13d-3 of the Exchange Act). Further, the 2,000 shares of Series E Preferred Stock held by Epic as of June 30, 2009 are entitled to vote, on an as-converted basis, with the Common Stock on any matter presented to the holders of our Common Stock for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting).

In addition, in connection with subsequent closings of the transactions contemplated by the Epic Strategic Alliance Agreement, Epic could acquire an additional 1,000 shares of Series E Preferred Stock and warrants to purchase up to 40,000,000 shares of Common Stock. Further, with respect to the products developed by Epic at the Facility under the Epic Strategic Alliance Agreement, the Company would also be obligated to issue to Epic (a) warrants to purchase up to an aggregate of 56,000,000 shares of its Common Stock upon the receipt by Elite from Epic of written notices of Epic's receipt of an acknowledgment from the FDA that the FDA accepted for filing an ANDA for certain controlled-release and immediate-release products developed by Epic at Elite's facility and (b) up to an aggregate of 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 such additional securities to Epic in accordance with the Epic Strategic Alliance Agreement, Epic could beneficially own in excess of 50% of the issued and outstanding Common Stock or other voting securities of the Company. Further, under the Epic Strategic Alliance Agreement, at such time as Epic owns more than 50% of the issued and outstanding Common Stock or other voting securities of Elite, the number of Epic Directors that the Purchaser will be entitled to designate under the Epic Strategic Alliance Agreement will be equal to a majority of the Board of Directors.

### Equity Compensation Plan Information

For information regarding securities authorized for issuance under equity compensation plans as of March 31, 2010, please refer to the disclosure contained in Item 5 in Part II of this Annual Report on Form 10-K, under the heading "Equity Compensation Plan Information," which is incorporated herein by reference.

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

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



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

#### CERTAIN RELATED PERSON TRANSACTIONS

##### Transactions with Mark Gittelman and Gittelman & Co. P.C. (“Gittelman”)

On February 26, 1998, we entered into an agreement with Gittelman and Co., P.C., whereby fees are paid to Gittelman and Co., PC., a firm wholly-owned by Mark I. Gittelman, our Chief Executive Officer, Secretary and Treasurer until July 1, 2009, in consideration for services rendered by the firm as internal accountant and financial and management consultant to us. The firm’s services included the services rendered by Mr. Gittelman in his capacity as Chief Financial Officer, Secretary and Treasurer until July 1, 2009. For the period April 1, 2009 to June 30, 2010 and the fiscal years ended March 31, 2009 and 2008, the fees paid by us under the agreement were \$40,185, \$233,181 and \$176,206, respectively. The services rendered by the firm to us for the period April 1, 2009 to June 30, 2009 and the fiscal years ended March 31, 2009 and 2008 averaged 157, 111 and 105 hours per month, respectively, of which a monthly average 21 hours for the period April 1, 2009 to June 30, 2009 and 28 hours for the fiscal years ended March 31, 2009 and 2008, respectively, were services rendered by Mr. Gittelman in his capacity as an officer of Elite.

On July 15, 2009, we entered into a settlement agreement and release Gittelman and Co., P.C., (the “Gittelman Settlement”) for payment of outstanding invoices totaling \$85,531, representing all invoices issued by Gittelman to us and outstanding as of July 15, 2009. The Gittelman Settlement requires the Company to pay the principal sum of \$75,000, plus interest accruing on the outstanding balance of such \$75,000 at the rate of 6% per annum, in twelve equal, monthly installments, beginning on July 20, 2009 and due on the 20th of the next 11 months thereafter. The monthly payments, consisting of principal reduction and interest equal \$6,454.98 with all twelve required payments equal to \$77,460, in aggregate. The Company made all payments required in the Gittelman Settlement and Gittelman released the Company from all further claims related to the outstanding invoices as of July 15, 2009.

Gittelman has not rendered any services to the Company since June 30, 2009 and as of June 23, 2010, no amounts were due to Gittelman.

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

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

|   |   |   |
|---|---|---|
|   | § | Mr. Nigalaye, President and CEO of Epic Pharma, LLC;  |
| § |   | Mr. Narine, Executive Vice President of Manufacturing and Operations of Epic Pharma, LLC; and |
|   | § | Mr. Potti, Vice President of Business Development of Epic Pharma, LLC.                        |

As part of the operation of the strategic alliance, the Company identified certain raw materials used in its operations which were also used by Epic Pharma LLC and for which Epic Pharma LLC was achieving lower acquisition costs, mainly as a result of greater purchase volume discounts. The strategic alliance allowed the Company to purchase these raw materials from Epic, at the Epic acquisition cost, without markup. During the fiscal year ended 3/31/2010, an aggregate amount of \$100,056 in such raw materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma’s acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC’s acquisition cost.

In September 2009 Carter Ward, our Chief Financial Officer, acquired a less than 2.5% interest in Epic Investments LLC in exchange for a cash payment of \$50,000. Epic Investments LLC owns (i) 2,000 shares of the Company’s Series E Preferred Stock, which is convertible into 73,237,821 shares of the Company’s Common Stock, (ii) warrants to purchase 80,000,000 shares of the Company’s Common Stock, and (iii) 62.5 shares of the Company’s Series E Preferred Stock convertible into 2,289,377 shares of the Company’s Common Stock and warrants to purchase 2,500,000 shares of the Company’s Common Stock, which have been paid for in full but have not yet been issued. The Series E Preferred Stock and the warrants represent all of the assets of Epic Investments LLC. If Epic Investments LLC were to make distributions to its members in the future, Mr. Ward will be entitled to his pro rata share of any such distribution. Any distributions would likely be made only if Epic Investments LLC sells shares of the Company’s Common Stock that it would acquire after converting the Series E Preferred Stock or exercising the warrants.



## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Effective January 1, 2009, Miller, Ellin & Company, LLP (“Miller Ellin”), the independent accountant of Elite, and the principal accountant engaged to audit Elite’s financial statements, consummated a merger of its practice into the practice of Rosen Seymour, with Rosen Seymour Shapss Martin & Company LLP (“Rosen Seymour”) succeeding to the business and operations of Miller Ellin, subject to certain conditions and exceptions, as agreed upon by the parties under the terms of the Merger. Upon consummation of the Merger on January 1, 2009, Miller Ellin effectively resigned as Elite’s independent accountant, and Rosen Seymour, pursuant to the terms of its agreement with Miller Ellin, became Elite’s new independent accountant and principal accountant to audit its financial statements, as the successor in interest of Miller Ellin.

On January 14, 2010, the Audit Committee engaged Demetrius & Company LLC (“Demetrius”) as its new independent registered public accounting firm and dismissed Rosen Seymour as the Company’s independent registered public accounting firm. The appointment of Demetrius was disclosed in a current report on Form 8-K filed with the SEC on January 15, 2010, and incorporated herein by reference.

The following table presents fees, including reimbursements for expenses, for professional audit services rendered by Demetrius & Co, Rosen Seymour and Miller Ellin for the audits of our annual financial statements and interim reviews of our quarterly financial statements for the years ended March 31, 2010 and March 31, 2009 and fees billed for other services rendered by Rosen Seymour and Miller Ellin during those periods.

|                                | 2010      | 2009      |
|--------------------------------|-----------|-----------|
| Audit Fees(1)                  |           |           |
| Rosen Seymour and Miller Ellin | \$ 90,850 | \$ 90,315 |
| Demetrius & Co.                | 61,750    | —         |
| Audit-Related Fees             | —         | —         |
| Tax Fees                       | \$ 10,000 | \$ 10,000 |
| All Other Fees                 | —         | —         |

(1) Audit Fees relate to the audit of our financial statements and reviews of financial statements included in our quarterly reports on Form 10-Q.

## PART IV

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

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

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

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

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

(c) None.



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

| Exhibit No. | Description  |
|-------------|--|
| 3.1(a)      | Certificate of Incorporation of the Company, together with all other amendments thereto, as filed with the Secretary of State of the State of Delaware, incorporated by reference to (a) Exhibit 4.1 to the Registration Statement on Form S-4 (Reg. No. 333-101686), filed with the SEC on December 6, 2002 (the "Form S-4"), (b) Exhibit 3.1 to the Company's Current Report on Form 8-K dated July 28, 2004 and filed with the SEC on July 29, 2004, (c) Exhibit 3.1 to the Company's Current Report on Form 8-K dated June 26, 2008 and filed with the SEC on July 2, 2008, and (d) Exhibit 3.1 to the Company's Current Report on Form 8-K dated December 19, 2008 and filed with the SEC on December 23, 2008. |
| 3.1(b)      | Certificate of Designations, Preferences and Rights of Series A Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K dated October 6, 2004, and filed with the SEC on October 12, 2004.   |
| 3.1(c)      | Certificate of Retirement with the Secretary of the State of the Delaware to retire 516,558 shares of the Series A Preferred Stock, as filed with the Secretary of State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 10, 2006, and filed with the SEC on March 14, 2006.   |
| 3.1(d)      | Certificate of Designations, Preferences and Rights of Series B 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated March 15, 2006, and filed with the SEC on March 16, 2006.   |
| 3.1(e)      | Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.   |
| 3.1(f)      | Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007.   |
| 3.1(g)      | Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated April 24, 2007, and filed with the SEC on April 25, 2007  |
| 3.1(h)      | Amended Certificate of Designations of Preferences, Rights and Limitations of Series B 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.   |
| 3.1(i)      | Amended Certificate of Designations, Preferences and Rights of Series C 8% Convertible Preferred Stock, as filed with the Secretary of the State of Delaware, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.   |

- 3.1(j) Amended Certificate of Designations of Preferences, Rights and Limitations of Series D 8% Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K dated September 15, 2008, and filed with the SEC on September 16, 2008.
- 3.1(k) Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 3.1(l) Amended Certificate of Designations of the Series D 8% Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 3.1(m) Amended Certificate of Designations of the Series E Convertible Preferred Stock as filed with the Secretary of State of the State of Delaware on June 29, 2010, incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 3.2 By-Laws of the Company, as amended, incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form SB-2 (Reg. No. 333-90633) made effective on February 28, 2000 (the "Form SB-2").
- 4.1 Form of specimen certificate for Common Stock of the Company, incorporated by reference to Exhibit 4.1 to the Form SB-2.
- 4.2 Form of specimen certificate for Series A 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.

- 4.3 Form of specimen certificate for Series B 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.4 Form of specimen certificate for Series C 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.5 Warrant to purchase 100,000 shares of Common Stock issued to DH Blair Investment Banking Corp., incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended September 30, 2004.
- 4.6 Warrant to purchase 50,000 shares of Common Stock issued to Jason Lyons incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.
- 4.7 Form of Warrant to purchase shares of Common Stock issued to designees of lender with respect to financing of an equipment loan incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ended June 30, 2004.
- 4.8 Form of Short Term Warrant to purchase shares of Common Stock issued to purchasers in the private placement which initially closed on October 6, 2004 (the "Series A Financing"), incorporated by reference to Exhibit 4.6 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.9 Form of Long Term Warrant to purchase shares of Common Stock issued to purchasers in the Series A Financing, incorporated by reference to Exhibit 4.7 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.10 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series A Financing, incorporated by reference to Exhibit 4.8 to the Current Report on Form 8-K, dated October 6, 2004, and filed with the SEC on October 12, 2004.
- 4.11 Form of Replacement Warrant to purchase shares of Common Stock in connection with the offer to holders of Warrants in the Series A Financing (the "Warrant Exchange"), incorporated by reference as Exhibit 4.1 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.
- 4.12 Form of Warrant to purchase shares of Common Stock to the Placement Agent, in connection with the Warrant Exchange, incorporated by reference as Exhibit 4.2 to the Current Report on Form 8-K, dated December 14, 2005, and filed with the SEC on December 20, 2005.
- 4.13 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on March 15, 2006 (the "Series B Financing"), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.14 Form of Warrant to purchase shares of Common Stock issued to purchasers in the Series B Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.



- 4.15 Form of Warrant to purchase shares of Common Stock issued to the Placement Agent, in connection with the Series B Financing, incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 4.16 Form of Warrant to purchase 600,000 shares of Common Stock issued to Indigo Ventures, LLC, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated July 12, 2006 and filed with the SEC on July 18, 2006.
- 4.17 Form of Warrant to purchase up to 478,698 shares of Common Stock issued to VGS PHARMA, LLC, incorporated by reference as Exhibit 3(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 4.18 Form of Non-Qualified Stock Option Agreement for 1,750,000 shares of Common Stock granted to Veerappan Subramanian, incorporated by reference as Exhibit 3(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.

