

ELITE PHARMACEUTICALS INC /DE/  
Form 10-K  
June 29, 2009

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, 2009

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:  Common Stock - \$.01 par value  
 The Common Stock is quoted on the OTC Bulletin Board

Securities registered pursuant to Section 12(g) of the Act:  None

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

Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-K

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 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated file and larger accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting common equity held by non-affiliates of the Registrant as of September 30, 2008 was approximately \$4,006,873 based upon the closing price per share of \$0.17 of the Registrant's common stock, par value \$0.01 per share, on the American Stock Exchange on such date as reported by Bloomberg L.P. (For purposes of determining this amount, only directors, executive officers, and, based on Schedule 13(d) filings as of September 30, 2008, 10% or greater stockholders, and their respective affiliates, have been deemed affiliates).

The Registrant had 69,969,781 shares of common stock, par value \$0.01 per share, outstanding as of June 23, 2009.

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). N/A

## FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated herein contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. When used in this 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,” “anticipate,” “estimate,” or “continue” 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.

## Table of Contents

## Form 10-K Index

	PAGE
<b>PART I</b>	
Item 1. Business	4
Item 1A. Risk Factors	15
Item 1B. Unresolved Staff Comments	28
Item 2. Properties	28
Item 3. Legal Proceedings	29
Item 4. Submission of Matters to a Vote of Security Holders	29
<b>PART II</b>	
Item 5. Market for Company's Common Equity and Related Stockholder Matters	29
Item 6. Selected Financial Data	36
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation	36
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	51
Item 8. Financial Statements and Supplementary Data	51
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	51
Item 9AT. Controls and Procedures	51
Item 9B. Other Information	53
<b>PART III</b>	
Item 10. Directors and Executive Officers of the Company	53
Item 11. Executive Compensation	60
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	83
Item 13. Certain Relationships and Related Transactions	87
Item 14. Principal Accounting Fees and Services	89
<b>PART IV</b>	
Item 15. Exhibits, Financial Statements and Schedules	89
Signatures	99
Consolidated Financial Statements	F-1

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, and a pipeline of five additional drug candidates under active development in the therapeutic areas that include pain management, allergy and infection. Of the products under development, ELI-216, a once-a-day, abuse-deterrent oxycodone product, and ELI-154, a once-a-day oxycodone product, are in clinical trials and we have completed pilot studies on two of our other generic product candidates. We have also submitted an abbreviated new drug application (“ANDA”) with the United States Food and Drug Administration (the “FDA”) with our co-development partner, The PharmaNetwork, for a pain management generic product. We estimate, as to which there is no assurance, the addressable market for the pipeline of products is approximately \$6 billion. Our facility in Northvale, New Jersey is a Good Manufacturing Practice (“GMP”) and United States Drug Enforcement Agency (“DEA”) registered facility for research, development and manufacturing.

### Strategy

We are focusing our efforts on the following areas: (i) development of our pain management products, (ii) manufacturing of Lodrane 24® and Lodrane 24D® product; (ii) the development of the other products in our pipeline; and (iii) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations, and (iv) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

We intend to continue to collaborate in the development of additional products with our current partners, which includes Epic Pharma LLC pursuant to the Epic Strategic Alliance Agreement (as defined below). Under the Epic Strategic Alliance Agreement (i) at least eight additional generic drug products will be developed by Epic at Elite’s facility located at 165 Ludlow Avenue, Northvale, New Jersey (the “Facility”) with the intent of filing ANDAs 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 with each other 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.

We also plan to seek additional collaborations to develop more drug products.

We believe that our business strategy enables us to reduce our 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 us to share costs of development and to improve cash-flow.

### Research and Development

During each of the last three fiscal years, we have focused on research and development activities. We spent \$3,631,425 for the fiscal year ended March 31, 2009, \$5,795,779 for the fiscal year ended March 31, 2008 and \$5,777,865 for the fiscal year ended March 31, 2007 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 and scale up work in preparation for Phase III clinical trials for ELI-216 and ELI-154.

Of our five products in the pipeline, three are for treatment or management of pain. They are ELI-216, which is an abuse-resistant oxycodone; ELI-154, which is a once-daily oxycodone; and a generic drug product that is an analgesic. The other non-pain products are a generic product that is an anti-infective, and a generic product that is for gastrointestinal disorders

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. In this instance, we believe that disclosure of the information in the following table is helpful for the description of the general nature, orientation and activity of the Company, and the disclosures are made for such purpose. No inference should be made as to the occurrence of matters or events not specifically described. We may or may not disclose such information in the future based on competitive reasons and/or contractual obligations. We believe that the information is helpful on a one-time basis for the purpose described above.

The following table provides information concerning the products that Elite is currently developing and to which we are devoting substantial resources and attention. None of these products has been approved by the FDA and all are in development.

Product	Approx. U.S. Sales for Brand and/or Generic Products (2008) \$MM(a)	NDA/ ANDA (b)	Partner	Indication
ELI 154 Once Daily oxycodone	N/A(c)	NDA	None	Pain Management
ELI 216 Once daily oxycodone with abuse resistant technology (ART™)	N/A(c)	NDA	None	Pain Management
Generic	\$33	ANDA	None	Infection
Generic	\$3,000	ANDA	IntelliPharmaceutics (Toronto, Canada)	Gastrointestinal disorders(d)
Generic	\$48	ANDA	The PharmaNetwork, LLC (Montvale, NJ)	Pain Management

(a) Indicates the approximate amount of sales of our competitor's product and any generics (if there are any). It does not represent the sales of any of our products.

(b) "NDA" represents a new drug application which is filed with the FDA for new drug products and "ANDA" represents an abbreviated new drug application which is filed with the FDA for generic drug products.

(c) N/A means not applicable because there is no branded product on the market. There is neither a once-daily oxycodone nor an abuse-resistant oxycodone on the market. The market for sustained-release oxycodone was approximately \$2.8 billion in 2008.

(d) This includes an agreement that grants to Elite a percentage of payments paid to IntelliPharmaCeutics Corp., its Canadian partner for commercial sale of a generic of this product.



The table below presents information with respect to the development of our five products under development. For some of the products, we intend to make NDA filings under Sections 505(b)(1) or 505(b)(2) of the Drug Price Competition Act. Accordingly, we anticipate, as to which there is no assurance, that the development timetable for the products for which such NDA filings are made would be shorter and less expensive. Completion of development of products by us depends on a number of factors, however, and there can be no assurance that specific time frames will be met during the development process or that the development of any particular products will be continued.

In the table below, Pilot Phase I studies for the NDA products are generally preliminary studies done in healthy human subjects to assess the tolerance/safety and pharmacokinetics of the product. The Phase II study listed below was done in recreational drug users and a visual analog scale for euphoria was measured in the study. Additional larger studies in humans will be required prior to submission of the product to the FDA for review. Pilot bioequivalence studies are initial studies done in humans for generic products and are used to assess the likelihood of achieving bioequivalence for generic products. Larger pivotal bioequivalence studies will be required prior to submission of the product to the FDA for review.

Development Stage	Number of Products	NDA/ANDA
Filed	1	ANDA
Pilot bioequivalence study	2	ANDA
Pilot Phase I study	1	NDA
Phase II	1	NDA

#### 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 on 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 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, 2009, 2008 and 2007 aggregated \$2,274,825, \$1,413,119 and \$1,143,841, respectively.

#### 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. ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hours and equivalent blood levels to the twice-a-day product at the end of 24 hours. We are now scaling up that product using commercial size equipment for manufacture of batches. ELI-154 is targeted primarily for markets outside the United States, including Europe.



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. When crushed, however, 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 such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., have been approved by the FDA and are being marketed in the United States.

In further studies, ELI-216 demonstrated the euphoria-blocking effect when the product is crushed. This study 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 intends to complete and submit to the FDA a second stage of this study that will be a double-blinded, cross-over pivotal study.

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 begun scale up of ELI-216 to commercial size batches and 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 a 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 for sales and distribution. 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 with Elan. If Elite were to sell the product itself, Elite would pay a 1% royalty to Elan based on the product’s net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite’s net revenues from this product (Elite’s net product revenues would include license fees, royalties, manufacturing profits and milestones). Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

#### Epic Strategic Alliance Agreement

On March 18, 2009, Elite entered into a Strategic Alliance Agreement (as amended by an Amendment, dated as of April 30, 2009 (the “First Amendment”), and Second Amendment, dated as of June 1, 2009 (the “Epic Strategic Alliance Agreement”) with Epic Pharma, LLC (the “Parent”) and Epic Investments, LLC, a subsidiary controlled by the Parent (the “Purchaser”, and collectively with the Parent, “Epic”), 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.



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 with each other 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 such disclosures are incorporated herein by reference.

#### Manufacturing, Co-Development and License Agreements

On June 21, 2005, Elite entered into a product development and commercialization agreement with IntelliPharmaCeutics Corp. (“IPC”), a Canadian privately-held, specialty pharmaceutical company, which develops generic controlled-release drug products. It is affiliated with IntelliPharmaCeutics, Ltd. The agreement provides for the co-development and commercialization of a controlled-released generic product. IPC has taken a formulation for the product into a pilot bioequivalence biostudy. Upon commercialization, Elite is to share the profits, if any, realized upon sales. A successful pivotal biostudy and an approved ANDA filing is required to commercialize this product.

On December 12, 2005, Elite and IPC amended their obligations to suspend their obligations under their product and commercialization agreement with respect to the development and commercialization of the controlled-release drug product in Canada. IPC, in turn, entered into an agreement with Ratiopharm, Inc., a Canadian company, for the development and commercialization of the product in Canada and will pay Elite a certain percentage of any payments received by IPC with respect to the commercial sale of this product by Ratiopharm, Inc. in Canada.

On November 10, 2006, Elite entered into a product collaboration agreement with The PharmaNetwork, LLC (“TPN”) for the development of the generic product equivalent of a synthetic narcotic analgesic drug product. TPN is to perform development services and prepare and file an ANDA in the name of TPN with the FDA. Elite is to provide development support, including the purchase of active pharmaceutical ingredients and materials and supplies to manufacture the batch, provide adequate facilities to TPN for use in its development work and following ANDA approval, Elite will manufacture the drug product developed. Elite is to pay TPN for the development services rendered upon the attainment of certain milestones. The out-of-pocket costs are to be shared by TPN and Elite, with TPN’s obligation to be payable from the royalty compensation. An ANDA was submitted and the application was accepted for review by the FDA in September 2008.

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. In order to value Elite’s ownership in Novel, Elite has made numerous requests to Novel for financial and pipeline information. As of the date hereof, Elite has yet to receive any responses from Novel to such requests.

Novel has publicly disclosed the following information:

§	Novel has filed eleven ANDAs.
§	One of Novel’s ANDAs has been approved.
§	Four of Novel’s ANDAs have been granted first-to-file status. Another ANDA filed by Novel is expected to be granted first-to-file status.
§	Novel acquired three ANDAs to supplement its own in-house products.
§	Novel has identified over 50 drug products in development.
§	Novel intends to launch as many as six products in 2009 beginning in first quarter.
§	Novel employs approximately 50 people.