- 4.19 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on April 24, 2007 (the “Series C Financing”), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.20 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series C Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 4.21 Form of specimen certificate for Series D 8% Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.22 Form of Warrant to purchase shares of Common Stock issued to purchasers in the private placement which closed on September 15, 2008 (the “Series D Financing”), incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.23 Form of Warrant to purchase shares of Common Stock issued to the placement agent in the Series D Financing, incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 4.24 Form of specimen certificate for Series E Convertible Preferred Stock of the Company, incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 4.25 Warrant to purchase shares of Common Stock issued to Epic Investments, LLC in the initial closing of the Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 10.1 2004 Employee Stock Option Plan approved by stockholders on June 22, 2004, incorporated by reference to Exhibit A to the Proxy Statement filed on Schedule 14A with respect to the Annual Meeting of Stockholders held on June 22, 2004.
- 10.2 Form of Confidentiality Agreement (corporate), incorporated by reference to Exhibit 10.7 to the Form SB-2.
- 10.3 Form of Confidentiality Agreement (employee), incorporated by reference to Exhibit 10.8 to the Form SB-2.
- 10.4 Amended and Restated Employment Agreement dated as of September 2, 2005 between Bernard Berk and the Company, incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.5 Option Agreement between Bernard Berk and the Company dated as of July 23, 2003 incorporated by reference to Exhibit 10.7 to the Quarterly Report on Form 10-Q for three months ended June 30, 2003 (the “June 30, 2003 10Q Report”).
- 10.6

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Option Agreement between Bernard Berk and the Company dated as of July 23, 2003, incorporated by reference to Exhibit 10.8 to the June 30, 2003 10Q Report.

- 10.7 Amendment, dated as of September 2, 2005, by and between, the Company and Bernard Berk, to the Stock Option Agreement, dated as of July 23, 2003, incorporated by reference to Exhibit 10.2 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.8 Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.9 Stock Option Agreement, dated as of September 2, 2005, by and between the Company and Bernard Berk, incorporated by reference to Exhibit 10.4 to Current Report on Form 8-K, dated September 2, 2005, and filed with the SEC on September 9, 2005.
- 10.10 Engagement letter dated February 26, 1998, between Gittelman & Co. P.C. and the Company incorporated by reference to Exhibit 10.10 to the Form 10-K for the period ended March 31, 2004 filed with the SEC on June 29, 2004.

- 10.11 Product Development and Commercialization Agreement, dated as of June 21, 2005, between the Company and IntelliPharmaceutics, Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated June 21, 2005 and originally filed with the SEC on June 27, 2005, as amended on the Current Report on Form 8-K/A filed September 7, 2005, as further amended by the Current Report on Form 8-K/A filed December 7, 2005 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.12 Agreement, dated December 12, 2005, by and among the Company, Elite Labs, and IntelliPharmaCeutics Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated December 12, 2005, and originally filed with the SEC on December 16, 2005, as amended by the Current Report on Form 8-K/A filed March 7, 2006 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.13 Loan Agreement, dated as of August 15, 2005, between New Jersey Economic Development Authority (“NJEDA”) and the Company, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.14 Series A Note in the aggregate principal amount of \$3,660,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.15 Series B Note in the aggregate principal amount of \$495,000.00 payable to the order of the NJEDA, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.16 Mortgage from the Company to the NJEDA, incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.17 Indenture between NJEDA and the Bank of New York as Trustee, dated as of August 15, 2005, incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, dated August 31, 2005 and filed with the SEC on September 6, 2005.
- 10.18 Form of Warrant Exercise Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 14, 2005 and filed with the SEC on December 20, 2005.
- 10.19 Form of Registration Rights Agreement, between the Registrant and signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated December 14, 2005 and filed with the SEC on December 20, 2005.
- 10.20 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.21 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated March 15, 2006 and filed with the SEC on March 16, 2006.
- 10.22

Form of Placement Agent Agreement, between the Registrant and Indigo Securities, LLC, incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated March 15, 2006, and filed with the SEC on March 16, 2006.

- 10.23 Financial Advisory Agreement between the Registrant and Indigo Ventures LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated July 12, 2006 and filed with the SEC on July 18, 2006.
- 10.24 Seconded Amended and Restated Employment Agreement between the Registrant and Bernard Berk, incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.
- 10.25 Employment Agreement between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.
- 10.26 Employment Agreement between the Registrant and Chris Dick, incorporated by reference as Exhibit 10.3 to the Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 and filed with the SEC on November 14, 2006.
- 10.27 Product Collaboration Agreement between the Registrant and ThePharmaNetwork LLC, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated November 10, 2006 and filed with the SEC on November 15, 2006. (Confidential Treatment granted with respect to portions of the Agreement).

- 10.28 Strategic Alliance Agreement among the Registrant, VGS Pharma (“VGS”) and Veerappan S. Subramanian (“VS”), incorporated by reference as Exhibit 10(a) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 10.29 Advisory Agreement, between the Registrant and VS, incorporated by reference as Exhibit 10(b) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 10.30 Registration Rights Agreement between the Registrant, VGS and VS, incorporated by reference as Exhibit 10(c) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 10.31 Employment Agreement between Novel Laboratories Inc. (“Novel”) and VS, incorporated by reference as Exhibit 10(d) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 10.32 Stockholders’ Agreement between Registrant, VGS, VS and Novel, incorporated by reference as Exhibit 10(e) to the Current Report on Form 8-K, dated December 6, 2006 and filed with the SEC on December 12, 2006.
- 10.33 Amended and Restated Employment Agreement, between the Registrant and Charan Behl, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated February 9, 2007 and filed with the SEC on February 14, 2007.
- 10.34 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 10.35 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 10.36 Form of Placement Agent Agreement, between the Company and Oppenheimer & Company, Inc., incorporated by reference as Exhibit 10.3 to the Current Report on Form 8-K, dated April 24, 2007 and filed with the SEC on April 25, 2007.
- 10.37 Form of Securities Purchase Agreement, between the Registrant and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.
- 10.38 Form of Registration Rights Agreement, between the Registrant and the signatories thereto, incorporated by reference as Exhibit 10.2 to the Current Report on Form 8-K, dated July 17, 2007 and filed with the SEC on July 23, 2007.
- 10.39 Consulting Agreement, dated as of July 27, 2007, between the Registrant and Willstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.
- 10.40

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

- 10.41 Employment Agreement, dated as of January 3, 2008, by and between the Registrant and Dr. Stuart Apfel, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated January 3, 2008 and filed with the SEC on January 9, 2008.
- 10.42 Form of Securities Purchase Agreement, between the Company and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 10.43 Form of Placement Agent Agreement, between the Company, ROTH Capital Partners, LLC and Boenning & Scattergood, Inc., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 10.44 Separation Agreement and General Release of Claims, dated as of October 20, 2008, by and between the Company and Stuart Apfel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.

- 10.45 Consulting Agreement, dated as of October 20, 2008, by and between the Company and ParalleX Clinical Research, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 15, 2008 and filed with the SEC on October 21, 2008.
- 10.46 Separation Agreement and General Release of Claims, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.
- 10.47 Consulting Agreement, dated as of November 3, 2008, by and between the Company and Charan Behl, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated October 28, 2008 and filed with the SEC on November 3, 2008.
- 10.48 Separation Agreement and General Release of Claims, dated as of November 5, 2008, by and between the Company and Bernard J. Berk, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated November 6, 2008 and filed with the SEC on November 6, 2008.
- 10.49 Amendment to Employment Agreement, dated as of November 10, 2008, by and between the Company and Chris Dick, incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ended September 30, 2008 and filed with the SEC on November 14, 2008.
- 10.50 Compensation Agreement, dated as of December 1, 2008, by and between the Company and Jerry I. Treppel, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated December 1, 2008 and filed with the SEC on December 4, 2008.
- 10.51 Strategic Alliance Agreement, dated as of March 18, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated March 18, 2009 and filed with the SEC on March 23, 2009.
- 10.52 Amendment to Strategic Alliance Agreement, dated as of April 30, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated April 30, 2009 and filed with the SEC on May 6, 2009.
- 10.53 Second Amendment to Strategic Alliance Agreement, dated as of June 1, 2009, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated June 1, 2009, and filed with the SEC on June 5, 2009.
- 10.54 Employment Agreement, dated as of July 1, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K dated July 1, 2009 and filed with the SEC on July 8, 2009.
- 10.55 Third Amendment to Strategic Alliance Agreement, dated as of Aug 18, 2009, by and among the Company, Epic Pharma LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q, for the period ending June 30, 2009 and filed with the SEC on August 19, 2009.
- 10.56 Employment Agreement, dated as of November 13, 2009, by and between the Company and Chris Dick, , incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.



- 10.57 Employment Agreement, dated as of November 13, 2009, by and between the Company and Carter J. Ward, incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, for the period ending September 30, 2009 and filed with the SEC on November 16, 2009.
- 10.58 Elite Pharmaceuticals Inc. 2009 Equity Incentive Plan, as adopted November 24, 2009, incorporated by reference to Exhibit 10.1 to the Registration Statement Under the Securities Act of 1933 on Form S-8, dated December 18, 2009 and filed with the SEC on December 22, 2009.
- 10.59 Stipulation of Settlement and Release, dated as of June 25, 2010, by and among the Company, Midsummer Investment, Ltd., Bushido Capital Master Fund, LP, BCMF Trustees, LLC, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010

- 10.60 Amendment Agreement, dated as of June 25, 2010, by and among the Company, and the investors signatory thereto, incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 10.61 Amendment Agreement, dated as of June 2010, by and among the Company, Epic Pharma, LLC and Epic Investments, LLC, incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated July 1, 2010 and filed with the SEC on July 1, 2010
- 21 Subsidiaries of the Company.\*
- 23.1 Consent of Demetrius & Company, L.L.C.\*
- 23.2 Consent of Rosen Seymour Shapss Martin & Company LLP\*
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 32.1\*\* Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*
- 32.2\*\* Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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\* Filed herewith.

\*\* As contemplated by SEC Release No. 33-8212, these exhibits are furnished with this Annual Report on Form 10-K and are not deemed filed with the Securities and Exchange Commission and are not incorporated by reference in any filing of Elite Pharmaceuticals, Inc. under the Securities Act or the Securities Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filings.

SIGNATURES

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

ELITE PHARMACEUTICALS, INC.

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

Dated: July 7, 2010

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

Dated: July 7, 2010

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

| Signature                                | Title   | Date         |
|--|---|--------------|
| /s/ Jerry Treppel<br>Jerry Treppel       | Chairman, Chief Executive Officer   | July 7, 2010 |
| /s/ Chris Dick<br>Chris Dick             | President, Chief Operating<br>Officer and Director<br>(Principal Executive<br>Officer)      | July 7, 2010 |
| /s/ Carter J. Ward<br>Carter J. Ward     | Chief Financial Officer<br>and Treasurer (Principal<br>Financial and Accounting<br>Officer) | July 7, 2010 |
| /s/ Ashok Nigalaye<br>Ashok Nigalaye     | Director  | July 7, 2010 |
| /s/ Barry Dash<br>Barry Dash             | Director  | July 7, 2010 |
| /s/ Ram Potti<br>Ram Potti               | Director  | July 7, 2010 |
| /s/ Jeenarine Narine<br>Jeenarine Narine | Director  | July 7, 2010 |



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2010 AND 2009

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Report of Independent Registered Public Accounting Firm

To The Board of Directors and Shareholders of Elite Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Elite Pharmaceuticals, Inc. and its subsidiaries as of March 31, 2010 and the related consolidated statements of operations, stockholders' deficit and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and subsidiaries as of March 31, 2010 and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

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

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

Wayne, New Jersey  
July 7, 2010

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Elite Pharmaceuticals, Inc. and Subsidiaries:

We have audited the accompanying consolidated balance sheet of Elite Pharmaceuticals, Inc. and subsidiaries (the "Company") as of March 31, 2009, and the related consolidated statements of operations, shareholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and subsidiaries as of March 31, 2009, and the consolidated results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that The Company will continue as a going concern. As shown in the financial statements, the Company has experienced significant losses and negative cash flows, resulting in decreased capital and accumulated deficits. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are described in Note 2.

/S/ ROSEN SEYMOUR SHAPSS MARTIN & COMPANY LLP

New York, New York  
June 29, 2009

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
March 31, 2010 and 2009

ASSETS

|  | 2010                 | 2009                 |
|--|----------------------|----------------------|
| <b>CURRENT ASSETS</b>  |                      |                      |
| Cash and cash equivalents  | \$ 578,187           | \$ 282,578           |
| Accounts receivable, (net of allowance for doubtful accounts of zero)  | 404,961              | 1,177                |
| Inventories (net of allowance of \$494,425 and \$ 0, respectively)   | 1,371,292            | 1,703,766            |
| Prepaid expenses and other current assets  | 131,507              | 331,622              |
| <b>Total current assets</b>  | <b>2,485,947</b>     | <b>2,319,143</b>     |
| <b>PROPERTY AND EQUIPMENT, net of accumulated depreciation and amortization of \$3,840,279 and \$3,360,606</b> |                      |                      |
|  | 4,095,814            | 4,575,487            |
| <b>INTANGIBLE ASSETS – net of accumulated amortization of \$76,434 and \$131,677</b>                           |                      |                      |
|  | 96,407               | 27,743               |
| <b>OTHER ASSETS</b>  |                      |                      |
| Accrued interest receivable  | —                    | 8,539                |
| Deposit on equipment   | —                    | 14,073               |
| Investment in Novel Laboratories Inc.  | 3,329,322            | 3,329,322            |
| Security deposits  | 14,652               | 13,488               |
| Restricted cash – debt service for EDA bonds   | 294,836              | 327,435              |
| EDA Bond offering costs, net of accumulated amortization of \$64,767 and \$49,534                              | 289,685              | 304,918              |
| <b>Total other assets</b>  | <b>4,024,902</b>     | <b>3,997,775</b>     |
| <b>TOTAL ASSETS</b>  | <b>\$ 10,606,663</b> | <b>\$ 10,920,148</b> |

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



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
March 31, 2010 and 2009

LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY

|   | 2010              | 2009             |
|---|-------------------|------------------|
| <b>CURRENT LIABILITIES</b>  |                   |                  |
| Current portion of EDA Bonds  | \$ 3,385,000      | \$ 210,000       |
| Short term loans and current portion of long-term debt  | 82,302            | 10,788           |
| Accounts payable and accrued expenses   | 986,777           | 981,058          |
| Preferred share derivative interest payable   | 306,440           | —                |
| Dividends payable   | —                 | 358,621          |
| <b>Total Current Liabilities</b>  | <b>4,760,519</b>  | <b>1,560,467</b> |
| <b>LONG TERM LIABILITIES</b>  |                   |                  |
| EDA bonds – net of current portion  | —                 | 3,385,000        |
| Long-term debt, less current portion  | 19,823            | 31,600           |
| Derivative Liability – Preferred Shares   | 7,924,763         | —                |
| Derivative Liability – Warrants   | 8,499,423         | —                |
| <b>Total Long-Term Liabilities</b>  | <b>16,444,009</b> | <b>3,416,600</b> |
| <b>Total Liabilities</b>  | <b>21,204,528</b> | <b>4,977,067</b> |
| <b>COMMITMENTS AND CONTINGENCIES:</b>   |                   |                  |
| <b>STOCKHOLDERS (DEFICIT) EQUITY</b>  |                   |                  |
| Preferred Stock - \$0.01 par value;   |                   |                  |
| Authorized 4,483,442 shares (originally 5,000,000 shares of which 516,558 shares of Series A Convertible Preferred Stock were retired) and 0 shares outstanding as of March 31, 2010 and 2009, respectively |                   |                  |
|   | —                 | —                |
| Authorized 10,000 Series B convertible Preferred Stock – issued and outstanding 896 and 1,046 shares, respectively – Reclassified as a liability as of April 1, 2009  |                   |                  |
|   | —                 | 11               |
| Authorized 20,000 Series C convertible Preferred Stock – issued and outstanding 5,418 and 1,3705 shares, respectively – Reclassified as a liability as of April 1, 2009                                     |                   |                  |
|   | —                 | 137              |
| Authorized 30,000 Series D convertible Preferred Stock – issued and outstanding 9,008 and 9,154 shares, respectively – Reclassified as a liability as of April 1, 2009                                      |                   |                  |
|   | —                 | 91               |
| Common Stock – par value of \$0.001 and \$0.01 as of March 31, 2010 and 2009, respectively  |                   |                  |
| Authorized 355,516,558 and 210,000,000 shares as of March 31, 2010 and 2009, respectively   |                   |                  |
| Issued and outstanding – 83,950,168 shares and 60,839,374 shares, as of March 31, 2010 and 2009, respectively   | 83,950            | 608,394          |

|   |               |               |
|---|---------------|---------------|
| Subscription receivable                             | —             | (75,000)      |
| Additional paid-in capital                          | 90,903,896    | 95,718,082    |
| Accumulated deficit                                 | (101,278,870) | (90,001,793)  |
| Treasury stock, at cost (100,000 common shares)     | (306,841)     | (306,841)     |
| Total Stockholders (Deficit) / Equity               | (10,597,865)  | 5,943,081     |
| TOTAL LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY | \$ 10,606,663 | \$ 10,920,148 |

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

|  | Years Ended<br>March 31, |                       |
|--|--------------------------|-----------------------|
|  | 2010                     | 2009                  |
| <b>REVENUES:</b>   |                          |                       |
| Manufacturing Revenues   | \$ 2,575,942             | \$ 1,927,062          |
| Lab Fee Revenues   | 4,429                    | —                     |
| Royalties  | 763,928                  | 347,763               |
| <b>Total Revenues</b>  | <b>3,344,298</b>         | <b>2,274,825</b>      |
| Cost of Revenues (including depreciation of \$294,615 for the year ended March 31, 2010)     | 2,305,763                | 1,464,568             |
| <b>Gross Profit</b>  | <b>1,038,536</b>         | <b>810,257</b>        |
| <b>OPERATING EXPENSES</b>  |                          |                       |
| Research and Development   | 794,433                  | 3,631,425             |
| General and Administrative   | 1,841,425                | 2,146,895             |
| Non-cash compensation through issuance of stock options and warrants                         | 125,004                  | 921,442               |
| Depreciation and amortization  | 213,995                  | 500,817               |
| <b>Total Operating Expenses</b>  | <b>2,974,857</b>         | <b>7,200,579</b>      |
| <b>LOSS FROM OPERATIONS</b>  | <b>(1,936,321)</b>       | <b>(6,390,322)</b>    |
| <b>OTHER INCOME / (EXPENSES):</b>  |                          |                       |
| Interest income  | 1,064                    | 40,917                |
| Interest expense   | (261,401)                | (252,183)             |
| Change in fair value of outstanding warrant derivatives                                      | (3,792,130)              | —                     |
| Change in fair value of preferred share derivatives  | (283,920)                | —                     |
| Interest expense attributable to dividends accrued to preferred share derivative liabilities | (1,271,254)              | —                     |
| Discount in Series E issuance attributable to beneficial conversion features                 | (512,912)                | —                     |
| <b>Total Other Expense</b>   | <b>(6,120,553)</b>       | <b>(211,266)</b>      |
| <b>LOSS BEFORE PROVISION FOR INCOME TAXES</b>  | <b>(8,056,874)</b>       | <b>(6,601,588)</b>    |
| Provision for Income Taxes   | —                        | (3,120)               |
| <b>NET LOSS</b>  | <b>(8,056,874)</b>       | <b>(6,604,708)</b>    |
| Preferred Stock Dividends  |                          | (2,206,683)           |
| <b>NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>  | <b>\$ (8,056,874)</b>    | <b>\$ (8,811,391)</b> |
| <b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>   | <b>\$ (0.11)</b>         | <b>\$ (0.27)</b>      |

|  |            |            |
|--|------------|------------|
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES<br>OUTSTANDINGS | 75,581,345 | 32,047,421 |
|--|------------|------------|

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT)EQUITY  
FOR THE YEAR ENDED MARCH 31, 2009  
(page 1 of 2)

|   | Series B                  |        | Series C                  |        | Series D                  |        | Common Stock |            |
|---|---------------------------|--------|---------------------------|--------|---------------------------|--------|--------------|------------|
|   | Preferred Stock<br>Shares | Amount | Preferred Stock<br>Shares | Amount | Preferred Stock<br>Shares | Amount | Shares       | Amount     |
| Balance at March 31,<br>2008  | 8,410                     | \$ 84  | 19,155                    | \$ 192 | —                         | —      | 23,131,035   | \$ 231,310 |
| Sale of Series D<br>Preferred   | —                         | —      | —                         | —      | 1,777                     | 18     | —            | —          |
| Conversion of Series<br>B Preferred and<br>Series C Preferred<br>into Series D<br>Preferred | (7,139)                   | (71)   | (4,898)                   | (49)   | 12,037                    | 120    | —            | —          |
| Conversion of Series<br>B, Series C and<br>Series D preferred<br>shares into common         | (225)                     | (2)    | (552)                     | (6)    | (4,660)                   | (47)   | 23,682,161   | 236,822    |
| Issuance of stock for<br>consulting services  | —                         | —      | —                         | —      | —                         | —      | 125,000      | 1,250      |
| Costs Associated<br>with raising capital  | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Non-cash<br>compensation<br>through issuance of<br>stock options and<br>warrants            | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Net Loss for the year<br>ended March 31,<br>2009  | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Dividends   | —                         | —      | —                         | —      | —                         | —      | 13,901,178   | 139,012    |
| Balance at March 31,<br>2009  | 1,046                     | 11     | 13,705                    | 137    | 9,154                     | 91     | 60,839,374   | 608,394    |

Schedule continues on next page

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT) EQUITY  
FOR THE YEAR ENDED MARCH 31, 2009  
(page 2 of 2)

(schedule continued from preceding page)

|   | Subscription<br>Receivable | Additional Paid<br>in Capital | Treasury Stock |              | Accumulated<br>Deficit | Stockholders<br>(Deficit) Equity |
|---|----------------------------|-------------------------------|----------------|--------------|------------------------|----------------------------------|
|   |                            |                               | Shares         | Amount       |                        |                                  |
| Balance at March 31, 2008   | \$ (75,000)                | \$ 91,889,978                 | (100,000)      | \$ (306,841) | \$ (81,190,402)        | \$ 10,549,321                    |
| Sale of Series D Preferred  | —                          | 1,776,982                     | —              | —            | —                      | 1,777,000                        |
| Conversion of Series B Preferred and Series C Preferred into Series D Preferred | —                          | —                             | —              | —            | —                      | —                                |
| Conversion of Series B, Series C and Series D preferred shares into common      | —                          | (236,767)                     | —              | —            | —                      | —                                |
| Issuance of stock for consulting services                                       | —                          | 100,000                       | —              | —            | —                      | 101,250                          |
| Costs Associated with raising capital   | —                          | (342,454)                     | —              | —            | —                      | (342,454)                        |
| Non-cash compensation through issuance of stock options and warrants            | —                          | 921,442                       | —              | —            | —                      | 921,442                          |
| Net Loss for the year ended March 31, 2009                                      | —                          | —                             | —              | —            | (6,604,708)            | (6,604,708)                      |
| Dividends   | —                          | 1,608,901                     | —              | —            | (2,206,683)            | (458,770)                        |
| Balance at March 31, 2009   | (75,000)                   | 95,718,082                    | (100,000)      | (306,841)    | (90,001,793)           | 5,943,081                        |