Using the above information for guidance, Elite has estimated a net present value of cash flows for 2009, 2010, 2011 and 2012, based upon the following assumptions:

§	Sales potential for Novel’s products;
§	Capital and operating costs for Novel;
§	Stock option shares that might be issued;
§	Assuming a terminal value based on a 12.50% discount rate on 2012 net cash flow; and
§	\$1 million in capital expenditures per year.

Based solely upon the above publicly disclosed information and our assumptions, Elite’s investment in Novel as of March 31, 2009 was estimated to be \$3,400,000. Novel has not provided Elite with its current financial information and therefore such estimate is based on limited information.

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:

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

We have pending applications for three additional U.S. patents. The pending patent applications relate to two different controlled-release pharmaceutical products on which we are working. Two 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.

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

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

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

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

#### ANDAs

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



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

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

#### Controlled Substances

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

#### 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 successor legally 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 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) proprietary controlled-release pharmaceutical products. In both areas, our competition consists of those companies which develop controlled-release drugs and alternative drug delivery systems.

In recent years, 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 Alpharma, Inc., Pain Therapeutics (which has an agreement with Durect Corporation), Shire Pharmaceuticals Group plc (which purchased New River Pharmaceuticals Inc.), Endo Pharmaceuticals, Inc. through an agreement with 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

We manufacture for commercial sale by our partner, ECR, two products, Lodrane 24® and Lodrane 24D®, for which to date we have obtained sufficient amounts of the raw materials for its production. We are not currently in the manufacturing phase for any other products and do not expect that significant amounts of raw materials will be required for their production. We currently obtain the raw materials that we need from over twenty suppliers.

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, 2009, we had 12 employees. Full-time employees are engaged in 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. We incurred net losses of \$6,604,708, \$13,893,060, \$11,803,512, \$6,883,914, and \$5,906,890 for the years ended March 31, 2009, 2008, 2007, 2006 and 2005, respectively. We expect to incur losses for the current year of operation and 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 3, 2009, after giving effect to the initial closing of the Epic Strategic Alliance Agreement, we had cash reserves of \$737,000 which permits us to continue at our anticipated level of operations, including, but not limited to, the continued development of our pipeline products, through September 2009. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement, including the consummation of the second and third closings 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 and the launch of the ANDA for a pain management generic product that we submitted last year with our co-development partner, The Pharma Network,, Elite could be profitable. In addition, the commercialization of the Epic products developed at the Facility 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 closing of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate the second and third 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 \$2.75 million. Even if we were able to successfully complete the second and third 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 such disclosures 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 3, 2009, after giving effect to the initial closing of the Epic Strategic Alliance Agreement, we had cash and cash equivalents of \$737,000. 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 September 2009. We will require additional funding in order to continue to operate thereafter. If the second and third 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 second and third 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 second and third 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 the Registrant will be able to obtain such 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 filed in 2008, 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 three 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 our 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 our 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 of the FDA;
- filing citizens' petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues;
- developing controlled-release or other "next-generation" products, which often reduce demand for the generic version of the existing product for which we may be seeking approval;
  - changing product claims and product labeling;
- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

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

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

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

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

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

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

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

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

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and





- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

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

Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight.

Even if regulatory approval is obtained for a particular product candidate, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or 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, 2009.

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, 2009, the closing sale price on the American Stock Exchange (“AMEX”) of our Common Stock fluctuated from a high of \$0.83 per share to a low of \$0.03 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 second and third closings of the transactions contemplated by the Epic Strategic Alliance Agreement

The voluntary delisting from the American Stock Exchange listing of our Common Stock in order to commence quotation of our Common Stock on the OTC Bulletin Board could have a material adverse affect on the market for our Common Stock and our market price.

On May 21, 2009, we announced that our Common Stock would begin trading on the over-the-counter markets, on the OTC Bulletin Board, under the symbol ELTP:US. We believe that our commencement of the quotation of our Common Stock on the OTC Bulletin Board, in accordance with the terms of the Epic Strategic Alliance Agreement, is an important step in our continuing efforts to reduce costs. However, our voluntary delisting from the American Stock Exchange listing of the Common Stock in order to commence quotation the Common Stock on the OTC Bulletin Board could have a material adverse affect on the market for our Common Stock and our market price.

The OTC Bulletin Board market is a regulated quotation service that displays real-time quotes, last-sale prices and volume information for over 3,000 companies. Our move to the OTC Bulletin Board market does not affect our business operations and will not change our SEC reporting requirements.

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 second and third closings under the Epic Strategic Alliance Agreement, Elite will issue to Epic an aggregate of 2,000 shares of Series E Preferred Stock, convertible into an aggregate of 40,000,000 shares of Common Stock, and warrants to purchase an additional 80,000,000 shares of Common Stock. If Epic converts such shares of Series E Preferred Stock into shares of Common Stock and exercises such warrants 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 at the Facility 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 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. The existing holders of our Common Stock will also experience substantial dilution upon the issuance of such warrants and such additional shares of its Common Stock to Epic in accordance with the Epic Strategic Alliance Agreement.

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 (the "Board" or "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.

If penny stock regulations become applicable to our Common Stock they will impose restrictions on the marketability of our Common Stock and the ability of our stockholders to sell shares of our stock could be impaired.

The SEC has adopted regulations that generally define a “penny stock” to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share subject to certain exceptions. Exceptions include equity securities issued by an issuer that has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operation for more than three years, (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average revenue of at least \$6,000,000 for the preceding three years. Unless an exception is available, the regulations require that prior to any transaction involving a penny stock, a risk of disclosure schedule must be delivered to the buyer explaining the penny stock market and its risks. Our Common Stock is currently trading at under \$5.00 per share. Although we currently fall under one of the exceptions, if at a later time we fail to meet one of the exceptions, our Common Stock will be considered a penny stock. As such, the market liquidity for our Common Stock will be limited to the ability of broker-dealers to sell it in compliance with the above-mentioned disclosure requirements.

You should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include:

- Control of the market for the security by one or a few broker-dealers;
- “Boiler room” practices involving high-pressure sales tactics;
- Manipulation of prices through prearranged matching of purchases and sales;
- The release of misleading information;
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer loss.

We are aware of the abuses that have occurred in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, we will strive within the confines of practical limitations to prevent such abuses with respect to our Common Stock.

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, the Purchaser 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 the Purchaser at all of the then applicable Closings or (2) 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 (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 the Purchaser, 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, 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 at our Facility 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 the certain actions specifically enumerated therein. Notwithstanding the foregoing, if at any time after Epic has acquired 25% or more of the shares of the capital stock of Elite, on an as-converted basis, pursuant to the terms of Alliance Agreement or the Warrants, the Epic's ownership percentage of the shares of capital stock of Elite falls below 20% of the shares of the capital stock of Elite, on an as-converted basis, as a result of transfers made by Epic, then the prior written consent of Epic will not be required prior to the consummation of such actions under the Epic Strategic Alliance Agreement.

Pursuant to the Alliance Agreement, subject to the satisfaction of certain conditions precedent contained therein, the Purchaser will not, without the prior written consent of Elite, transfer any Common Stock acquired by it upon conversion of the Series E Preferred Stock or otherwise acquired or purchased under the Alliance Agreement or the other transaction documents for a period commencing on the Initial Closing Date 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 (such period, the “Lock-Up Period”).

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.

The Facility, which we own, is located at 165 Ludlow Avenue, Northvale, New Jersey, and contains approximately 20,000 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.

We have entered into a lease for a portion of a one-story warehouse for the storage of pharmaceutical finished goods, raw materials, equipment and documents. We have exercised an option to rent the property through July 31, 2009.

We are currently using our facilities as a laboratory, manufacturing, storage and office space. Properties used in our operations are considered suitable for the purposes for which they are used and are believed to be adequate to meet our needs for the reasonably foreseeable future.

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 ANDAs 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 with each other 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 disclosures are incorporated herein by reference.





ITEM 3.

LEGAL PROCEEDINGS.

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.

ITEM 4.

SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

In connection with the transactions contemplated by the Epic Strategic Alliance Agreement, the Registrant sought the written consent of holders of a majority of, in number, of the shares of our outstanding Series B Preferred Stock, par value \$0.01 per share, Series C Preferred Stock, par value \$0.01 per share, and Series D Preferred Stock, par value \$0.01 per share (collectively, the "Existing Preferred Stock") to the consummation of the transactions contemplated by the Epic Strategic Alliance Agreement, including the creation and issuance of our Series E Preferred Stock. As of March 23, 2009, the holders of the Existing Preferred Stock voted in favor of such actions, in accordance with the respective terms and conditions of the Existing Preferred Stock, by written consent of the holders 13,919 shares of Existing Preferred Stock, or 57.6% of the then-outstanding Existing Preferred Stock.

The holders of our Common Stock took the following actions at the Special Meeting of the Stockholders held on December 19, 2008:

1. Approved and ratified the sale of up to 30,000 shares of Series D Preferred Stock, convertible into shares of Common Stock; the exchange of certain shares of the Company's Series B Preferred Stock and Series C Preferred Stock for shares of Series D Preferred Stock; and the issuance of related warrants to purchase additional shares of Common Stock, by a vote of a majority of the shares of Common Stock then outstanding with: 8,720,253 shares FOR; 2,825,853 shares AGAINST; and 13,287 shares ABSTAINING; and
2. Approved and ratified an amendment to our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 150,000,000 to 210,000,000, by a vote of a majority of the shares of Common Stock then outstanding with: 20,571,216 shares FOR; 4,734,415 shares AGAINST; and 18,557 shares ABSTAINING.

PART II

ITEM 5. MARKET FOR COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our Common Stock was quoted on NYSE Amex (formerly, the American Stock Exchange) under the symbol "ELI" until May 21, 2009, at which time Elite's Common Stock commenced trading on the over-the-counter markets under the symbol ELTP:US on the OTC Bulletin Board. The following table shows, for the periods indicated, the high and low sales prices per share of our Common Stock as reported by the American Stock Exchange.

Quarter ended	Common Stock	
	High	Low
<b>Fiscal Year ending March 31, 2009:</b>		
March 31, 2009	\$ 0.24	\$ 0.03
December 31, 2008	\$ 0.16	\$ 0.05
September 30, 2008	\$ 0.45	\$ 0.06
June 30, 2008	\$ 0.80	\$ 0.48
<b>Fiscal Year ending March 31, 2008:</b>		
March 31, 2008	\$ 1.80	\$ 0.72
December 31, 2007	\$ 2.75	\$ 1.45
September 30, 2007	\$ 2.77	\$ 1.95
June 30, 2007	\$ 2.70	\$ 2.08

On June 23, 2009, the last reported sale price of our Common Stock, as quoted by the OTC Bulletin Board, was \$0.069 per share.

As of June 25, 2009, there were approximately 118 holders of record of our Common Stock. There were approximately 2,947 beneficial owners of our Common Stock as of November 7, 2008, the latest practicable date for which such information is available to us. We are informed and believe that as of June 25, 2009, Cede & Co. held 39,180,485 shares of our Common Stock as nominee for Depository Trust Company, 55 Water Street, New York, New York 10004. It is our understanding that Cede & Co. and Depository Trust Company both disclaim any beneficial ownership therein and that such shares are held for the account of numerous other persons.

We have never paid cash dividends on our Common Stock. During the fiscal year ended March 31, 2009, we have paid dividends in the aggregate principal amount of \$2,206,683 on our Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock. Of such amount, \$100,148 was paid in cash and the remaining amount was paid in 13,901,178 shares of Common Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business.