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT)EQUITY  
FOR THE YEAR ENDED MARCH 31, 2010  
(page 1 of 2)

|   | Series B                  |        | Series C                  |        | Series D                  |        | Common Stock |            |
|---|---------------------------|--------|---------------------------|--------|---------------------------|--------|--------------|------------|
|   | Preferred Stock<br>Shares | Amount | Preferred Stock<br>Shares | Amount | Preferred Stock<br>Shares | Amount | Shares       | Amount     |
| Balance at March 31,<br>2009  | 1,046                     | \$ 11  | 13,705                    | \$ 137 | 9,154                     | \$ 91  | 60,839,374   | \$ 608,394 |
| Cumulative effect of<br>reclassification of<br>preferred stock and<br>warrants  |                           | (11)   |                           | (137)  |                           | (91)   | —            | —          |
| Proceeds received in<br>exchange for<br>beneficial conversion<br>features embedded in<br>Series E preferred<br>shares | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Conversion of Series<br>B, Series C and Series<br>D preferred shares<br>into common                                   | (150)                     |        | (8,287)                   |        | (146)                     |        | 5,383,010    | 53,830     |
| Costs associated with<br>raising capital  | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Non-cash<br>compensation through<br>Issuance of stock<br>options and warrants   | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Net Income for the<br>year ended March 31,<br>2010  | —                         | —      | —                         | —      | —                         | —      | —            | —          |
| Dividends   | —                         | —      | —                         | —      | —                         | —      | 3,914,944    | 39,149     |
| Common shares<br>issued in lieu of cash<br>in payment of<br>preferred share<br>derivative interest<br>expense         | —                         | —      | —                         | —      | —                         | —      | 12,699,749   | 93,504     |



|  |     |   |       |   |       |   |            |           |
|--|-----|---|-------|---|-------|---|------------|-----------|
| Reduction in Par Value   | —   | — | —     | — | —     | — | —          | (712,040) |
| Common shares issued in lieu of cash in payment of legal and consulting expenses | —   | — | —     | — | —     | — | 1,113,091  | 1,113     |
| Write-off of subscription receivable from defunct company                        | —   | — | —     | — | —     | — | —          | —         |
| Balance at March 31, 2010  | 896 | — | 5,418 | — | 9,008 | — | 83,950,168 | 83,950    |

Schedule continues on next page

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDER'S (DEFICIT) EQUITY  
FOR THE YEAR ENDED MARCH 31, 2010  
(page 2 of 2)

(schedule continued from preceding page)

|  | Subscription<br>Receivable | Additional Paid<br>in Capital | Treasury Stock<br>Shares | Treasury Stock<br>Amount | Accumulated<br>Deficit | Stockholders<br>(Deficit) Equity |
|--|----------------------------|-------------------------------|--------------------------|--------------------------|------------------------|----------------------------------|
| Balance at March 31,<br>2009   | \$ (75,000)                | \$ 95,718,082                 | (100,000)                | \$ (306,841)             | \$ (90,001,793)        | \$ 5,943,081                     |
| Cumulative effect of<br>reclassification of<br>preferred stock and<br>warrants                                     | —                          | (7,144,131)                   | —                        | —                        | (3,220,203)            | (10,364,573)                     |
| Proceeds received in<br>exchange for beneficial<br>conversion features<br>embedded in Series E<br>preferred shares | —                          | 512,912                       | —                        | —                        | —                      | 512,912                          |
| Conversion of Series B,<br>Series C and Series D<br>preferred shares into<br>common                                | —                          | 14,000                        | —                        | —                        | —                      | 67,830                           |
| Costs associated with<br>raising capital   | —                          | (183,456)                     | —                        | —                        | —                      | (183,456)                        |
| Non-cash compensation<br>through Issuance of stock<br>options and warrants   | —                          | 125,004                       | —                        | —                        | —                      | 125,004                          |
| Net Income for the year<br>ended March 31, 2010  | —                          | —                             | —                        | —                        | (8,056,874)            | (8,056,874)                      |
| Dividends  | —                          | 319,472                       | —                        | —                        | —                      | 358,621                          |
| Common shares issued in<br>lieu of cash in payment of<br>preferred share derivative<br>interest expense            | —                          | 805,882                       | —                        | —                        | —                      | 899,386                          |
| Reduction in Par Value   | —                          | 712,040                       | —                        | —                        | —                      | —                                |
|  | —                          | 99,091                        | —                        | —                        | —                      | 100,204                          |

|   |        |            |           |           |               |              |
|---|--------|------------|-----------|-----------|---------------|--------------|
| Common shares issued in lieu of cash in payment of legal expenses |        |            |           |           |               |              |
| Write-off of subscription receivable from defunct company         | 75,000 | (75,000)   | —         | —         | —             | —            |
| Balance at March 31, 2010   | —      | 90,903,896 | (100,000) | (306,841) | (101,278,870) | (10,597,865) |

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(page 1 of 2)

|   | Years Ended March 31, |                    |
|---|-----------------------|--------------------|
|   | 2010                  | 2009               |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>   |                       |                    |
| Loss from Continuing Operations   | \$ (8,056,874)        | \$ (6,604,708)     |
| Adjustments to reconcile net loss to cash used in operating activities:               |                       |                    |
| Depreciation and amortization   | 508,610               | 500,817            |
| Inventory adjustment  | 311,986               | —                  |
| Change in fair value of warrant derivative liability                                  | 3,792,130             | —                  |
| Change in fair value of preferred shares derivative liability                         | 283,920               | —                  |
| Discount in Series E issuance attributable to embedded beneficial conversion feature  | 512,912               | —                  |
| Preferred shares derivative interest satisfied by the issuance of common stock        | 964,814               | —                  |
| Derivative interest accrued and payable   | 306,440               | —                  |
| Legal and consulting expenses satisfied by the issuance of common stock               | 100,204               | —                  |
| Non-cash compensation satisfied by the issuance of common stock, options and warrants | 125,004               | 921,442            |
| Changes in assets and liabilities:  |                       |                    |
| Accounts and interest receivable  | (395,245)             | 143,512            |
| Inventories   | 20,488                | 420,654            |
| Prepaid expenses and other current assets   | 16,659                | (52,400)           |
| Security deposit  | 12,909                | —                  |
| Accounts payable, accrued expenses and other current liabilities                      | 131,294               | 130,615            |
| <b>NET CASH USED IN OPERATING ACTIVITIES</b>  | <b>(1,364,748)</b>    | <b>(4,540,068)</b> |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>   |                       |                    |
| Purchases of property and equipment   | —                     | (45,892)           |
| Costs incurred for intellectual property assets                                       | (96,404)              | —                  |
| (Deposits) to / Withdrawals from restricted cash, net                                 | 32,599                | 104,644            |
| <b>NET CASH PROVIDED BY / (USED IN) INVESTING ACTIVITIES</b>                          | <b>(63,805)</b>       | <b>58,752</b>      |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>   |                       |                    |
| Other loan payments   | (65,839)              | (9,864)            |
| Dividends paid  | —                     | (163,403)          |
| NJEDA bond principal payments   | (210,000)             | (200,000)          |
| Costs associated with raising capital   | —                     | (342,454)          |
| Proceeds from issuance of Series D 8% Convertible Preferred Stock and Warrants        | —                     | 1,777,000          |
| Proceeds from issuance of Series E Convertible Preferred Stock and Warrants           | 2,000,000             | —                  |
| <b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>                                      | <b>1,724,161</b>      | <b>1,061,279</b>   |
| <b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>  | <b>295,609</b>        | <b>(3,420,037)</b> |
| <b>CASH AND CASH EQUIVALENTS – beginning of period</b>                                | <b>282,578</b>        | <b>3,702,615</b>   |
| <b>CASH AND CASH EQUIVALENTS – end of period</b>                                      | <b>\$ 578,187</b>     | <b>\$ 282,578</b>  |

Schedule continues on next page

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

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(page 2 of 2)

(schedule continued from preceding page)

|   | Years Ended March 31, |            |
|---|-----------------------|------------|
|   | 2010                  | 2009       |
| <b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>  |                       |            |
| Cash paid for interest  | \$ 262,685            | \$ 253,402 |
| Cash paid for income taxes  | —                     | 3,120      |
| <b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>  |                       |            |
| Preferred stock dividends for the year ended March 31, 2009, of \$2,106,535 paid by issuance of 13,901,178 shares of common stock | —                     | —          |
| Cumulative effect of reclassification of Preferred Stock and Warrants as Derivative Liabilities                                   | 10,364,573            | —          |
| Reduction in par value of common stock from \$0.01 per share to \$0.001 per share   | 712,954               |            |
| Consulting services paid by issuance of 125,000 shares of common stock  | —                     | 101,250    |

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

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2010 AND 2009

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF PRESENTATION

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

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries, (collectively the "Company") including its wholly-owned subsidiaries, Elite Laboratories, Inc. ("Elite Labs") and Elite Research, Inc. ("ERI") for the years ended March 31, 2010 ("Fiscal Year 2010") and 2009 ("Fiscal Year 2009"). Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2010, the financial statements of all wholly-owned entities are consolidated and all significant intercompany accounts are eliminated upon consolidation.

NATURE OF BUSINESS

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

CASH AND CASH EQUIVALENTS

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

INVENTORIES

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

## LONG-LIVED ASSETS

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

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

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

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

## RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense as incurred.

## CONCENTRATION OF CREDIT RISK

The Company maintains cash balances, which, at times, may exceed the amounts insured by the Federal Deposit Insurance Corp. (\$250,000). Uninsured balances at March 31, 2010 are \$328,187. Management does not believe that there is any significant risk of losses.

The Company in the normal course of business extends credit to its customers based on contract terms and performs ongoing credit evaluations. An allowance for doubtful accounts due to uncertainty of collection is established based on historical collection experience. Amounts are written off when payment is not received after exhaustive collection efforts. Currently the Company generates all its revenues from one company. The termination of the contract with that Company will result in the loss of all revenues currently earned.

## USE OF ESTIMATES

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, the recognition of revenue, the amount of the allowance for doubtful accounts receivable and the fair value of intangible assets, stock-based awards and derivatives.



## INCOME TAXES

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

Effective April 1, 2007, the Company adopted the provisions of FASB's Interpretation ("FIN") No. 48, "Accounting for Uncertainty in Income Taxes – an interpretation of FASB No. 109." Fin 48 prescribes a recognition threshold and measurement attribute for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. FIN 48 requires that the financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without considering time values. No such amounts were accrued for April 1, 2008. Additionally, no adjustments related to uncertain tax positions were recognized during the year ended March 31, 2010.

The Company recognizes interest and penalties related to uncertain tax positions as a reduction of the income tax benefit. No interest and penalties related to uncertain tax positions were accrued as of March 31, 2010.

The Company operates in multiple tax jurisdictions within the United States of America. Although we do not believe that we are currently under examination in any of our major tax jurisdictions, we remain subject to examination in all of our tax jurisdiction until the applicable statutes of limitation expire. As of March 31, 2010, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal and State – 2005 and forward. The Company does not expect to have a material change to unrecognized tax positions within the next twelve months.

## EARNINGS PER COMMON SHARE

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

## REVENUE RECOGNITION

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

Revenues derived from royalties to the extent that they cannot be reasonably estimated are recognized when the payment is received.

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

Revenues earned by licensing certain pharmaceutical products developed by the Company are recognized at the beginning of a license term when the Company's customer has legal right to the use of the product. To date, no revenues have been earned by licensing products and there are no continuing obligations under any licensing agreements.

## TREASURY STOCK

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

## FAIR VALUE OF FINANCIAL INSTRUMENTS

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

## STOCK-BASED COMPENSATION

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

The Company accounts for the granting of share purchase options to employees using the fair value method whereby all awards to employees will be recorded at fair value on the date of the grant. Share based awards granted to employees with a performance condition are measured based on the probable outcome of that performance condition

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

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

The compensation expense recognized for the years ended March 31, 2010 and 2009 was \$125,004 and \$921,442, respectively.

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

In May 2009, the FASB issued ASC No. 855, "Subsequent Events," which established general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued. It sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date and up to the date the financial statements are issued. ASC 855 was effective for financial statements issued for interim and annual periods ending after June 15, 2009 and did not have any impact on the Company's financial statements.

In June 2009, the Financial Accounting Standards Board, or FASB, established the FASB Accounting Standards Codification, or ASC, as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles in the United States. All other accounting literature not included in the ASC is now non-authoritative. The ASC was effective for financial statements issued for interim and annual periods ending after September 15, 2009 and its adoption did not have any impact on the Company's financial statements.