Please see our Quarterly Reports on Form 10-Q for the quarterly periods ended September 30, 2008 and December 31, 2008 and our Current Report on Form 8-K, filed with the SEC on September 16, 2008, each of which is incorporated herein by reference for information concerning our sale of unregistered securities in connection with the private placement of our Series D Preferred Stock that closed on September 15, 2008. Please see Items 1 and 7 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, each of which is incorporated herein by reference, for information concerning our sales of unregistered securities in connection with the initial closing of the Epic Strategic Alliance Agreement on June 3, 2009. Please see Notes 9 and 12 to the Consolidated Financial Statements attached to this Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2008, September 30, 2008 and December 31, 2008 and our Current Reports on Form 8-K, filed with the SEC on November 3, 2008 and December 4, 2008, each of which is incorporated herein by reference, for information concerning other issuances of unregistered securities during the 12 months ended March 31, 2009, including securities issued in exchange for property, services, or other securities of ours, and new securities resulting from the modification of outstanding securities.

## EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth certain information regarding Elite's equity compensation plans as of March 31, 2009.

Plan Category	Number of securities to be issued upon exercise of outstanding options and warrants and rights (a)	Weighted-average exercise price per share of outstanding options, warrants and securities reflected in column (a) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,479,900(1)	\$ 1.90	7,520,100
Equity compensation plans not approved by security holders	75,000(2)	\$ 1.12	—
<b>Total:</b>	<b>2,554,900</b>	<b>\$ 1.87</b>	<b>7,520,100</b>

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

(2) Represents 75,000 non-qualified options to The Investor Relations Group.

## 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"), 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 full Board of Directors or, at the Board of Directors' discretion, by a committee of the Board of Directors consisting of at least two persons who are "disinterested persons" as defined under Rule 16b-2(c)(ii) under the Securities Exchange Act of 1934, as amended (the "Committee").

Recipients of options under the Stock Option Plan ("Optionees") are selected by the Board of Directors or the Committee. The Board of Directors or Committee 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 or Committee, 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 or Committee 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.

**FEDERAL INCOME TAX CONSEQUENCES.** The following is a brief discussion of the Federal income tax consequences of transactions under the Stock Option Plan. This discussion is not intended to be exhaustive and does not describe state or local tax consequences.

#### Incentive Options

No taxable income is realized by the Optionee upon the grant or exercise of an Incentive Option, except as noted below with respect to the alternative minimum tax. If Common Stock is issued to an Optionee pursuant to the exercise of an Incentive Option, and if no disqualifying disposition of such shares is made by such Optionee within two years after the date of grant or within one year after the transfer of such shares to such Optionee, then (1) upon sale of such shares, any amount realized in excess of the option price will be taxed to such Optionee as a long-term capital gain and any loss sustained will be a long-term capital loss, and (2) no deduction will be allowed to the Optionee's employer for Federal income tax purposes.

Except as noted below for corporate "insiders," if the Common Stock acquired upon the exercise of an Incentive Stock Option is disposed of prior to the expiration of either holding period described above, generally (1) the Optionee will realize ordinary income in the year of disposition in an amount equal to the excess (if any) of the fair market value of such shares at exercise (or, if less, the amount realized on the disposition of such shares) over the option price paid for such shares and (2) the Optionee's employer will be entitled to deduct such amount for Federal income tax purposes if the amount represents an ordinary and necessary business expense. Any further gain (or loss) realized by the Optionee will be taxed as short-term or long-term capital gain (or loss), as the case may be, and will not result in any deduction by the employer.

Subject to certain exceptions for disability or death, if an Incentive Stock Option is exercised more than three months following termination of employment, the exercise of the Option will generally be taxed as the exercise of a Non-Qualified Option.

For purposes of determining whether an Optionee is subject to any alternative minimum tax liability, an Optionee who exercises an Incentive Stock Option generally would be required to increase his or her alternative minimum taxable income, and compute the tax basis in the stock so acquired, in the same manner as if the Optionee had exercised a Non-Qualified Option. Each Optionee is potentially subject to the alternative minimum tax. In substance, a taxpayer is required to pay the higher of his/her alternative minimum tax liability or his/her "regular" income tax liability. As a result, a taxpayer has to determine his potential liability under the alternative minimum tax.

### Non-Qualified Options

With respect to Non-Qualified Options: (1) no income is realized by the Optionee at the time the Option is granted; (2) generally, at exercise, ordinary income is realized by the Optionee in an amount equal to the difference between the option price paid for the shares and the fair market value of the shares, if unrestricted, on the date of exercise, and the Optionee's employer is generally entitled to a tax deduction in the same amount subject to applicable tax withholding requirements; and (3) at sale, appreciation (or depreciation) after the date of exercise is treated as either short-term or long-term capital gain (or loss) depending on how long the shares have been held.

Pursuant to Section 409A of the Internal Revenue Code (the "Code"), Non-Qualified Options must be issued at fair market value at the time of the grant in order to achieve the federal tax consequences described above and to avoid substantial penalties.

### Compliance with Section 409A of the Code

To the extent that the Board of Directors or Committee determines that any option granted under the Stock Option Plan is subject to Section 409A of the Code, the award agreement evidencing such option shall incorporate the terms and conditions required by Section 409A. To the extent applicable, the Stock Option Plan and award agreements shall be interpreted in accordance with Section 409A. Notwithstanding any provision of the Stock Option Plan to the contrary, in the event that, following the effective date of this amendment to the Stock Option Plan, the Board of Directors or Committee determines that any option may be subject to Section 409A of the Code, the Board of Directors or Committee may adopt such amendments to the Stock Option Plan and the applicable award agreement or adopt such other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions that the Board of Directors or Committee determines are necessary or appropriate to (a) exempt the option from Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to the option or (b) comply with the requirements of Section 409A of the Code.

### Special Rules Applicable to Corporate Insiders

As a result of the rules under Section 16(b) of the Exchange Act, "insiders" (as defined in the Securities Exchange Act of 1934), depending upon the particular exemption from the provisions of Section 16(b) utilized, may not receive the same tax treatment as set forth above with respect to the grant and/or exercise of options. Generally, insiders will not be subject to taxation until the expiration of any period during which they are subject to the liability provisions of Section 16(b) with respect to any particular option. Insiders should check with their own tax advisers to ascertain the appropriate tax treatment for any particular option.

### COMPARATIVE STOCKHOLDER RETURN

The graph and table that follows compares the yearly percentage change in Elite's cumulative total stockholder return on its Common Stock for the five year period ended March 31, 2009 with the cumulative total stockholder return of (1) all United States companies traded on the American Stock Exchange (where Elite's Common Stock was traded until May 21, 2009 when it commenced quotation on the OTC Bulletin Board) and (2) all companies traded on the American Stock Exchange which carry the Standard Industrial Classification (SIC) code 283 (Pharmaceuticals). The graph and table were prepared by the Research Data Group, Inc.

Elite's Common Stock was traded on the NASDAQ over-the-counter bulletin board from July 23, 1998 until February 24, 2000. Elite's Common Stock was traded on the American Stock Exchange from February 24, 2000 until May 21, 2009. Elite's Common Stock began trading on the OTC Bulletin Board on May 21, 2009. Elite's fiscal year ends on March 31.

The data represented in the above graph is also set out below in tabular form.

34

---

Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-K

	Elite Pharmaceuticals Inc	AMEX Composite	Amex Stocks (SIC 2830-2839 US Companies)
03/04	100.00	100.00	100.00
04/04	109.43	95.77	91.18
05/04	101.01	94.42	89.02
06/04	77.78	97.83	88.79
07/04	74.07	97.06	71.75
08/04	44.11	97.61	67.10
09/04	40.40	99.94	66.96
10/04	58.92	104.20	71.59
11/04	109.43	112.25	80.41
12/04	123.57	115.31	95.68
01/05	139.73	115.18	89.94
02/05	161.28	122.56	83.69
03/05	148.15	120.58	76.96
04/05	119.53	119.41	76.17
05/05	101.01	121.44	75.50
06/05	103.70	128.83	79.80
07/05	97.64	132.13	85.76
08/05	92.59	138.78	74.10
09/05	100.34	146.31	67.96
10/05	82.49	136.34	67.07
11/05	60.94	139.62	72.18
12/05	61.95	145.81	70.86
01/06	68.35	154.50	83.85
02/06	78.45	152.83	89.69
03/06	83.84	161.83	86.15
04/06	76.77	166.89	88.51
05/06	74.07	160.77	79.80
06/06	77.44	160.23	77.12
07/06	74.07	162.35	73.32
08/06	80.81	168.88	79.41
09/06	80.47	161.37	70.64
10/06	68.69	165.72	73.99
11/06	71.72	175.75	73.60
12/06	73.40	173.96	77.12
01/07	67.34	177.39	79.34
02/07	67.68	178.01	73.30
03/07	79.12	184.40	75.63
04/07	74.41	187.40	80.16
05/07	77.44	201.23	79.54
06/07	86.20	200.14	73.77
07/07	79.12	192.80	67.52
08/07	80.81	188.83	66.10
09/07	77.44	204.26	68.19
10/07	92.59	214.82	70.39
11/07	70.71	202.37	59.05
12/07	70.03	207.73	55.49
01/08	30.64	192.70	51.07
02/08	52.19	205.41	49.70



Edgar Filing: ELITE PHARMACEUTICALS INC /DE/ - Form 10-K

03/08	30.98	199.00	47.02
04/08	26.60	204.16	43.25
05/08	21.21	208.23	49.32
06/08	17.85	197.61	39.82
07/08	11.72	189.98	38.08
08/08	7.74	184.45	41.55
09/08	5.72	159.27	33.62
10/08	3.36	131.99	27.86
11/08	1.85	123.62	22.35
12/08	2.36	127.35	26.62
01/09	2.36	129.57	23.99
02/09	1.35	122.50	20.05
03/09	4.38	126.25	21.99

35

---

## ITEM 6.

## SELECTED FINANCIAL DATA

The following consolidated selected financial data, at the end of and for the last five fiscal years, should be read in conjunction with our Consolidated Financial Statements and related Notes thereto appearing elsewhere in this Annual Report on Form 10-K. The consolidated selected financial data are derived from our audited Consolidated Financial Statements. The audit report of Rosen Seymour Shapss Martin & Company LLP, our independent auditors, for the year ended March 31, 2009, and the audit report of Miller, Ellin & Company LLP, our former independent auditors, for the years ended March 31, 2008 and 2007, are included in this Annual Report on Form 10-K. The selected financial data provided below is not necessarily indicative of our future results of operations or financial performance.