#### NOTE 2 - MANAGEMENT'S LIQUIDITY PLANS

The Company reported net losses of \$8,056,874 and \$6,604,708 for the fiscal years ended March 31, 2010 and 2009, respectively. At March 31, 2010, the Company had an accumulated deficit of approximately \$101.3 million, consolidated assets of approximately \$10.6 million, negative stockholders' equity of approximately \$10.6 million, and a working capital deficit of approximately \$2.3 million. The Company has not generated any significant profits to date. During the fiscal year ended March 31, 2010, the Company raised \$2,000,000 of net proceeds from the sale of Series E Preferred Stock, and received \$62,500 in payment of Series E Preferred Stock which were paid for but not yet issued.

The Company's strategy is to continue to be engaged in the development and manufacturing of oral controlled-release products. It will continue to develop generic versions of controlled-release drug products with high barriers to entry and assist partner companies in the life cycle management of products to improve off-patent drug products. The Company has two products currently being sold commercially; a generic product recently purchased and being transferred to Elite but not yet being sold; an approval for a generic product not yet being sold; and a pipeline of products under development.

As of March 31, 2010, the Company's principal source of liquidity was approximately \$578,000 of cash and cash equivalents, or approximately 12 months of cash available based on its current operations. The Company may also receive funds through the exercise of outstanding stock options and warrants and \$1.6875 million from the issuance of the Company's Series E Convertible Preferred Stock pursuant to the Strategic Alliance Agreement with Epic Pharma. However, there can be no assurance of the exercise of any outstanding options or warrants, the performance

of Epic Pharma under the Strategic Alliance Agreement, or that any cash received from such sources will be material to contribute sufficient amounts to continue operating activities.

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

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NOTE 3 -

INVENTORIES

Inventories are recorded at the lower of cost or market. As of March 31, 2010 the Company had an inventory valuation reserve totaling \$494,425 resulting in a net charge to operations of \$311,986 during the year ended March 31, 2010.

NOTE 4 -

INVESTMENT IN NOVEL LABORATORIES INC.

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

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 HalfLyte<sup>®</sup>. 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, 2010. The valuation of the Company's investment in Novel remains at \$3,329,322, an amount equal to the valuation as of March

31, 2009 with no impairment write downs.

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## NOTE 5 -

## PROPERTY AND EQUIPMENT

Property and equipment at March 31, 2010 and 2009 consists of the following:

|   | 2010         | 2009         |
|---|--------------|--------------|
| Laboratory manufacturing, and warehouse equipment | \$ 5,089,540 | \$ 5,089,540 |
| Office equipment                                  | 56,961       | 56,961       |
| Furniture and fixtures                            | 62,406       | 62,406       |
| Transportation equipment                          | 66,855       | 66,855       |
| Land, building and improvements                   | 2,492,152    | 2,492,152    |
| Equipment under capital lease                     | 168,179      | 168,179      |
|   | 7,936,093    | 7,936,093    |
| Less: Accumulated depreciation and amortization   | (3,840,279)  | (3,360,606)  |
|   | \$ 4,095,814 | \$ 4,575,487 |

Depreciation and amortization expense amounted to \$508,610 and \$500,817 for the years ended March 31, 2010 and 2009, respectively.

## NOTE 6 -

## INTANGIBLE ASSETS

Intangible assets at March 31, 2010 and 2009, consist of the following:

|                                | 2010       | 2009       |
|--------------------------------|------------|------------|
| Patents                        | \$ 172,841 | \$ 151,300 |
| Trademarks                     | —          | 8,120      |
|                                | 172,841    | 159,420    |
| Less: Accumulated amortization | (76,434)   | (131,677)  |
|                                | \$ 96,407  | \$ 27,743  |

Amortization of intangible assets, excluding \$20,210 expensed in Fiscal Year 2010 due to impairment, amounted to \$22,762 and \$7,530 for the years ended March 31, 2010 and 2009, respectively.

## NOTE 7 -

## NJEDA BONDS and LONG TERM DEBT

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

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



Interest is payable semiannually on March 1 and September 1 of each year. The Bonds are collateralized by a first lien on the Company's facility and equipment acquired with the proceeds of the original and refinanced Bonds. The related Indenture requires the maintenance of a \$415,500 Debt Service Reserve Fund consisting of \$366,000 from the Series A Notes proceeds and \$49,500 from the Series B Notes proceeds. The Debt Service Reserve is maintained in restricted cash accounts that are classified in Other Assets. \$1,274,311 of the proceeds had been deposited in a short-term restricted cash account to fund the purchase of manufacturing equipment and development of the Company's facility. As of March 31, 2010, all of these proceeds were utilized to upgrade the Company's manufacturing facilities and for the purchase of manufacturing and laboratory equipment.

Bond issue costs of \$354,000 were paid from the bond proceeds and are being amortized over the life of the bonds. Amortization of bond financing costs amounted to \$15,233, \$14,178 and \$14,178 for the years ended March 31, 2009, 2008 and 2007, respectively.

The NJED 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 and the interest payments due on September 1, 2009 and March 1, 2010, totaling \$120,775 and \$113,075, respectively were all paid from the debt service reserve held in the restricted cash account, due to the Company not having sufficient available funds to make such payments when due. Pursuant to the terms of the NJED Bonds, the Company is required to replenish any amounts withdrawn from the debt service reserve and used to make principal or interest payments in six monthly installments, each being equal to one-sixth of the amount withdrawn and with the first installment due on the 15th of the month in which the withdrawal from debt service reserve occurred and the remaining five monthly payments being due on the 15th of the five immediately subsequent months. The Company has, to date, made all payments required in relation to the withdrawals made from the debt service reserve on September 1, 2009 and March 1, 2010. The Company is required to make two additional payments of \$18,846 each, on July 15, 2010 and August 15, 2010, in order to fully replenish the March 1, 2010 withdrawal from the debt service reserve.

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

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

Bond financings consisted of the following at March 31:

|  | 2010         | 2009         |
|--|--------------|--------------|
| Refinanced NJEDA Bonds                       | \$ 3,385,000 | \$ 3,595,000 |
| Current portion                              | (3,385,000)  | (210,000)    |
| Long term portion, net of current maturities | \$ —         | \$ 3,385,000 |

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

| YEAR ENDING MARCH 31, | AMOUNT       |
|-----------------------|--------------|
| 2011                  | \$ 225,000   |
| 2012                  | 245,000      |
| 2013                  | 260,000      |
| 2014                  | 185,000      |
| 2015                  | 195,000      |
| Thereafter            | 2,275,000    |
|                       | \$ 3,385,000 |



Long-term debt consists of the following at March 31:

|   | 2010      | 2009      |
|---|-----------|-----------|
| Note payable to First Niagara Bank in 60 monthly installments of \$1,180, including interest at the rate of 9.00% per annum; Final payment in September 2012 ; Secured by vehicle purchased with proceeds of loan | \$ 31,616 | \$ 42,388 |
| Less: Current portion   | (11,793)  | (10,788)  |
| Long term debt, net of current maturities   | \$ 19,823 | \$ 31,600 |

Maturities of Long Term Debt for the next five years are as follows:

| YEAR ENDING MARCH 31, | AMOUNT    |
|-----------------------|-----------|
| 2011                  | \$ 11,793 |
| 2012                  | 12,899    |
| 2013                  | 6,924     |
| 2014                  | —         |
| 2015                  | —         |
| Thereafter            | —         |
|                       | \$ 31,616 |

NOTE 8 - PREFERRED SHARE DERIVATIVE INTEREST PAYABLE

Preferred share derivative interest payable as of March 31, 2010 consisted of \$306,440 in derivative interest accrued as of March 31, 2010. The full amount of derivative interest payable as of March 31, 2010 was paid via the issuance of 3,402,813 shares of Common Stock, in lieu of cash, in April 2010.

## NOTE 9 -

## INCOME TAXES

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

|                 | YEAR ENDED MARCH 31, |          |
|-----------------|----------------------|----------|
|                 | 2010                 | 2009     |
| <b>Federal:</b> |                      |          |
| Current         | \$ —                 | \$ —     |
| Deferred        | —                    | —        |
| <b>State:</b>   |                      |          |
| Current         | —                    | 3,120    |
| Deferred        | —                    | —        |
|                 | \$ —                 | \$ 3,120 |

The major components of deferred tax assets at March 31, 2010 and 2009 are as follows:

|                                   | 2010          | 2009          |
|-----------------------------------|---------------|---------------|
| Net operating loss carry forwards | \$ 17,604,348 | \$ 17,048,800 |
| Valuation allowance               | (17,604,348)  | (17,048,800)  |
|                                   | \$ —          | \$ —          |

At March 31, 2010 and 2009, a 100% valuation allowance is provided, as it is uncertain if the deferred tax assets will provide any future benefits because of the uncertainty about the Company's ability to generate the future taxable income necessary to use the net operating loss carryforwards. The valuation allowance increased during 2010 and 2009 by \$555,548 and 1,920,078, respectively.

At March 31, 2010, for federal income tax purposes, the Company has unused net operating loss carryforwards of \$52,214,510 expiring in fiscal years ending in 2011 through 2025. For state tax purposes, the Company has \$31,013,316 of unused net operating losses, which are net of the \$19,784,360 of the New Jersey net-operating losses sold in prior periods, with the last such sale occurring during the fiscal year ended March 31, 2007.

## NOTE 10 -

## COMMITMENTS AND CONTINGENCIES

## EMPLOYMENT AGREEMENTS

On November 12, 2009, the Company entered into an employment agreement (the "Dick Agreement") with Chris Dick, President and Chief Operating Officer, effective upon the November 13, 2009 expiration of the employment agreement dated November 13, 2006 and amended on November 10, 2008. A copy of the Dick Agreement is attached to the Quarterly Report on Form 10-Q and filed on November 16, 2009, incorporated herein by reference, and the summary of material terms of the Dick Agreement set forth in this Annual Report on Form 10-K is qualified in its entirety by reference to such exhibit.

Pursuant to the terms of the Dick Agreement, commencing on November 13, 2009, Mr. Dick will be an at-will employee of the Company as its President and Chief Operating Officer. Mr. Dick will receive a base salary of

\$200,000, with \$175,000 of such amount being paid in accordance with the Company's payroll practices and \$25,000 of such amount being paid by issuance of restricted shares of common stock, in lieu of cash, as stipulated in the Dick Agreement.

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On July 1, 2009, the Company appointed Carter J. Ward as its Chief Financial Officer, replacing Mark I. Gittelman who served as the Company's Chief Financial Officer through the same date. In connection with such appointment,

Mr. Ward and Company entered into a letter agreement (the "First Ward Agreement"). A copy of the First Ward Agreement is attached to the Current Report on Form 8-K, filed on July 8, 2009, incorporated herein by reference and the summary of material terms of the First Ward Agreement set forth in this Annual Report on Form 10-K is qualified in its entirety by reference to such exhibit.

Pursuant to the terms of the First Ward Agreement, Mr. Ward became an at-will employee of the Company as its Chief Financial Officer. Mr. Ward was required to dedicated at least 2 business days per week toward fulfilling his responsibilities as Chief Financial Officer and received an annual base salary of \$60,000, payable in accordance with the Company's payroll practices. The Company and Mr. Ward also entered into the Company's standard Employee Proprietary Information and Non-Solicitation Agreement that the Company requires its employees to execute in connection with their employment with the Company.

On November 12, 2009, the Company entered into an employment agreement with Carter J. Ward, Chief Financial Officer (the "Second Ward Agreement"), replacing the First Ward Agreement. A copy of the Second Ward Agreement is attached to the Quarterly Report on Form 10-Q and filed on November 16, 2009, incorporated herein by reference, and the summary of material terms of the Second Ward Agreement set forth in this Annual Report on Form 10-K is qualified in its entirety by reference to such exhibit.

Pursuant to the terms of the Second Ward Agreement, Mr. Ward will continue as an at-will employee of the Company as its Chief Financial Officer Mr. Ward will receive a base salary of \$150,000, with \$125,000 of such amount being paid in accordance with the Company's payroll practices and \$25,000 of such amount being paid by issuance of restricted shares of common stock, in lieu of cash, as stipulated in the Second Ward Agreement. Mr. Ward is required to dedicate his full-time efforts towards fulfilling his responsibilities as Chief Financial Officer and discontinue any consulting arrangements which were previously in place with Epic Pharmaceuticals LLC.

#### CHIEF EXECUTIVE OFFICER

Effective as of September 15, 2009, the Company appointed its Chairman, Jerry I. Treppel as its Chief Executive Officer, replacing Chris Dick who was the Company's interim Chief Executive Officer. Mr. Dick remained with the Company as its President and Chief Operating Officer. Biographical information for Mr. Treppel in included in Part III of this Annual Report on Form 10-K.

In order to assist the Company in its cost control efforts, Mr. Treppel agreed to forego any additional compensation, above that which he receives as the Company's Chairman. Details of Mr. Treppel's compensation as Chairman are included in Part III of this Annual Report on Form 10-K.

#### CHIEF SCIENTIFIC OFFICER

Effective as of September 15, 2009, the Company appointed Dr. Ashok G. Nigalaye as its Chief Scientific Officer, replacing Dr. Stuart Apfel who resigned as Chief Scientific Officer on September 15, 2009. Dr. Apfel also resigned as the Company's Chief Medical Officer, with no replacement being appointed. Biographical information for Mr. Treppel in included in Part III of this Annual Report on Form 10-K.

In order to assist the Company in its cost control efforts, Dr. Nigalaye agreed to forego any additional compensation, above that which he receives as a member of the Company's Board of Directors. Details of Dr. Nigalaye's compensation as Director are included in Part III of this Annual Report on Form 10-K.





## COLLABORATIVE AGREEMENTS

## Development and License Agreements

The Company is a party to two separate and distinct development and license agreements with ECR Pharmaceuticals (“ECR”). Pursuant to the agreements, the Company agreed to commercially develop two products, Lodrane 24® and Lodrane 24D® in exchange for development fees, certain payments, royalties and manufacturing rights. The products are currently being marketed by ECR which also has the responsibility for regulatory matters. In addition to receiving revenues for manufacture of these products, the Company also receives a royalty on in-market sales.

## Leases of Rental Properties

The following leases for rental properties were either operative during Fiscal 2010 or entered into subsequent to March 31, 2010 but prior to the filing of this annual report on Form 10-K.

|   | 80 Oak Street<br>Unit 101 | 80 Oak Street<br>Unit 102 | 135 Ludlow Ave                                    |
|---|---------------------------|---------------------------|---|
| Effective date  | August 1, 2007            | August 1, 2009            | July 1, 2010                                      |
| Termination date                                      | December 31, 2009         | July 31, 2010             | December 31, 2015                                 |
| Renewal options                                       | None                      | None                      | Two tenant options for extensions of 5 years each |
| Rent expense for the fiscal year ended March 31, 2010 | \$ 24,871                 | \$ 44,121                 | None  |
| Minimum 5 Year Lease Payments *:                      |                           |                           |   |
| Fiscal year ended March 31, 2011                      | None                      | \$ 13,837                 | \$ 19,689   |
| Fiscal year ended March 31, 2012                      | None                      | None                      | 79,248  |
| Fiscal year ended March 31, 2013                      | None                      | None                      | 81,228  |
| Fiscal year ended March 31, 2014                      | None                      | None                      | 83,259  |
| Fiscal year ended March 31, 2015                      | None                      | None                      | 85,344  |
| Total Minimum 5 Year Lease Payments                   | None                      | \$ 13,837                 | \$ 348,768  |

\* Minimum lease payments for 135 Ludlow avenue are exclusive of additional expenses related to certain expenses incurred in the operation and maintenance of the premises, including, without limitation, real estate taxes and common area charges, which may be due under the terms and conditions of the lease, but which are not quantifiable at the time of filing of this annual report on Form 10-K.

## Sources and Availability of Raw Materials; Manufacturing

We contract manufacture two products for commercial sale by our customer, ECR Pharmaceuticals. We have recently experienced delays when passing imported raw materials through customs. We have also had a shipment for one of the imported raw materials rejected at customs under Federal Drug & Cosmetic Act (FD&CA) Sections 502(f)(1) and 801(a)(3). ECR Pharmaceuticals is responsible for regulatory matters related to these products. We have notified

ECR Pharmaceuticals and they have initiated a discussion with the FDA. If rejection of this raw material at customs continues, it could prevent us from manufacturing these products.

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 currently obtain the raw materials that we need from over twenty suppliers.

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## GENERAL CONTINGENCIES

In the ordinary course of business we may be subject to litigation from time to time. 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.

## NOTE 11 -

## STOCKHOLDERS' EQUITY

On October 23, 2009, at the annual meeting of the stockholders of the Company, the stockholders approved an amendment to the Company's Certificate of Incorporation to increase the number of our authorized shares of common stock (the "Common Stock") from 210,000,000 to 355,516,558, reduce the authorized shares of Preferred Stock from 5,000,000 to 4,483,442 and reduce the par value of the authorized shares of Common Stock from \$0.01 to \$0.001 per share.

## LOSS PER COMMON SHARE

Basic net loss per common share has been calculated by dividing the net loss by the weighted average number of shares outstanding during the periods presented. Diluted earnings per share is not presented because the effect of the Company's common stock equivalents is antidilutive. For the two years ended March 31, the following potentially dilutive securities were not included in the computation of diluted loss per share:

|                             | 2010<br>Shares | 2009<br>Shares |
|-----------------------------|----------------|----------------|
| Stock Options               | 3,287,000      | 2,554,900      |
| Convertible Preferred Stock | 94,370,379     | 54,971,921     |
| Warrants                    | 125,469,740    | 39,667,853     |
|                             | 223,127,119    | 97,194,674     |

## SERIES C 8% CONVERTIBLE PREFERRED STOCK

As of April 1, 2009, in accordance with GAAP, the preferred shares were recognized as a derivative instrument and were re-characterized as a derivative liability. Please refer to Note 15.

## SERIES D 8% CONVERTIBLE PREFERRED STOCK

As of April 1, 2009, in accordance with GAAP, the preferred shares were recognized as a derivative instrument and were re-characterized as a derivative liability. Please refer to Note 15.

## COMMON STOCK TRANSACTIONS

The following grants were made under the Company's 2004 Stock Option Plan in Fiscal Year 2010:

On January 18, 2010, the Company granted options to 14 employees to purchase an aggregate of 1,000,000 shares of common stock with an exercise price of \$0.10 to vest over a period of three years from grant date.

During the year ended March 31, 2010, 150 shares of Series B 8% Preferred Stock were converted into 96,154 shares of common stock.

During the year ended March 31, 2010, 8,287 shares of Series C 8% Preferred Stock were converted into 5,147,206 shares of common stock.

During the year ended March 31, 2010, 146 shares of Series D 8% Preferred Stock were converted into 730,000 shares of common stock.

During the year ended March 31, 2010, 12,699,749 shares of Common Stock were issued in lieu of cash payment of derivative interest due to holders of the Company's Series B Preferred, Series C Preferred and Series D Preferred shares.

During the year ended March 31, 2010, 3,914,944 shares of Common Stock were issued in lieu of cash payment of dividends due to holders of the Company's Series B Preferred, Series C Preferred and Series D Preferred shares.

During the year ended March 31, 2010, 909,091 shares of Common Stock were issued to Richardson and Patel, in lieu of cash payment of amounts due for legal services provided to the Company.

During the year ended March 31, 2010, 204,000 shares of Common Stock were issued to Brockington Securities Inc. as part of consideration paid for financial advisory, investment banking and placement agent services provided to the Company.

During the year ended March 31, 2009, 225 shares of Series B 8% Preferred Stock were converted into 191,168 shares of common stock. In connection with such conversions, the Company issued 46,968 shares of common stock in satisfaction of dividend obligations of the Company on such shares of Series B Preferred Stock, which such dividend obligations accrued through the date of such conversion.

During the year ended March 31, 2009, 552 shares of Series C 8% Preferred Stock were converted into 241,775 shares of common stock. In connection with such conversions, the Company issued 3,844 shares of common stock and \$93 in cash in satisfactory dividend obligations of the Company on such shares of Series C Preferred Stock, which such dividend obligations accrued through the date of such conversions.

During the year March 31, 2009, 4,660 shares of Series D 8% Preferred Stock were converted into 23,300,000 shares of common stock. In connection with such conversions, the Company has accrued dividends of \$27,312 through the date of such conversions.

## WARRANTS

As of April 1, 2009, in accordance with GAAP, the warrants were recognized as a derivative instrument and were re-characterized as a derivative liability. Please refer to Note 15.

## NOTE 12 – STOCK OPTION PLANS

### STOCK-BASED COMPENSATION

During the years ended March 31, 2010 and 2009, the Company issued 1,000,000 and 258,000, respectively, options to purchase Common Stock to employees, consultants, financial advisors and to members of the board of directors. The options have an exercise price ranging from \$.06 to \$3.00 per share and all vest over three years.. The options expire between five and ten years from the date of grant, including those whose vesting is based on the achievement of certain milestones. The Company has recorded compensation expense of \$125,004 and \$921,442 for the years ended March 31, 2010 and 2009, respectively, which represents the fair value of the options vested computed using the Black-Scholes options pricing model on each grant date.

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

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

|                                  | 2010      |  | 2009        |                                       |
|----------------------------------|-----------|--|-------------|---------------------------------------|
|                                  | Options   | Weighted<br>Average<br>Exercise<br>Price | Options     | Weighted<br>Average<br>Exercise Price |
| Outstanding at beginning of year | 2,554,900 | \$ 1.87                                  | 5,543,300   | \$ 2.16                               |
| Granted                          | 1,000,000 | \$ 0.10                                  | 258,000     | 0.07                                  |
| Exercised                        | —         | —  | —           | —                                     |
| Expired                          | (267,900) | \$ 0.87                                  | (3,246,400) | 2.40                                  |
| Outstanding at end of year       | 3,287,000 | \$ 1.41                                  | 2,554,900   | \$ 1.87                               |

The following table summarizes information about stock options outstanding at March 31, 2010:

| Range of<br>Exercise Price | Options<br>Outstanding | Weighted<br>Average<br>Remaining<br>Contractual Life<br>(Years) | Weighted<br>Average<br>Exercise Price | Options<br>Exercisable | Weighted<br>Average<br>Exercisable<br>Price |
|----------------------------|------------------------|---|---------------------------------------|------------------------|---|
| \$ 0.01 – 1.00             | 1,198,000              | 8.70  | \$ 0.09                               | 198,000                | \$ 0.06                                     |
| 1.01 – 2.00                | 99,000                 | 7.82  | 1.08                                  | 95,999                 | 1.08  |
| 2.01 – 3.00                | 1,990,000              | 5.90  | 2.22                                  | 1,240,000              | 2.23  |
| \$ 0.01 – 3.00             | 3,287,000              | 7.19  | \$ 1.41                               | 1,533,999              | \$ 1.88                                     |

During the fiscal year ended March 31, 2010, 1,000,000 options with an initial aggregate valuation of \$93,425 were granted. The per shares weighted-average fair value of each option granted during such fiscal year was \$0.0935 on the date of the grant using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 111%; risk-free interest rate of 3.73%; and expected life of 10 years. The per share weighted-average fair value of each option granted during fiscal year ended March 31, 2009 was \$0.0156 and the per share weighted average fair value of each option granted during the fiscal year March 31, 2008 ranged from \$.56 to \$1.20 on the date of grant using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 128% and 33.0% for fiscal 2009 and 2008, respectively; risk-free interest rates of 3.00% and 4.00% for fiscal 2009 and 2008, respectively and expected lives ranging from 5 to 10 years.

There are 6,520,100 options available for future grant under our Stock Option Plan.

#### NOTE 13 – MAJOR CUSTOMERS

For the years ended March 31 2010 and 2009, one customer accounted for 100 percent of revenues and at March 31, 2010 and 2009, 100 percent of accounts receivable.

#### NOTE 14 – SUBSEQUENT EVENTS

##### COMMON STOCK TRANSACTIONS

During the first quarter of the fiscal year ending March 31, 2011, the Company issued a total of 3,402,813 shares of Common Stock in lieu of cash in payment of derivative interest, totaling \$306,440 owed to holders of the Company's Series B Preferred, Series C Preferred and Series D Preferred shares during the quarter ended March 31, 2010.

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

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.

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## 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 Releasers”) 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’ Releases”) 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 Releasers 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 Releasers 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’ Releasers”) 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’ Releasers 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’ Releasers 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.