	2009	2008	2007	2006	2005
Net revenues	\$ 2,274,825	\$ 1,413,119	\$ 1,143,841	\$ 550,697	\$ 301,480
Net (loss)	\$ (6,604,708)	\$ (13,893,060)	\$ (11,803,512)	\$ (6,883,914)	\$ (5,906,890)
Net (loss) per common share	\$ (.27)	\$ (0.73)	\$ (0.64)	\$ (0.49)	\$ (0.47)
Total assets	\$ 10,920,148	\$ 15,310,270	\$ 9,208,006	\$ 15,702,241	\$ 9,245,292
Long-term obligations	\$ 3,416,600	\$ 3,637,388	\$ 3,795,000	\$ 3,980,000	\$ 2,367,128
Weighted average number of common shares outstanding	32,047,421	21,801,042	19,815,780	18,463,514	12,869,924

## 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. It 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, and a pipeline of five additional drug candidates under active development in the therapeutic areas that include pain management, allergy and infection. Of the products under development, ELI-216, a once-a-day, abuse deterrent oxycodone product, and ELI-154, a once-a-day oxycodone product, are in clinical trials and Elite has completed pilot studies on two of Elite's other generic product candidates. Elite has also submitted an ANDA with Elite's co-development partner, The PharmaNetwork, for a pain management generic product. The addressable market for the pipeline of products is approximately \$6 billion. The Facility in Northvale, New Jersey is a Good Manufacturing Practice ("GMP") and DEA registered facility for research, development and manufacturing.

In January 2006, the FDA accepted Elite's Investigational New Drug Application (an "IND") for ELI-154, Elite's once-a-day oxycodone painkiller. Elite has completed two pharmacokinetic studies to evaluate ELI-154's controlled-release formation of which the most recent study was completed in 2006. Elite is currently scaling up the product and it will begin its Phase III studies for this product upon the completion of a joint development and distribution agreement. Currently there is no once-daily oxycodone available commercially.

In May 2005, the FDA accepted Elite's IND for ELI-216, Elite's once-a-day, abuse resistant oxycodone painkiller. After the acceptance of the IND, Elite completed two pharmacokinetic studies and a euphoria study in recreational drug users to assess the abuse deterrent properties of ELI-216. Elite met with the FDA in October 2006 and received guidance for the ELI-216 development program and in November 2007, Elite reached agreement with the FDA on a Special Protocol Assessment for the Phase III protocol for ELI-216. Elite is currently scaling up the product and preparing for additional studies including a multi-dose study in opioid dependent patients, a food effect study and the Phase III study for ELI-216. Currently there is no abuse deterrent oxycodone product available commercially. Elite estimate that the U.S. market for controlled-release, twice-daily oxycodone was about \$2.8 billion in 2008.

### Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite's pain management products, (ii) manufacturing of Lodrane 24(R) and Lodrane 24D(R) products; (ii) the development of the other products in Elite's pipeline; and (iii) commercial exploitation of Elite's products either by license and the collection of royalties, or through the manufacture of Elite's formulations, and (iv) development of new products and the expansion of Elite's licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

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

### Epic Strategic Alliance Agreement

On March 18, 2009, Elite entered into the Epic Strategic Alliance Agreement, 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 (other than Facility-related expenses), 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 of Epic (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 will 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

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 Purchaser, 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 \$0.01 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 the Purchaser'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. The Purchaser 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 the Purchaser's consent was not required under the Alliance Agreement, at a price less than the then applicable Exercise Price of the Initial Warrant. The Purchaser 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 Purchaser 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 the Purchaser at the Initial Closing.

On the fifth trading day following the Special Meeting of Stockholders (as defined in the Epic Strategic Alliance Agreement) at which the Shareholder Approval (as defined in the Epic Strategic Alliance Agreement) is obtained, Elite and Epic will conduct a second closing (the “Second Closing” and the date of such Second Closing, the “Second Closing Date”), provided that all conditions precedent to such Second Closing contained in the Epic Strategic Alliance Agreement have been satisfied or waived by the appropriate party on or before the Second Closing Date. The Second Closing must occur within 180 days of the Initial Closing Date. At the Second Closing, 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 such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, into 20,000,000 shares of Common Stock, and a warrant (the “Second Warrant”) to purchase an additional 40,000,000 shares of Common Stock. The Second Warrant will be exercisable until the date that is the seventh anniversary of the Second Closing Date and will 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 Second Warrant will 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 Second Warrant, for which Epic’s consent was not required under the Epic Strategic Alliance Agreement.

On the first trading day following the first anniversary of the Initial Closing Date, 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. The Third Closing must occur within thirty days following the first anniversary of the Initial Closing Date. At the Third Closing, 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 such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, 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 will be exercisable until the date that is the seventh anniversary of the Third Closing Date and will 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 will 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 Purchaser’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.

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 our new partner, 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. In order to value Elite's ownership in Novel, Elite has made numerous requests to Novel for financial and pipeline information. As of the date hereof, Elite has yet to receive any responses from Novel to such requests.

Novel has publicly disclosed the following information:

§	Novel has filed eleven ANDAs.
§	One of Novel's ANDAs has been approved.
§	Four of Novel's ANDAs have been granted first-to-file status. Another ANDA filed by Novel is expected to be granted first-to-file status.
§	Novel acquired three ANDAs to supplement its own in-house products.
§	Novel has identified over 50 drug products in development.
§	Novel intends to launch as many as six products in 2009 beginning in first quarter.
§	Novel employs approximately 50 people.

Using the above information for guidance, Elite has estimated a net present value of cash flows for 2009, 2010, 2011 and 2012, based upon the following assumptions:

§	Sales potential for Novel's products;
§	Capital and operating costs for Novel;
§	Stock option shares that might be issued;
§	Assuming a terminal value based on a 12.50% discount rate on 2012 net cash flow; and
§	\$1 million in capital expenditures per year.

Based solely upon the above publicly disclosed information and our assumptions, Elite's investment in Novel as of March 31, 2009 was estimated to be \$3,400,000. Novel has not provided Elite with its current financial information and therefore such estimate is based on limited information.

#### Critical Accounting Policies and Estimates

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

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its Consolidated Financial Statements. Our most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. We also assess a need for an allowance to reduce our deferred tax assets to the amount that we believe is more likely than not to be realized. We assess the recoverability of 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.

Recently Issued Accounting Pronouncements Not Yet Effective

Effective for fiscal year beginning after December 15, 2008

Statements of Financial Accounting Standards (SFAS):

SFAS 157, "Fair Value Measurements" - defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, where the Board previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged, provided that the reporting entity has not yet issued financial statements for that fiscal year, including financial statements for an interim period within that fiscal year.

SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities-including an amendment of FASB Statement No. 115" - permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. This Statement is expected to expand the use of fair value measurement, which is consistent with the Board's long-term measurement objectives for accounting for financial instruments. This Statement is effective as of the beginning of an entity's first fiscal year that begins after November 15, 2007, and interim periods within those fiscal years. Early adoption is permitted as of the beginning of a fiscal year that begins on or before November 15, 2007, provided the entity also elects to apply the provisions of FASB Statement No. 157, "Fair Value Measurements".

Effective for fiscal years and interim periods beginning after November 15, 2008. Early application is encouraged.

FASB Statement No. 161, "Disclosures about Derivative Instruments and Hedging Activities - an Amendment of FASB Statement 133" - enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how: (a) an entity uses derivative instruments; (b) derivative instruments and related hedged items are accounted for under FASB Statement No. 133, Accounting for Derivative Instruments and Hedging Activities; and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. Specifically, Statement 16 1 requires:

- Disclosure of the objectives for using derivative instruments be disclosed in terms of underlying risk and accounting designation;
  - Disclosure of the fair values of derivative instruments and their gains and losses in a tabular format;
    - Disclosure of information about credit-risk-related contingent features; and

- Cross-reference from the derivative footnote to other footnotes in which derivative related information is disclosed.

SFAS 141 (R), "Business Combinations"- retains the fundamental requirements in Statement 141 that the acquisition method of accounting (which Statement 141 called the purchase method) be used for all business combinations and for an acquirer to be identified for each business combination. This Statement defines the acquirer as the entity that obtains control of one or more businesses in the business combination and establishes the acquisition date as the date that the acquirer achieves control.

- replaces Statement 141's cost-allocation process and requires an acquirer to recognize the assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date,
- requires the acquirer in a business combination achieved in stages (sometimes referred to as a step acquisition) to recognize the identifiable assets and liabilities, as well as the noncontrolling interest in the acquiree, at the full amounts of their fair values,
- requires that an acquirer evaluate new information and measure a liability at the higher of its acquisition-date fair value or the amount that would be recognized if applying Statement 5, then measuring an asset at the lower of its acquisition-date fair value or the best estimate of its future settlement amount,
- requires the acquirer to recognize contingent consideration at the acquisition date, measured at its fair value at that date,

Effective for fiscal years beginning after November 15, 2007

SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements" - changes the way the consolidated income statement is presented. It requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It also requires disclosure, on the face of the consolidated statement of income, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interest. Previously, net income attributable to the noncontrolling interest generally was reported as an expense or other deduction in arriving at consolidated net income. It also was often presented in combination with other financial statement amounts. Effective for fiscal years beginning after December 15, 2008.

FASB Staff Positions (FSP):

FSP APB 14-1, "Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)" - clarifies that convertible debt instruments that may be settled in cash upon conversion (including partial cash settlement) are not addressed by paragraph 12 of APB Opinion No. 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants. Additionally, this FSP specifies that issuers of such instruments should separately account for the liability and equity components in a manner that will reflect the entity's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years.

FSP FAS 140-3, "Accounting for Transfers of Financial Assets and Repurchase Financing Transactions" - amends FASB Statement 140 to state that a transferor and transferee shall not separately account for a transfer of a financial asset and a related repurchase financing unless (a) the two transactions have a valid and distinct business or economic purpose for being entered into separately and (b) the repurchase financing does not result in the initial transferor regaining control over the financial asset. This FSP is effective for financial statements issued for fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. Earlier application is not permitted.

FSP FAS 142-3, "Determination of the Useful Life of Intangible Assets"- amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, Goodwill and Other Intangible Assets. Paragraph 1 l(d) of Statement 142 precluded an entity from using its own assumptions about renewal or extension of an arrangement where there is likely to be substantial cost or material modifications. This FSP amends paragraph 1 l(d) of Statement 142 so that an entity will use its own assumptions about renewal or extension of an arrangement, adjusted for the entity-specific factors in paragraph 11 of Statement 142, even when there is likely to be substantial cost or material modifications. Therefore, in determining the useful life of the asset for amortization purposes, an entity shall consider the period of expected cash flows used to measure the fair value of the recognized intangible asset, adjusted for the entity-specific factors including, but are not limited to, the entity's expected use of the asset and the entity's historical experience in renewing or extending similar arrangements. This FSP shall be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited.

FSP FAS 157-1, Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13" - amends FASB Statement No. 157, Fair Value Measurements, to exclude FASB Statement No. 13, Accounting for Leases, and other accounting pronouncements that address fair value measurements for purposes of lease classification or measurement under Statement 13. However, this scope exception does not apply to assets acquired and liabilities assumed in a business combination that are required to be measured at fair value under FASB Statement No. 141, Business Combinations, or No. 141 (revised 2007), Business Combinations, regardless of whether those assets and liabilities are related to leases.

FSP FAS 157-2, "Effective Date of FASB Statement No. 157" - delays the effective date of FASB Statement No. 157, Fair Value Measurements, for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The delay is intended to allow the Board and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of Statement 157. This FSP defers the effective date of Statement 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years for items within the scope of this FSP.

FSP SOP 07-1-1, - indefinitely delays the effective date of AICPA Statement of Position 07-1, "Clarification of the Scope of the Audit and Accounting Guide Investment Companies and Accounting by Parent Companies and Equity Method Investors for Investments in Investment Companies."

EITF Consensuses (EITF):

EITF Issue No. 07-1, "Accounting for Collaborative Arrangement" - when entities enter into arrangements to participate in a joint operating activity a collaborative arrangement may provide that one participant has sole or primary responsibility for certain activities or that two or more participants have shared responsibility for certain activities. Participants should evaluate whether an arrangement is a collaborative arrangement at the inception of the arrangement based on the facts and circumstances present at that time. Revenue generated and costs incurred by participants from transactions with parties should be reported gross or net on the appropriate line item in each participant's respective financial statements depending on the nature of the participation. Disclosures should include information about the nature and purpose of its collaborative arrangements, the entity's rights and obligations under the collaborative arrangements, the accounting policy for collaborative arrangements, and the income statement classification and amounts attributable to transactions arising from the collaborative arrangement. Effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years.

Year Ended March 31, 2009 vs. Year Ended March 31, 2008

Elite's revenues for the year ended March 31, 2009 were \$2,274,825, an increase of \$861,706 over revenues for the prior year, and consisted of \$1,927,062 in manufacturing fees and \$347,763 in royalty fees. Revenues for the year ended March 31, 2008 consisted of \$1,173,890 in manufacturing fees and \$239,229 in royalty fees. Manufacturing fees increased by approximately 70% and royalties increased by approximately 45% due to growth of product sales.

Research and development costs for the year ended March 31, 2009 were \$3,631,425, a decrease of \$2,164,354, or approximately 37%, from \$5,795,779 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. To conserve cash, Elite has reduced its number of employees from 41 employees in March 2008, to 14 employees in May 2009. The reduction in force was primarily implemented in the third quarter with cost savings beginning in the later part of the year. 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, 2009, were \$2,146,895, a decrease of \$287,908, or approximately 12% from \$2,434,803 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 and accounting fees from Elite's preferred stock offering in September 2008 and other one-time events.

Non-cash compensation satisfied by the issuance of stock options and warrants decreased \$1,686,028 to \$921,442 for the year ended March 31, 2009 from \$2,607,470 for the year ended March 31, 2008. 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 \$24,076, or approximately 5%, from \$524,893 for the prior year to \$500,817. The decrease was due to the cessation of acquisition of new machinery and equipment in the current year.

Other income (expenses) for the year ended March 31, 2009 were (\$211,266) compared to income of \$63,997 for the year ended March 31, 2008. Decreases in interest expense of \$40,094 were more than offset by decreases in interest income of \$315,357 due to lower compensating balances as a result of the use of cash to sustain Elite's operating activities.

Elite's prior years financial statements were restated as a result of Elite's decision not to continue to fund Novel and therefore not include Novel's expenses as part of Elite's operating activities for years ending March 31, 2009 and 2008. Consequently, losses from discontinued operations of \$-0- and \$2,979,600, respectively, are reflected in the 2009



and 2008 financial statements.

As a result of the foregoing, Elite's net loss for the year ended March 31, 2009 was \$6,604,708 compared to \$13,893,060 for the year ended March 31, 2008.

Year Ended March 31, 2008 vs. Year Ended March 31, 2007

Our revenues for the year ended March 31, 2008 were \$1,413,119, an increase of \$269,278 or approximately 24%, over revenues for the prior year, and consisted of \$1,173,890 in manufacturing fees and \$239,229 in royalty fees. Revenues for the year ended March 31, 2007 consisted of \$1,038,916 in manufacturing fees and \$104,925 in royalty fees. The increase in manufacturing fees and royalties was primarily due to the launch of our second product, Lodrane 24D® in the later part of the fiscal year ended March 31, 2007.

Research and development costs for the year ended March 31, 2008 were \$5,795,779, a negligible increase of \$17,914 from \$5,777,865 of such costs for the prior year, primarily due to costs associated with increased spending on raw materials which are primarily for scale up of the pain products.

General and administrative expenses (“G&A”) for the year ended March 31, 2008 were \$2,434,803, an increase of \$238,649, or approximately 11% from \$2,196,154 of G&A for the prior year. The increase was attributable to increases in salaries and fringe benefits as a result of the hiring of managerial level employees and consulting fees associated with seeking potential strategic transactions.

Non-cash compensation satisfied by the issuance of stock options and warrants decreased \$871,600 to \$2,607,470 for the year ended March 31, 2008 from \$3,479,070 for the year ended March 31, 2007. Decreases were the result of previously issued options becoming vested and therefore fully amortized and newly issued options being priced at lower values due to the reduction in Elite’s stock price.

Depreciation and amortization for the year ended March 31, 2008 increased by \$116,079 from \$408,814 for the prior year to \$524,893. The increase in 2008 was due to acquired new machinery and equipment and continued upgrading of the corporate and warehouse facilities.

Other income (expenses) for the year ended March 31, 2008 were \$63,997, a decrease of \$324,835, or approximately 84%, from \$388,832 for the prior year due an increase in interest income of \$69,671, due to higher compensating balances as a result of the Series C private placement offset by a decrease of \$377,259 in sale of New Jersey tax losses, and an increase of \$17,247 in interest expense resulting from a loan to finance the purchase of a new truck.

Our prior year financial statements were restated as a result of the Company's decision not to continue to fund Novel and therefore not include Novel's expenses as part of the Company's operating activities for the year ending March 31, 2008 and 2007. Consequently, losses from discontinued operations of \$2,979,600 and \$642,032 respectively are reflected in the 2008 and 2007 financial statements.

As a result of the foregoing, our net loss for the year ended March 31, 2008 was \$13,893,060 compared to \$11,803,512 for the year ended March 31, 2007.

Material Changes in Financial Condition

Our working capital (total current assets less total current liabilities), decreased to \$758,676 as of March 31, 2009 from \$5,029,930 as of March 31, 2008, primarily due to our net loss from operations, exclusive of non-cash charges offset by net proceeds received as a result of our private placement of Series D 8% Convertible Preferred Stock.

We experienced negative cash flows from operations of \$4,540,068 for the year ended March 31, 2009, primarily due to our net loss from operations of \$6,604,708, an increase in accrued interest receivable and prepaid expenses of \$56,195, offset by increases in accounts payable, accrued expenses and other liabilities of \$130,615 and reductions in accounts receivable of \$147,307 and by non-cash charges of \$1,422,259 which included \$921,442 in connection with the issuance of stock options and warrants and \$500,817 in depreciation and amortization expenses.

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, 2009 was \$1,927,062 and \$347,763, 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.

#### Liquidity and Capital Resources

As of March 31, 2009, our principal source of liquidity was approximately \$283,000 of cash and cash equivalents, or approximately two months of cash or cash equivalents available based on our current operations. On June 3, 2009, in connection with the Initial Closing of the Epic Strategic Alliance Agreement, we received \$1 million in cash from Epic (including \$250,000 previously paid to us by Epic as a good faith deposit) in exchange for 1,000 shares of Series E Preferred Stock and a warrant to purchase 40 million shares of Common Stock. Our strategic alliance with Epic may also generate (i) an additional \$2.75 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 over our ability to continue as a going concern.

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

For the year ended March 31, 2009, we expended \$4,540,068 in operating activities which we funded through the \$1,777,000 in gross proceeds raised through our private placement of Series D Preferred Stock and from cash on hand as of March 31, 2008. Our working capital at March 31, 2009 was \$.8 million compared with working capital of \$5.0 million at March 31, 2008. Cash and cash equivalents at March 31, 2009 were \$.3 million, a decrease of \$3.4 million from the \$3.7 million at March 31, 2008.

We spent approximately \$46,000 on improvements and machinery and equipment during the year ended March 31, 2009.

On September 15, 2008, Elite 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 Elite’s Common Stock, par value \$0.01 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 Elite’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 Elite’s Series B Preferred Stock and Series C Preferred Stock (collectively, the “Existing Preferred Stock”). Elite has authorized, in total, 30,000 shares of Series D Preferred Stock.

The gross proceeds of the private placement for shares of Elite’s Series D Preferred Stock were \$1,777,000 before payment of \$263,743 in expenses. Pursuant to the placement agent agreement, Elite issued to the placement agent warrants to purchase 355,400 shares of Common Stock exercisable at \$0.25 per share. Elite 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 Elite’s financial position or results of operations.

As part of the private placement for shares of Elite’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 Elite’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.

As of March 31, 2009 our principal source of liquidity was approximately \$283,000 of cash and cash equivalents. On June 3, 2009, we consummated the Initial Closing of the transactions contemplated by the Epic Strategic Alliance Agreement, and received from Epic a cash payment of \$1,000,000 (including \$250,000 previously paid to us as a good faith deposit) in exchange for 1,000 shares of our Series E Preferred Stock, which provides us additional capital necessary for the product development and synergies presented by the strategic relationship with Epic. The Epic Strategic Alliance Agreement also contemplates two additional closings, which together could generate an additional \$2.75 million in cash proceeds through Epic’s purchase of additional shares of Series E Preferred Stock.

The Company had outstanding, as of March 31, 2009, bonds in the aggregate principal amount of \$3,595,000 consisting of \$3,280,000 of 6.5% tax exempt bonds with an outside maturity of September 1, 2030 and \$315,000 of 9.0% bonds with an outside maturity of September 1, 2012. The bonds are secured by a first lien on the Facility in Northvale, New Jersey. Pursuant to the terms of the bonds, several restricted cash accounts have been established for the payment of bond principal and interest. 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 \$415,500 debt service reserve. The interest payment due on March 1, 2009 was paid from this restricted cash and will be repaid when funds become available. All of the restricted cash, other than the debt service, was expended within the year ended March 31, 2007. Pursuant to the terms of the related bond indenture agreement, the Company is required to observe certain covenants, including covenants relating to the incurrence of additional indebtedness, the granting of liens and the maintenance of certain financial covenants. As of March 31, 2009, the Company was in compliance with the bond covenants.

The following table depicts our obligations and commitments to make future payments under existing contracts or contingent commitments.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	4-5 Years	After 5 Years
Contractual Obligations					
NJEDA Bonds payable	\$ 3,595,000	\$ 210,000	\$ 730,000	\$ 380,000	\$ 2,275,000
Note Payable-Niagara Bank	\$ 42,388	\$ 10,788	\$ 31,600	\$ —	\$ —

Off-balance sheet arrangements

None.

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

We do not invest in or own any market risk sensitive instruments entered into for trading purposes or for purposes other than trading. All loans to us have been made at fixed interest rates and accordingly, the market risk to us prior to maturity is minimal.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

#### ITEM 9AT. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our acting Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and

15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our acting Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit 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 management, including our acting Chief Executive Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

## 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.

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, 2009. 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, 2009, our internal control over financial reporting was effective.

As previously reported in our Annual Report on Form 10-K/A for the year ended March 31, 2008, filed with the SEC on January 16, 2009, and our Quarterly Report on Form 10-Q for the quarterly period ended December 31, 2008, filed with the SEC on February 17, 2009, which reports are incorporated herein by reference, in October 2008, we learned that certain reimbursements of expenses were made by Elite to Bernard J. Berk, its then-President, Chief Executive Officer and Chairman of Board, without prior receipt from Mr. Berk of adequate substantiation of such expenses. In light of this information regarding Mr. Berk, we determined that our disclosure controls and procedures as of September 30, 2008 had deficiencies that caused our controls and procedures to be ineffective, particularly with respect to our expense reimbursement procedures. As a result, our management conducted an assessment of our internal control over financial reporting, which assessment was limited in scope to a review of the revised accounting procedures and internal controls over expenditures and expense reimbursement that were implemented by the Audit Committee of after it learned of the information regarding Mr. Berk described above.