## NOTE 15 - CHANGE IN ACCOUNTING PRINCIPAL AND DERIVATIVE LIABILITIES

The following discussion of derivative liabilities consists of the following sections:

- Overview of Derivative Liability accounting
- Preferred Stock Derivative Liabilities
- Warrant Derivative Liabilities
- Beneficial Conversion Feature of Series E Preferred Stock
- Summary of effects of derivatives on the financial statements

In June 2008, the FASB finalized Emerging Issues Task Force (“EITF”) 07-5, “Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity’s Own Stock”, effective for fiscal years beginning after December 15, 2008. Under EITF 07-5, instruments which do not have fixed settlement provisions are deemed to be derivative

instruments. The conversion features within, and the detachable warrants issued with the Registrant's Series B, Series C, Series D and Series E preferred stock, do not have fixed settlement provisions because their conversion and exercise prices may be lowered if the Registrant issues securities at lower prices in the future. The Registrant was required to include the reset provisions in order to protect the preferred share and warrant holders from potential dilution associated with future financings. In accordance with EITF 07-5, the preferred shares and warrants were recognized as a derivative instrument and have been re-characterized as derivative liabilities at their fair value. "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133") requires that the fair value of these liabilities be re-measured at the end of every reporting period, with the change in value reported in the statement of operations. EITF 07-5 requires that the cumulative effect of this change in accounting principal, for all periods prior the period of implementation, be recognized as an adjustment in the opening balance of retained earnings/(accumulated deficit)

In addition, the Series E Preferred shares included an option, exercisable from the issuance date, to convert to common shares at a price which was below the share price on the date of issuance. The excess of value based on the share price over the cost of shares, based on the option price represents a beneficial conversion feature existing on the issue date. In accordance with EITF 98-5, the beneficial conversion feature was valued separately at issuance and allocated to additional paid in capital. As the options which comprise the beneficial conversion feature were exercisable when issued, a discount resulting from and in the full amount of the beneficial conversion feature was recorded at the time of issuance.

#### SERIES C 8% CONVERTIBLE PREFERRED STOCK

On April 24, 2007, the Company sold 15,000 shares of its Series C 8% Convertible Preferred Stock, par value \$0.01 (the "Series C Preferred Stock"), and 1,939,655 warrants for gross proceeds of \$15,000,000. The 15,000 shares of Series C Preferred Stock are convertible into 6,465,517 shares of Common Stock. The warrants are exercisable at \$3.00 per share and are exercisable through April 24, 2012. The Company paid \$1,050,000 in commissions to the placement agent and others in connection with the sale of the Series C Preferred Stock. In addition, the Company granted the placement agent 193,965 warrants exercisable at \$3.00 per share which were valued at \$129,627. The gross proceeds of the private placement were \$15,000,000 before payment of \$1,050,000 in commissions to the placement agent and selected dealers. In addition, the Company agreed to reimburse the placement agent for all documented out-of-pocket expenses incurred by the placement agent in connection with the private placement, including reasonable fees and expenses of its counsel, which the Company and placement agent agreed to be limited to \$25,000. Based on the relative fair values, the Company has attributed \$1,182,101 of the total proceeds to the warrants and has recorded the warrants as additional paid-in capital. The remaining portion of the proceeds of \$13,817,899 was used to determine the value of the 6,465,517 shares of the Company Common Stock underlying the Series C Preferred Stock, or \$2.1372 per share. Since the value was \$0.1628 lower than the fair market value of the Company's Common Stock on April 24, 2007, the \$1,052,790 fair value of the conversion option resulted in the recognition of a preferred stock dividend and an increase to additional paid-in capital.

On July 17, 2007, the Company sold the remaining 5,000 authorized shares of its Series C Preferred Stock. Each share of Series C Preferred Stock was sold at a price of \$1,000 per share and is initially convertible at \$2.32 into 431.0345 shares of the Company's Common Stock, or an aggregate of 2,155,172 shares of Common Stock. Each purchaser of Series C Preferred Stock also received a warrant to purchase shares of the Company's Common Stock in an amount equal to 30% of the aggregate number of shares of Common Stock into which the shares of Series C Preferred Stock purchased by such purchaser may be converted. The warrants are exercisable on or before July 17, 2012 and represent the right to purchase an aggregate of 646,554 shares of Common Stock, at an exercise price of \$3.00 per share. The lead placement agent for the offering was Oppenheimer & Company, Inc. The gross proceeds of the private placement were \$5,000,000 before payment of \$350,000 in commissions to the placement agent and its selected dealers and \$18,000 in expenses incurred by the placement agent and its selected dealers. Pursuant to the placement agent agreement, the Company issued to the placement agent and its designees warrants (the "Placement Warrants") to purchase 64,655 shares of Common Stock. Such Placement Warrants are at an exercise price of \$3.00 per share, exercisable on or prior to July 17, 2012. The Company received net proceeds from the sale of the Series C 8% Preferred Stock of \$4,631,500. Based on the relative fair values, the Company has attributed \$534,407 of the total proceeds to the warrants and has recorded the warrants as additional paid-in capital. The remaining portion of the proceeds of \$4,465,593 was used to determine the value of the 2,155,172 shares of the Company Common Stock underlying the Series C Preferred Stock, or \$2.0720 per share. Since the value was \$0.6180 lower than the fair market value of the Company's Common Stock on July 17, 2007, the \$1,331,819 fair value of the conversion option resulted in the recognition of a preferred stock dividend and an increase to additional paid-in capital.

The Company sought and obtained the consent of 70% of the holders of its Series B Preferred Stock (the "Series B Consent"), as a condition to the sale of the Series C Preferred Stock, to modify to the Series B Certificate and to the



creation of the Series C Preferred Stock.

The holders of the Series B Preferred Stock consented to (i) the filing of the Amended Certificate of Designations of Preferences, Rights and Limitations of the Series B Preferred Stock (the “Amended Series B Preferred Certificate”) with the Secretary of State of the State of Delaware, which, inter alia, (a) provides for group voting by and among the holders of the Series B Preferred Stock and the holders of the Series C Preferred Stock, and (b) extends the date on which the cumulative dividend rate increases from 8% to 15% from March 16, 2008 to April 24, 2009; and (ii) the authorization, creation, offering and issuance of the Series C Preferred Stock. On April 24, 2007, pursuant to the authority of its Board of Directors, Company filed with the Secretary of State of Delaware the Amended Series B Preferred Certificate.

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On April 24, 2007, pursuant to the authority of its Board of Directors, the Company filed with the Secretary of State of the State of Delaware the Certificate of Designations of Preferences, Rights and Limitations of the Series C 8% Convertible Preferred Stock.

In consideration for the Series B Consent, (i) the Company agreed to extend the expiration date of certain warrants issued to each holder of Series B Preferred Stock at the time of the original issuance of the Series B Preferred Stock from March 16, 2011 to March 16, 2012; and (ii) each of Midsummer Investment, Ltd. and Bushido Capital Master Fund, LP (each, a "Principal Holder"), as the holders of the largest number of the currently outstanding shares of Series B Preferred Stock, were granted a covenant by the Company pursuant to which, so long as each Principal Holder continues to hold at least 20% of the then outstanding Series B Preferred Stock, the Company will not take any action which requires the consent of at least 70% of the holders of the Preferred Stock, unless each Principal Holder consents to such action.

#### SERIES D 8% CONVERTIBLE PREFERRED STOCK

On September 15, 2008, the Company completed a private placement of 1,777 shares of its Series D Preferred Stock, par value \$0.01 per share (the "Series D Preferred Stock"), for gross proceeds of \$1,777,000. The shares were issued at a price of \$1,000 per share with each share initially convertible at \$0.20 into 5,000 shares of the Company's Common Stock, par value \$0.001 per share (the "Common Stock"), or an aggregate of 8,885,000 shares of Common Stock. Each purchaser of Series D Preferred Stock also received a warrant to purchase shares of the Company's Common Stock. The warrants are exercisable on or before September 15, 2013 and represent the right to purchase an aggregate of 17,770,000 shares of Common Stock at an exercise price of \$0.25 per share. The newly-created Series D Preferred Stock is senior as to dividends, liquidation and redemption to the Company's Series B Preferred Stock and Series C Preferred Stock (collectively, the "Existing Preferred Stock"). The Company has authorized, in total, 30,000 shares of Series D Preferred Stock.

The gross proceeds of the private placement for shares of the Company's Series D Preferred Stock were \$1,777,000 before payment of \$263,743 in expenses. Pursuant to the placement agent agreement, the Company issued to the placement agent warrants to purchase 355,400 shares of Common Stock exercisable at \$0.25 per share. The Company will account for these warrants as a cost of raising capital and will include the instrument as equity in our financial statements. Accordingly, there will be no net impact on the Company's financial position or results of operations.

As part of the private placement for shares of the Company's Series D Preferred Stock, holders of existing preferred stock who met a pre-defined level of participation in this placement ("Qualifying Holders") received the right to exchange (the "Exchange"): (i) shares of their existing preferred stock for shares of Series D Preferred Stock at a rate equal to one share of Series D Preferred Stock for each share of existing preferred stock held by the Qualifying Holder and (ii) warrants to purchase Common Stock which were originally issued to each Qualified Holder in connection with the purchase of such exchanged existing preferred stock (such originally issued warrants, the "Original Warrants") for warrants exercisable for the same number of shares of Common Stock with terms identical to the warrants issued to the purchasers of Series D Preferred Stock (such warrants, the "Exchange Warrants"). The Exchange Warrants have an exercise price of \$0.25 per share. To be a Qualifying Holder, a holder of existing preferred stock was required to purchase shares of Series D Preferred Stock with a stated value of at least the lesser of (x) \$400,000 and (y) 20% of the aggregate stated value of the shares of Existing Preferred Stock then held by such holder. In connection with the private placement for shares of the Company's Series D Preferred Stock, Qualifying Holders exchanged (a) shares of their existing preferred stock for an aggregate of approximately 12,037 additional shares of Series D Preferred Stock, which such shares of Series D Preferred Stock are convertible into an aggregate of approximately 60,185,000 shares of Common Stock, and (b) their Original Warrants for Exchange Warrants to purchase an aggregate of approximately 2,336,000 shares of Common Stock.

On April 14, 2008, a holder of 872 shares of Series C 8% Preferred Stock converted 87 shares into 37,745 shares of common stock. The same holder converted an additional 87 shares into 38,427 shares of Common Stock on May 4, 2008. All accrued dividends were paid through dates of conversion.

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## SERIES E CONVERTIBLE PREFERRED STOCK

### 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.

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.

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## 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 or before December 31, 2010, it is anticipated that Elite and Epic will conduct a third closing (the "Third Closing" and the date of such Third Closing, the "Third Closing Date"), provided that all conditions precedent to such Third Closing contained in the Epic Strategic Alliance Agreement have been satisfied or waived by the appropriate party on or before such Third Closing Date. At the Third Closing, if such closing is held, Epic will pay to Elite a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which shares will be convertible, as described above, into 20,000,000 shares of Common Stock, and a warrant (the "Third Warrant" and collectively with the Initial Warrant and the Second Warrant, the "Warrants") to purchase an additional 40,000,000 shares of Common Stock. The Third Warrant is to be exercisable until the date that is the seventh anniversary of the Third Closing Date and is to have a per share exercise price equal to \$0.0625, subject to adjustments for certain events, including, but not limited to, dividends, stock splits, combinations and the like. The per share exercise price of the Third Warrant is to also be subject to adjustment for the sale of Common Stock or securities convertible into Common Stock at a price less than the then applicable per share exercise price of the Third Warrant, for which the Epic's consent was not required under the Epic Strategic Alliance Agreement.



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 and, as agreed upon with Elite, will resume payments beginning with the quarter ending September 30, 2010.

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.

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## Preferred Stock Derivative Liabilities

The portion of derivative liabilities related to the Series B, Series C, Series D and Series E preferred shares was valued at the market value of the underlying common shares, into which the preferred shares may be converted. Such valuations as of the beginning and end of the period are summarized as follows:

## PREFERRED STOCK DERIVATIVE LIABILITY AS OF APRIL 1, 2009

|   | Series B  | Series C     | Series D     | Series E | Total        |
|---|-----------|--------------|--------------|----------|--------------|
| Preferred shares Outstanding                              | 1,046     | 13,705       | 9,154        | —        | 23,905       |
| Underlying common shares into which Preferred may convert | 670,230   | 8,512,422    | 45,772,205   | —        | 54,954,857   |
| Closing price on valuation date                           | \$ 0.13   | \$ 0.13      | \$ 0.13      | \$ 0.13  | \$ 0.13      |
| Preferred stock derivative liability at April 1, 2009     | \$ 87,130 | \$ 1,106,615 | \$ 5,950,386 | \$ —     | \$ 7,144,131 |

As of April 1, 2009, the total preferred stock derivative liability was \$7,144,131. This amount represents the cumulative effect of the change in accounting principal for all periods prior to April 1, 2009 and in accordance with generally accepted accounting principles, is recognized as an adjustment in the opening accumulated deficit balance.

## PREFERRED STOCK DERIVATIVE LIABILITY AS OF MARCH 31, 2010

|  | Series B    | Series C     | Series D       | Series E     | Total        |
|--|-------------|--------------|----------------|--------------|--------------|
| Preferred shares Outstanding   | 896         | 5,418        | 9,008          | 2,000        | 17,322       |
| Underlying common shares into which Preferred may convert                  | 574,076     | 3,365,217    | 45,042,205     | 44,256,006   | 93,237,504   |
| Closing price on valuation date  | \$ 0.085    | \$ 0.085     | \$ 0.085       | \$ 0.085     | \$ 0.085     |
| Preferred stock derivative liability at March 31, 2010                     | \$ 48,796   | \$ 286,043   | \$ 3,828,587   | \$ 3,761,761 | \$ 7,925,188 |
| Series E liability at issue date (related to beneficial conversion option) |             |              |                | 512,912      | 512,912      |
| Change in preferred stock derivative liability for the year ended          | \$ (38,333) | \$ (820,571) | \$ (2,106,171) | \$ 3,248,995 | \$ 283,920   |

March 31, 2010

The change of \$283,920 in value of the preferred stock derivative liability occurring during the year ended March 31, 2010, is included in the amount reported in the “Other Income / (Expense)” section of the statement of operations. Increases in value are reported as other expenses and decreases in value are reported as other income.

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## WARRANTS

To date, the Company has authorized the issuance of Common Stock Purchase Warrants, with terms of five to six years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements. Exercise prices range from \$0.625 to \$3.74 per warrant. The warrants expire at various times through October 13, 2016.

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

|  | 2010           |                                 | 2009           |                                 |
|--|----------------|---------------------------------|----------------|---------------------------------|
|  | Warrant Shares | Weighted Average Exercise Price | Warrant Shares | Weighted Average Exercise Price |
| Balance at beginning of year                           | 39,667,853     | \$ 0.63                         | 9,281,391      | \$ 2.64                         |
| Warrants issued  | 80,000,000     | \$ 0.06                         | —              | —                               |
| Warrants issued pursuant to placement agent agreements | —              | —                               | 355,400        | 0.25                            |
| Warrants issued pursuant to private placement          | —              | —                               | 17,770,000     | 0.25                            |
| Exchange warrants issued                               | 5,806,887      | \$ 0.25                         | 12,261,062     | 0.33                            |
| Warrants exercised, forfeited or expired               | 175,000        | \$ 2.82                         | —              | —                               |
| Ending Balance   | 125,299,740    | \$ 0.25                         | 39,667,853     | \$ 0.63                         |

## Warrant Derivative Liabilities

The portion of derivative liabilities related to outstanding warrants was valued using the Black-Scholes option valuation model and the following assumptions on the following dates:

|   | March 31<br>2010 | March 31<br>2009 |
|---|------------------|------------------|
| Risk-Free interest rate                   | 2.44% – 3.28%    | 2.440%           |
| Expected volatility                       | 126% - 214%      | 118% - 321%      |
| Expected life (in years)                  | 0.5 – 6.6        | 0.2 – 5.3        |
| Expected dividend yield                   | —                | —                |
| Number of warrants                        | 125,299,740      | 39,667,853       |
| Fair value – Warrant Derivative Liability | \$ 8,499,423     | \$ 3,220,204     |

|  | Year Ended<br>March 31 2010 |
|--|-----------------------------|
| Initial derivative warrant value for those warrants existing at the beginning of the fiscal year | 3,220,204                   |
| Cumulative initial value of warrants issued during the fiscal year                               | 1,487,089                   |
| Year-to-Date Change in Warrant Derivative Liability  | 3,792,130                   |
| Fair Value – Warrant Derivative Liability  | \$ 8,499,423                |

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

The warrant derivative liability as of April 1, 2009 was \$3,220,204. This amount represents the cumulative effect of the change in accounting principal for all periods prior to April 1, 2009 and as per the requirements of EITF 07-5, is recognized as an adjustment in the opening accumulated deficit balance.

The increase of \$3,792,130 in value of the warrant derivative liability occurring during the year ended March 31, 2010, is reported in the "Other Income (Expenses)" section of the statement of operations.

## Beneficial Conversion Features of Series E Preferred Shares

The Series E Preferred shares include an option, exercisable from the issuance date, to convert to common shares at a price of \$0.05 per share. The share price on the date of issuance was \$0.09 and \$0.08 for the issuances of Series E Preferred shares at the first and second closings of the Epic Strategic Alliance Agreement (the “First and Second Closings”), respectively. The differences of \$0.04 and \$.03 between the share price and option price represents a beneficial conversion feature existing on the issue date.

In accordance with EITF 98-5, the beneficial conversion feature was valued separately and allocated to additional paid in capital. The beneficial conversion feature was valued at \$258,700 and \$254,212, for the First and Second closings, respectively, calculated using the relative fair value method, as required by FAS 14, allocating the proceeds of \$1 million from each issuance of the Series E Preferred shares to the conversion option and detachable warrants included with such issuance as follows:

|  | First<br>Closing<br>(Jun 2009) | Second<br>Closing<br>(Oct 2009) |
|--|--------------------------------|---------------------------------|
| Allocation % attributable to the Preferred shares conversion option  |                                |                                 |
| Proceeds from Issuance of Series E Preferred Shares  | \$ 1,000,000                   | \$ 1,000,000                    |
| Value of warrants issued with Series E Preferred Shares (see below for a description of the method of valuation)                 | 2,869,361                      | 2,931,983                       |
| Total of proceeds plus warrants  | 3,869,361                      | 3,931,983                       |
| Allocation % attributable to Preferred Shares conversion option (quotient of the proceeds divided by the proceeds plus warrants) |                                |                                 |
|  | 25.9%                          | 25.4%                           |
| Amount of proceeds attributed to conversion option   | 258,700                        | 254,212                         |
| Gross value of beneficial conversion feature   |                                |                                 |
| Share price as of issue date   | \$ 0.08                        | \$ .08                          |
| Conversion option price  | \$ 0.05                        | \$ .05                          |
| Beneficial conversion feature per share  | \$ 0.03                        | \$ .03                          |
| Number of common shares  | 20,000,000                     | 20,000,000                      |
| Gross value of beneficial conversion feature   | \$ 600,000                     | \$ 715,282                      |
| Beneficial conversion option recorded (lesser of the gross value or the amount of proceeds attributed to the conversion option)  |                                |                                 |
|  | \$ 258,700                     | \$ 254,212                      |

The warrants issued with the Series E Preferred shares were valued using the Black Scholes option valuation model, with the following assumptions:

|                          | First<br>Closing<br>(June 2009) | Second<br>Closing<br>(Oct 2009) |
|--------------------------|---------------------------------|---------------------------------|
| Risk-free interest rate  | 2.31%                           | 2.21%                           |
| Expected volatility      | 115.2%                          | 123.30%                         |
| Expected life (in years) | 7                               | 7                               |
| Number of warrants       | 40 million                      | 40 million                      |
| Fair value               | \$ 2,869,361                    | \$ 2,931,983                    |



A beneficial conversion option is required to be recognized as a discount and amortized from the date of issuance to the earliest conversion date. As the conversion options were exercisable on their issue date, the full value assigned to the conversion option was charged to interest expense.

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## Summary of effects of derivatives on the financial statements

|   | Derivative<br>Liabilities | Accumulated<br>Deficit<br>and<br>Paid-in Capital | Other Income<br>/<br>(Expense) |
|---|---------------------------|--|--------------------------------|
| Cumulative effect of change in accounting principle                   |                           |  |                                |
| - Preferred Stock Derivative Liability                                | \$ 7,144,131              | \$ (7,144,131)                                   | \$ —                           |
| Cumulative effect of change in accounting principle                   |                           |  |                                |
| - Warrant Derivative Liability  | 3,220,204                 | (3,220,204)                                      | —                              |
| Beneficial conversion feature of Series E                             | —                         | 512,912  | —                              |
| Warrants issued with Series E   | 1,487,088                 | —  | —                              |
| Amortization of beneficial conversion of Series E as interest expense | 512,912                   | —  | (512,912)                      |
| Change in value of preferred stock derivative liability               | 283,920                   | —  | (283,920)                      |
| Change in value of warrants derivative liability                      | 3,792,130                 | —  | (3,792,130)                    |
| Preferred stock derivatives converted into common shares              | (16,199)                  | (16,199)   | —                              |
| Net Effect of Derivatives   | 16,424,186                | (9,867,622)                                      | (4,588,962)                    |

NOTE 16 – TRANSACTIONS WITH RELATED PARTIES

Transactions with Mark Gittelman and Gittelman & Co. P.C. (“Gittelman”)

On February 26, 1998, we entered into an agreement with Gittelman and Co., P.C., whereby fees are paid to Gittelman and Co., PC., a firm wholly-owned by Mark I. Gittelman, our Chief Financial Officer, Secretary and Treasurer until July 1, 2009, in consideration for services rendered by the firm as internal accountant and financial and management consultant to us. The firm’s services included the services rendered by Mr. Gittelman in his capacity as Chief Financial Officer, Secretary and Treasurer until July 1, 2009. For the period April 1, 2009 to June 30, 2010 and the fiscal years ended March 31, 2009 and 2008, the fees paid by us under the agreement were \$40,185, \$233,181 and \$176,206, respectively. The services rendered by the firm to us for the period April 1, 2009 to June 30, 2009 and the fiscal years ended March 31, 2009 and 2008 averaged 157, 111 and 105 hours per month, respectively, of which a monthly average 21 hours for the period April 1, 2009 to June 30, 2009 and 28 hours for the fiscal years ended March 31, 2009 and 2008, respectively, were services rendered by Mr. Gittelman in his capacity as an officer of Elite.

On July 15, 2009, we entered into a settlement agreement and release Gittelman and Co., P.C., (the “Gittelman Settlement”) for payment of outstanding invoices totaling \$85,531, representing all invoices issued by Gittelman to us and outstanding as of July 15, 2009. The Gittelman Settlement requires the Company to pay the principal sum of \$75,000, plus interest accruing on the outstanding balance of such \$75,000 at the rate of 6% per annum, in twelve equal, monthly installments, beginning on July 20, 2009 and due on the 20th of the next 11 months thereafter. The monthly payments, consisting of principal reduction and interest equal \$6,454.98 with all twelve required payments equal to \$77,460, in aggregate. The Company made all payments required in the Gittelman Settlement and Gittelman released the Company from all further claims related to the outstanding invoices as of July 15, 2009.

Gittelman has not rendered any services to the Company since June 30, 2009 and as of June 23, 2010, no amounts were due to Gittelman.

Transactions with Epic Pharma LLC and Epic Investments LLC

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

|   |   |
|---|---|
| § | Mr. Nigalaye, President and CEO of Epic Pharma, LLC;  |
| § | Mr. Narine, Executive Vice President of Manufacturing and Operations of Epic Pharma, LLC; and |
| § | Mr. Potti, Vice President of Business Development of Epic Pharma, LLC.                        |

As part of the operation of the strategic alliance, the Company identified certain raw materials used in its operations which were also used by Epic Pharma LLC and for which Epic Pharma LLC was achieving lower acquisition costs, mainly as a result of greater purchase volume discounts. The strategic alliance allowed the Company to purchase these raw materials from Epic, at the Epic acquisition cost, without markup. During the fiscal year ended 3/31/2010, an aggregate amount of \$100,056 in such raw materials was purchased from Epic Pharma LLC. All purchases were at Epic Pharma’s acquisition cost, without markup and evidenced by supporting documents of Epic Pharma LLC’s

acquisition cost.

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