We took various remedial measures to correct deficiencies in our accounting procedures and internal controls over expenditures and expense reimbursement to prevent the reimbursement of unsubstantiated expenses in the future, including the following:

- At the direction of our audit committee, our Chief Financial Officer implemented check writing restrictions to our bank accounts that require the signatures of each of our acting Chief Executive Officer and Chief Financial Officer for all payments (including expense reimbursements) over \$5,000.
- We commenced a review of our internal control and compliance policies and procedures, including (1) reviewing, expanding, and formalizing our policies relating to all potential advances and/or extensions of credit to employees, executive officers and directors, including, without limitation, with respect to the use of our credit cards, and advances of any other kind; and (2) enhancing our training of employees, executive officers and directors regarding compliance with the letter and the spirit of our Code of Ethics.
- We engaged our registered independent accounting firm, Rosen Seymour Shapss Martin & Company, LLP (“Rosen Seymour”), to evaluate our revised accounting procedures and related internal controls over expenditures and expense reimbursements.

Rosen Seymour completed its review, on January 23, 2009, of the revised accounting procedures and related internal controls over expenditures and expense reimbursements implemented by the Audit Committee and concluded that they are effective.

#### 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 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ITEM 9B.

#### OTHER INFORMATION.

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, in accordance with the terms of the Epic Strategic Alliance Agreement. For additional information regarding Messrs. Nigalaye, Narine and Potti, please see our disclosures in this Annual Report on Form 10-K in Item 7, under the heading “Epic Strategic Alliance Agreement – Board of Directors Composition and Voting Rights”; Item 10, under the heading “Directors and Executive Officers”; and Item 13, under the heading “Certain Related Person Transactions - Transactions with Epic Pharma LLC and Epic Investments LLC,” which are incorporated herein by reference.

### 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 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	55	Director, Chairman of the Board
Barry Dash, Ph. D	77	Director
Robert J. Levenson	68	Director
Melvin M. Van Woert, M.D.	78	Director
Ashok G. Nigalaye	57	Director
Jeenarine Narine	59	Director
Ram Potti	56	Director
Chris Dick	54	Chief Operating Officer, President and Acting Chief Executive Officer and Former Director
Mark I. Gittelman	49	Chief Financial Officer, Secretary and Treasurer
Stuart Apfel	49	Chief Scientific Officer and Chief Medical Officer

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. 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.

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 American Home Products Corporation (now known as Wyeth) its Whitehall-Robins Healthcare Division, initially as Vice President of Scientific Affairs, then Senior Vice President of Scientific Affairs and then 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 Division 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.

Robert J. Levenson, Director since 2007, Member of the Audit Committee 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 June 2007 and Chairman of the Audit Committee since June 2008, Member of the Compensation Committee since June 2007 and Member of the Nominating Committee since June 2008. Since 2000, Mr. Levenson has been a Managing Member of the Lenox Capital Group, L.L.C. Mr. Levenson was previously an Executive Vice President of First Data Corporation from 1993 to 2000 and a member of its Board of Directors from 1992 to 2003. He was Senior Executive Vice President, Chief Operating Officer, Member of the Office of the President and Director of Medco Containment Services, Inc., a provider of managed care prescription benefits, from October 1990 to December 1992. From 1985 until October 1990, Mr. Levenson was a Group President and Director of Automatic Data Processing, Inc. (ADP-NYSE). Mr. Levenson was a Director of Emisphere Technologies, Inc., a biopharmaceutical company, from 1998 to 2005, and has been a director of several other companies, public and private.

Dr. Melvin Van Woert, Director since April 2005, Member of the Audit Committee since April 2005, Member and Chairman of the Nominating Committee since April 2005 and Member of the Compensation Committee since June 2007. Dr. Van Woert has been since 1974 a member of the staff of Mount Sinai Medical Center and, since 1978 has also been a Professor in the Department of Neurology and Pharmacology at Mount Sinai School of Medicine. Dr. Van Woert had been a consultant for Neuropharmacological Drug Products to the FDA from 1974 to 1980; Associate Editor for Journal of the Neurological Sciences; Member of the Editorial Board of the Journal of Clinical Neuropharmacology; and Medical Director of National Organization for Rare Disorders for which he received in 1993 the Humanitarian Award. Dr. Van Woert’s other awards include the U.S. Public Health Service Award for Exceptional Achievement in Orphan Products Development and the National Myoclonus Foundation Award. He has authored and co-authored more than 150 articles appearing in pharmacological, medical and other professional journals or publications.

Ashok G. Nigalaye, Director since June 24, 2009. Mr. 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, Mr. 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, Mr. 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. Mr. Nigalaye currently serves as a director of GTI Inc., a privately held company. Mr. 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. Mr. Nigalaye is also a licensed pharmacist in the State of New York.

Jeenarine Narine, Director since June 24, 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.

Ram Potti, Director since June 24, 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.

Chris Dick, Chief Operating Officer since October 2008, acting Chief Executive Officer since November 2008, and President since April 2009; Director from October 20, 2008 to June 24, 2009. Mr. Dick began at Elite in November 2002 as Vice President of Business Development. Since March 2002, 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.

Dr. Stuart Apfel, Chief Medical Officer since January 2008 and Chief Scientific Officer since April 2008. Dr. Apfel is also the founder and current President of Parallax Clinical Research, a New York-based consulting firm that provides strategic and practical assistance with clinical trial protocol design, planning, initiating and management to biotechnology and small pharmaceutical companies with making the transition from the bench to a clinical development program, and in this capacity he had served as a consultant to Elite from January 2007 through December 2007. From 2004 to 2006, Dr. Apfel was employed at DOV Pharmaceuticals, Inc. (OTC:DOVP), initially as a director of clinical research and then as a senior director of clinical research. From 2000 to 2004, Dr. Apfel was employed at Purdue Pharma L.P. Dr. Apfel initially worked as an associate director of clinical research at Purdue Pharma L.P. and then was promoted to a director of clinical research. Dr. Apfel is a board certified neurologist, and is currently on faculty as Associate Professor of Neurology at the Albert Einstein College of Medicine and at Downstate Medical School, where he continues to teach. From 1990 to 2000, he was a full time faculty member in the departments of Neurology and Neuroscience at Albert Einstein College of Medicine, where his research focused on the application of neurotrophic factors to neurologic disease.

Mark I. Gittelman, Chief Financial Officer, Secretary and Treasurer of the Company, is the President of Gittelman & Co., P.C., an accounting firm in Clifton, New Jersey. Prior to forming Gittelman & Co., P.C. in 1984, he worked as a certified public accountant with the international accounting firm of KPMG Peat Marwick, LLP. Mr. Gittelman holds a B.S. in accounting from New York University and a Masters of Science in Taxation from Fairleigh Dickinson University. He is a Certified Public Accountant licensed in New Jersey and New York, and is a member of the American Institute of Certified Public Accountants (“AICPA”), and the New Jersey State and New York State Societies of CPAs. Other than Elite Labs, no company with which Mr. Gittelman was affiliated in the past was a parent, subsidiary or other affiliate of the Company.

There is no family relationship among our directors and executive officers.

Each director holds office (subject to our By-Laws) until the next annual meeting of stockholders and until such director’s successor has been elected and qualified. There are no family relationships between any of our directors and executive officers.

#### Board Meetings

During the fiscal year ended March 31, 2009, our Board of Directors held 28 meetings and acted via written consent on 4 occasions. No incumbent director attended fewer than 75% of the meetings of the Board of Directors held during the fiscal year ended March 31, 2009 except for Jerry Treppel, who was not elected as a director until the third quarter of such fiscal year, on October 28, 2008. Mr. Treppel attended all meetings of the Board of Directors that were held from the date of his election as a member of the Board through the end of the fiscal year.

We do not have a formal policy regarding attendance by members of the Board of Directors at our annual meeting of stockholders, although we do encourage attendance by the directors. Historically, more than a majority of the directors have attended the annual meeting.

#### 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, 2009, the members of the Audit Committee were Barry Dash, Robert J. Levenson (Chairman of the Audit Committee) and Melvin Van Woert. The Audit Committee held 11 meetings during the fiscal year ended March 31, 2009. A copy of the Audit Committee's written charter (adopted by the Board of Directors) can be found on our website at [www.elitepharma.com](http://www.elitepharma.com). The Audit Committee reviews and discusses with management and our auditors our financial statements, the accounting principles applied in their preparation, the scope of the audit, any comments made by the auditors on our financial statements and our accounting controls and procedures, the independence of our auditors, our internal controls, the other matters set forth in its charter, as adopted by the Board of Directors, and such other matters as the Audit Committee deems appropriate. The Audit Committee is directly responsible for the appointment, compensation, retention and oversight of the work of our independent auditors for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us. 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, 2009, the members of the Nominating Committee were Melvin Van Woert (Chairman of the Nominating Committee), Robert J. Levenson and Barry Dash. The Nominating Committee held 2 meetings during the fiscal year ended March 31, 2009. This committee does not have a charter. The Nominating Committee assists the Board of Directors in identifying and recommending qualified Board candidates. The Nominating Committee identifies Board candidates through numerous sources, including recommendations from Directors, executive officers and our stockholders. The Nominating Committee seeks to have available to it qualified candidates from a broad pool of individuals with a range of talents, experience, backgrounds and perspectives. The Nominating Committee seeks to identify those individuals most qualified to serve as Board members and considers many factors with regard to each candidate, including judgment, integrity, diversity, prior experience, the interplay of the candidate's experience with the experience of other Board members, the extent to which the candidate would be desirable as a member of any committees of the Board of Directors, and the candidate's willingness to devote substantial time and effort to Board responsibilities. The Nominating Committee makes recommendations to the Board of Directors with respect to Director nominees.

#### Compensation Committee

During the fiscal year ended March 31, 2009, the members of the Compensation Committee were Barry Dash (Chairman of the Compensation Committee), Robert J. Levenson and Melvin Van Woert. The Compensation Committee held no meetings during the fiscal year ended March 31, 2009. The Compensation Committee was formed June 26, 2007 and adopted a charter which was included as an appendix to the proxy statement sent to stockholders in connection with the annual meeting of the stockholders held on June 26, 2008. The Compensation Committee reviews our compensation practices and policies, reviews and approves corporate goals and objectives relevant to the chief executive officer and other executive officer compensation, evaluates chief executive officer and executive officer performance in light of those goals and objectives and, either as a committee or together with other independent directors (as directed by the Board of Directors), determines and approves chief executive officer and executive officer compensation based on this evaluation, reviews and approves the terms of the offer letters, employment agreements, severance agreements, change-in-control agreements, indemnification agreements and other material agreements between the Company and its Chief Executive Officer and executive officers, annually reviews and approves perquisites for the chief executive officer and executive officers, considers and approves the report of the Compensation Committee for inclusion in the Company's proxy statement, makes recommendations to the Board of Directors with respect to the Company's employee benefit plans, administers incentive, deferred compensation and equity based plans, and has the other responsibilities as set forth in its charter, as adopted by the Board of Directors, and such other matters as the Compensation Committee deems appropriate. For more information on the

compensation of directors and officers of the Company, see the “Compensation Discussion and Analysis” and “Compensation” sections below.

## 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 for its officers and employees which it believes complies with the requirements for a company code of ethics for financial officers that were promulgated by the SEC pursuant to the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) as well as for the members of our Board of Directors. The directors will be surveyed annually regarding their compliance with the policies as set forth in the Code of Conduct for Directors. A copy of the Code of Business Conduct and Ethics is available on our website at [www.elitepharma.com](http://www.elitepharma.com). To receive a copy of our Code of Business Conduct and Ethics, at no cost, requests should be directed to the Secretary, Elite Pharmaceuticals, Inc., 165 Ludlow Avenue, Northvale, New Jersey 07647. We intend to disclose any amendment to, or waiver of, a provision of the Business Conduct and Ethics for Directors in a report filed under the Exchange Act within five business days of the amendment or waiver.

## Stockholder Communications

Stockholders and other interested parties may contact the Board of Directors or the non-management directors as a group at the following address: Board of Directors or Outside Directors, Elite Pharmaceuticals, Inc., 165 Ludlow Avenue, Northvale, NJ 07647. All communications received at the above address will be relayed to the Board of Directors or the non-management directors, as the case may be. Communications regarding accounting, internal accounting controls or auditing matters may also be reported to the Board of Directors using the above address.

Typically, we do not forward to our directors communications from our stockholders or other communications which are of a personal nature or not related to the duties and responsibilities of the Board, including:

- Junk mail and mass mailings
- New product suggestions
- Resumes and other forms of job inquiries
- Opinion surveys and polls
- Business solicitations or advertisements

## 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, 2009, 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. Charan Behl, the former Head of Technical Affairs of Elite, failed to file on a timely basis reports required by Section 16(a) of the Exchange Act following his resignation from such office, on November 3, 2008, to report that he was no longer subject to the reporting requirements of Section 16(a) and Elite’s grant to him on November 3, 2008 of a non-qualified stock option to purchase 50,000 shares of Common Stock in consideration of his entry into a separation and release agreement with Elite in connection with the termination of his status as an employee of Elite. Dr. Barry Dash, a member of Elite’s Board, failed to file on a timely basis four reports required by Section 16(a) of the Exchange Act during the fiscal year ended March 31, 2009 to report the Company’s issuance to him of Common Stock in respect of quarterly dividend obligations on his shares Series C Preferred Stock, on each of April 1, 2008, July 1, 2008, October 1, 2008 and January 1, 2009. Jerry Treppel, a member of Elite’s Board, failed to file on a timely basis two reports required to be filed by Section 16(a) of the Exchange Act during the fiscal year ended March 31, 2009 to report the Company’s issuance to Wheaten Healthcare Partners LP (“Wheaten”), of which Mr. Treppel is a general partner, of Common Stock in respect of quarterly dividend obligations on Series D Preferred Stock held by Wheaten, on each of October 1, 2008 and January 1, 2009.





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 Wheaten of 75 shares of Series D Preferred Stock into 375,000 shares of Common Stock and the Company's issuance to Wheaten 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 solely of independent non-employee directors. 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, 2009, the members of the Compensation Committee were Barry Dash, Robert J. Levenson and Melvin Van Woert. The Committee operates pursuant to a charter which was included as an appendix to the proxy statement sent to stockholders in connection with the annual meeting of the stockholders held on June 26, 2008. 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. In September, 2007, the Compensation Committee directly retained an independent compensation consultant, Pearl Meyer & Partners ("PM&P"), to assist the Committee in selecting a comparator group of companies for compensation purposes as well as benchmarking the Chief Executive Officer's compensation.

The compensation consultant reported directly and exclusively to the Compensation Committee and received no other fees from the Company outside its role as advisor to the Compensation Committee. PM&P periodically interacted with the Company's Compensation Committee, predominately with its Chairman, Dr. Barry Dash, to gather and review information related to the executive compensation program, but such work is done only at the direction of the Compensation Committee. PM&P does not perform any services unrelated to executive and director compensation for the Company. Accordingly, the Compensation Committee considers PM&P to be independent from our management.

#### Compensation Committee Interlocks and Insider Participation

No members of the Compensation Committee were officers or employees of the Company or any of its subsidiaries during the year ended March 31, 2009, or had any relationship otherwise requiring disclosure.

#### NAMED EXECUTIVE OFFICERS AND KEY EMPLOYEES

The named executive officers and key employees for the fiscal year ending March 31, 2009 are Chris C. Dick, President, Chief Operating Officer and acting Chief Executive Officer; Mark I. Gittelman, Chief Financial Officer, Secretary and Treasurer; Stuart Apfel, Chief Medical Officer and Chief Scientific Officer; and Dr. Charan Behl, Head of Technical Affairs until November 3, 2008 and a consultant of Elite since November 3, 2008; Bernard J. Berk, our President, Chief Executive Officer and Chairman until November 6, 2008; and Veerapan Subramanian, our Chief Scientific Officer until April 24, 2008. 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. 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 emphasis on the annual bonus opportunity and equity compensation components of the executive compensation program reflect our belief that a large 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. We have entered into employment agreements with four of our Named Executive Officers. Such employment agreements set forth base salaries, bonuses and stock option grants. Such stock option grants are predicated on our achievement of corporate performance goals as set forth in such agreements.

## ELEMENTS OF OUR EXECUTIVE COMPENSATION PROGRAM

### Base Salary

We pay a base salary to certain of the Named Executive Officers. 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.

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

As the pharmaceutical industry is characterized by a long product development cycle, including a lengthy research and product-testing period and a rigorous approval phase involving human testing and governmental regulatory approval, many of the traditional benchmarking metrics for vesting, such as product sales, revenues and profits are inappropriate for an early-stage pharmaceutical company such as Elite. We consider when determining vesting benchmarks the following which are aligned with our short-term and long-term corporate goals:

- clinical trial progress;
- achievement of regulatory milestones; and
- establishment of key strategic relationships.

### 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.

#### Perquisites

As described in more detail below, the perquisites provided to certain of the Named Executive Officers consist of car and parking 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 63 of this Annual Report on Form 10-K and “Agreements with Named Executive Officers” below.

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

In addition to retirement and deferred compensation benefits described above, we have arrangements with certain of the Named Executive Officers that may provide them with compensation following termination of employment. These arrangements are discussed below under “Agreements with Named Executive Officers”.

#### Tax Implications of Executive Compensation

Our aggregate deductions for each Named Executive Officer compensation are potentially limited by Section 162(m) of the Code to the extent the aggregate amount paid to an executive officer exceeds \$1.0 million, unless it is paid under a predetermined objective performance plan meeting certain requirements, or satisfies one of various other exceptions specified in the Code. At our 2006 Named Executive Officer compensation levels, we did not believe that Section 162(m) of the Code would be applicable, and accordingly, we did not consider its impact in determining compensation levels for our Named Executive Officers in 2007.

#### Agreements with Named Executive Officers and Key Employees

##### 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 “Dick Agreement”). The Dick Agreement is for an initial term ending November 13, 2009, subject to automatic one-year renewals unless terminated by Mr. Dick or us upon at least 60 days notice prior to the end of the then scheduled expiration date. 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 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 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, 2009 Mr. Dick is to receive a \$25,000 bonus.

The 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 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 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.

The 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.

Mr. Dick has agreed to a one-year non-competition covenant and a two-year non-solicitation covenant following termination of employment.

Mr. Dick is to be reimbursed for 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.

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, Elite disclosed that Jerry I. Treppel, a member of Elite'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 "Compensation Agreement") providing for the terms under which Mr. Treppel will serve as the non-executive Chairman of the Board. Pursuant to the Compensation 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 Compensation 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 Compensation 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 Compensation Agreement upon presentation of proper written evidence of such expenditures.

In addition, pursuant to the terms of the Compensation 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 \$0.01 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 Compensation 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 Compensation Agreement, effective immediately upon the giving of written notice to the other party.

#### Mr. Gittelman

On February 26, 1998, we entered into an agreement with Gittelman & Co., P.C., whereby fees are paid to Gittelman & Co., P.C., a firm wholly-owned by Mark I. Gittelman, our Chief Financial Officer, Secretary and Treasurer, in consideration for services rendered by the firm as internal accountant and financial and management consultant to us. The firm's services include the services rendered by Mr. Gittelman in his capacity as Chief Financial Officer, Secretary and Treasurer. For the fiscal years ended March 31, 2009, 2008 and 2007, the fees paid by us under the agreement were \$233,181, \$176,206 and \$151,214, respectively. The services rendered by the firm to us for the fiscal years ended March 31, 2009, 2008 and 2007 averaged 111, 105 and 98 hours per month, respectively, of which an average of 28 hours per month were services rendered by Mr. Gittelman in his capacity as an officer of Elite.

#### Dr. Stuart Apfel

On January 3, 2008, we entered into an employment agreement with Dr. Stuart Apfel (the "Apfel Agreement") providing for Dr. Apfel to serve as our Chief Medical Officer through January 3, 2009. However, as a result of Elite's continuing efforts to reorganize its workforce and decrease its operating expenses, Elite requested that Dr. Stuart Apfel, Elite's Chief Scientific Officer and Chief Medical Officer, change the status of his relationship with Elite from employee to consultant. Dr. Apfel agreed to such change in status and continues to provide his services as Elite's Chief Scientific Officer and Chief Medical Officer on an hourly basis, thereby reducing Elite's expenses as they relate to Dr. Apfel.

Accordingly, on October 20, 2008, Elite and Dr. Apfel entered into a Separation Agreement and General Release of Claims (the "Apfel Release"), whereby the Apfel Agreement was terminated and Dr. Apfel was terminated as an employee of Elite. Pursuant to the Apfel Release, Dr. Apfel waived his entitlement to certain notice and payment provisions upon termination of the Apfel Agreement. Dr. Apfel acknowledged that there were no payment amounts outstanding to him under the Apfel Agreement. Dr. Apfel acknowledged that his obligations under Sections 4 and 5: "Protection of Confidential Information and Trade Secrets; Non-Competition; No Solicitation" and "Continued Cooperation; Return of Documents and Property; Injunctive Relief; Non-Exclusivity and Survival" of the Apfel Agreement survive termination and that he would continue to be bound by and shall abide by such provisions. Additionally, Dr. Apfel released Elite from any claims he has or may have against Elite.

In his continuing service as Elite's Chief Scientific Officer and Chief Medical Officer on a consultancy basis, Dr. Apfel and Elite entered into a consulting agreement, dated as of October 20, 2008 (the "Apfel Consulting Agreement"), between Elite and Paralex Clinical Research ("Paralex"). Dr. Apfel is the founder and current president of Paralex. Pursuant to the Apfel Consulting Agreement, Paralex is to provide Elite consulting services for its opioid abuse-resistant product, sustained-release opioid product and other such products with which Elite may request assistance. Under the Apfel Consulting Agreement, Dr. Apfel is the primary person to provide such consulting services. As compensation for consulting services, Elite agreed to pay Dr. Apfel on an hourly basis at the rate of \$250 per hour and any other Paralex clinical research scientists at the rate of \$175 per hour; provided, however, that, in no event is Paralex entitled to compensation (together with its employees', representatives' or agents' billable hours) of more than \$10,000.00 in any month, unless it has obtained the prior written authorization of the Company. Paralex is entitled to reimbursement of reasonable and necessary travel expenses incurred by Paralex that have been approved in advance in writing by Elite.

Elite may terminate the Apfel Consulting Agreement at any time upon written notice to Paralex. Paralex and Dr. Apfel are subject to covenants not to disclose confidential information and assignment of intellectual property. In addition, during the term of the Apfel Consulting Agreement and for a period of one year thereafter, Dr. Apfel is subject to both non-competition and non-solicitation covenants.

Under the Apfel Agreement, prior to its termination on October 20, 2008 by the Apfel Release, Dr. Apfel was entitled to an initial base annual salary of \$220,000 and a discretionary bonus following the end of each calendar year, commencing with the calendar year beginning January 1, 2008, of up to 50% of Dr. Apfel's then annual base salary. The amount, if any, of the discretionary bonus to Dr. Apfel, pursuant the Apfel Agreement, was to be determined by the Board or the Compensation Committee, and was to 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. Such discretionary bonus could be paid in cash or shares of 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. Dr. Apfel was granted 400,000 options under the Apfel Agreement, as set forth in individual Incentive Stock Option Letter Agreements, dated January 3, 2008 (the "Apfel Option Agreements," and such options granted thereby, the "Apfel Options"). Pursuant to the Apfel Option Agreements, Dr. Apfel had 90 days following the termination of the status of Dr. Apfel as an employee of Elite pursuant to the Apfel Release to exercise such Apfel Options. Dr. Apfel did not exercise any Apfel Options within such 90-day period and, therefore, such Apfel Options expired without exercise.

During the fiscal year ended March 31, 2009, Elite paid Dr. Apfel an aggregate of \$124,114 for his service to Elite, representing the annual salary payable to Dr. Apfel under the Apfel Agreement for his employment as Elite's Chief Scientific Officer and Chief Medical Officer, prorated for the period beginning April 1, 2008 and ending October 20, 2008, the date of termination of Dr. Apfel's status as an employee of Elite. In addition, during such fiscal year, in consideration for entering into the Apfel Release, Elite paid Dr. Apfel \$4,219 less any payroll or withholding taxes, which such payment Elite and Dr. Apfel agreed constituted Elite's sole obligation to Dr. Apfel on account of his service as an Elite employee under the Apfel Agreement. As of March 31, 2009, there were no payments made to Dr. Apfel for consulting services rendered to Elite pursuant to the Apfel Consulting Agreement. No other compensation

was paid by Elite to Dr. Apfel during the fiscal year ended March 31, 2009.

For additional information regarding the Apfel Release, please see Elite's disclosures in its Current Reports on Form 8-K filed with the SEC on October 21, 2008, which such report is incorporated herein by reference.

#### Charan Behl

On February 9, 2007, Elite entered into an Amended and Restated Employment Agreement with Charan Behl (the "Behl Agreement"), providing for Dr. Behl's employment as Elite's Head of Technical Affairs, a position which required Dr. Behl to report to Elite's Executive Officer, Chief Scientific Officer and any additional executive officer designated by the Board. However, as a result of Elite's continuing efforts to reorganize its workforce and decrease its operating expenses, Elite requested that Dr. Charan Behl change the status of his relationship with Elite from employee to consultant. Dr. Behl agreed to such change in status and continues to provide his services as a consultant to Elite on an hourly basis, thereby reducing Elite's expenses as they relate to Mr. Behl.

Accordingly, on November 3, 2008, Elite and Dr. Behl entered into a Separation Agreement and General Release of Claims (the "Behl Release"), which terminated the Behl Agreement and Dr. Behl's status as an employee of Elite. Pursuant to the Behl Release, Dr. Behl waived his entitlement to certain notice and payment provisions upon termination of the Behl Agreement. Dr. Behl acknowledged that there were no payment amounts outstanding to him under the Behl Agreement. Dr. Behl acknowledged that his obligations under Sections 4 and 5: "Protection of Confidential Information and Trade Secrets; Non-Competition; No Solicitation" and "Continued Cooperation; Return of Documents and Property; Injunctive Relief; Non-Exclusivity and Survival" of the Behl Agreement survive termination and agreed that he would continue to be bound by and abide by such provisions. Additionally, Dr. Behl released Elite from any claims he has or may have against Elite.

In addition, Dr. Behl acknowledged that, of the options to purchase an aggregate of 750,000 shares of Common Stock previously granted to him under the Behl Agreement, evidenced by three Incentive Stock Option Letter Agreements, dated November 13, 2006, between Dr. Behl and Elite (the "Behl Option Agreements"), options to purchase 500,000 shares of Common Stock were unvested and terminated as of the date of termination of Dr. Behl's employment with Elite. Dr. Behl also acknowledged that he had 90 days following the date of his termination as an employee of Elite to exercise the remaining options to purchase up to 250,000 shares of Common Stock which had vested pursuant to the Behl Option Agreements (such vested options, the "Vested Behl Options"). Pursuant to the Behl Option Agreements, Dr. Behl had 90 days following the termination of the status of Dr. Behl as an employee of Elite pursuant to the Behl Release to exercise such Vested Behl Options. Dr. Behl did not exercise any Vested Apfel Options within such 90-day period and, therefore, such Vested Behl Options expired without exercise.

To set the terms of Dr. Behl's service as a consultant to Elite following termination of his employment relationship with Elite, Elite and Dr. Behl entered into a consulting agreement, dated as of November 3, 2008 (the "Behl Consulting Agreement"), pursuant to which Dr. Behl agreed to provide Elite consulting services for its opioid abuse-resistant product, sustained-release opioid product and other such products with which Elite may request assistance. Under the Behl Consulting Agreement, Elite has agreed to compensate Dr. Behl on an hourly basis for consulting services provided to Elite at the rate of \$200 per hour. In no event shall Dr. Behl be entitled to compensation of more than \$10,000.00 in any month without the prior written authorization of Elite. Dr. Behl is entitled to reimbursement of reasonable and necessary travel expenses incurred by Dr. Behl that have been approved in advance in writing by Elite.

Elite may terminate the Behl Consulting Agreement at any time upon written notice to Dr. Behl. Dr. Behl is subject to covenants not to disclose confidential information and assignment of intellectual property. In addition, during the term of the Behl Consulting Agreement and for a period of one year thereafter, Dr. Behl is subject to non-competition and non-solicitation covenants.

The Behl Consulting Agreement does not provide for any minimum amount of services to be performed pursuant thereto, and any services to be performed by Dr. Behl thereunder shall be solely in response to Elite's request for such services.

Under the Behl Agreement, prior to its termination on November 3, 2008 by the Behl Release, Dr. Behl was entitled to a 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 of the Behl Agreement and a \$700-per-month automobile allowance. The Behl Agreement also provided for payment of a discretionary bonus following the end of each fiscal year of up to 50% of Dr. Behl's then annual base salary. The amount, if any, of the discretionary bonus to Dr. Behl, pursuant the Behl Agreement, was to be determined by the Board or the Compensation Committee, and was to 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. Such discretionary bonus could be paid in cash or shares of 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.

During the fiscal year ended March 31, 2009, Elite paid Dr. Behl an aggregate of \$146,795 for his service to Elite in the capacity of Head of Technical Affairs, representing the annual salary payable to Dr. Behl under the Behl Agreement prorated for the period beginning April 1, 2008 and ending November 3, 2008, the date of termination of Dr. Behl's status as an employee of Elite. In addition, during such fiscal year, as consideration for Dr. Behl's entry into the Behl Release, Elite paid Dr. Behl \$20,548 less any payroll or withholding taxes and issued to Dr. Behl non-qualified stock options to purchase 50,000 shares of Common Stock, with a per share exercise price of \$0.10 (representing the closing price of the Common Stock on the American Stock Exchange on October 31, 2008), vested immediately upon issuance, subject to Elite's 2004 Stock Option Plan and the non-qualified stock option letter agreement between Elite and Dr. Behl, dated as of November 3, 2008. Further, pursuant to the Behl Release, Elite paid Dr. Behl (i) \$25,000 less any payroll or withholding taxes (representing the unpaid guaranteed bonus owed to Dr. Behl since March 2008 in accordance with the Behl Agreement), (ii) \$12,019 less any payroll or withholding taxes (representing 2.2 weeks of unpaid vacation for the 2008 fiscal year), and (iii) \$14,263 in expense reimbursements. As of March 31, 2009, there were no payments made to Dr. Behl for consulting services rendered to Elite pursuant to the Behl Consulting Agreement. No other compensation was paid to Mr. Behl by Elite during the fiscal year ended March 31, 2009.

For additional information regarding the Behl Release, please see Elite's disclosures in its Current Report on Form 8-K filed with the SEC on November 3, 2008, which such report is incorporated herein by reference.

Bernard Berk

On November 13, 2006, Elite entered into the Second Amended and Restated Employment Agreement with Mr. Berk, Elite's former President, Chief Executive Officer and Chairman of the Board (the "Berk Agreement"). On November 6, 2008 (the "Separation Date"), Elite and Mr. Berk entered into a Separation Agreement and General Release (the "Berk Release"), which provides for, among other things, the termination of the Berk Agreement. As of the Separation Date, Mr. Berk voluntarily resigned as Elite's President and Chief Executive Officer and also voluntarily resigned as the Chairman of the Board and as a Board member.

As consideration for a general release of Elite by Mr. Berk of all claims he asserted, or may assert in the future, against Elite in connection with his separation from Elite and in order to amicably resolve these matters without resorting to litigation in light of Elite's financial condition as of the Separation Date, Elite agreed to (i) pay Mr. Berk \$34,000 as severance less all applicable payroll or withholding taxes (the "Cash Severance Amount"), and (ii) charge to Mr. Berk, as additional income for taxation purposes, the aggregate amount of all reimbursed expenses paid to Mr. Berk which are determined by Elite's Audit Committee not to be in compliance with Elite's expense reimbursement policy.

The Berk Agreement provided for a base annual salary of \$330,140. During the fiscal year ended March 31, 2009, Elite paid Mr. Berk an aggregate of \$193,380 for his service to Elite, representing the base annual salary payable to Mr. Berk under the Berk Agreement for his employment as Elite's President, Chief Executive Officer and Chairman of the Board of Directors, prorated for the period beginning on April 1, 2008 and ending on the Separation Date.

Mr. Berk was entitled to an automobile allowance of \$800 per month. The Berk Agreement provided for payment of a discretionary bonus following the end of each fiscal year of up to 50% of Mr. Berk's then annual base salary. The amount, if any, of the discretionary bonus was to be determined by the Compensation Committee. Mr. Berk's discretionary bonus was to be based on any commercialization of products, merger or acquisition, business combination or collaborations, growth in revenues and earnings, additional financings or other strategic business transactions that inure to the benefit of Elite's stockholders. The discretionary bonus, if any, was to be paid in cash or shares of Common Stock, valued at the closing price of the Common Stock on the immediately preceding trading day. For the fiscal year ended March 31, 2008 Mr. Berk did not receive any discretionary bonus.

The Berk Agreement provided for the grant of options to purchase up to 300,000 additional shares of Common Stock (the "Opioid Product Options") at a \$3.00 exercise price per share, which were to 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 Elite's ownership rights in the United States (only once for each product) for Elite's first drug developed by Elite for which the FDA approval sought under a NDA (including a 505(b) (2) application) for oxycodone, hydrocodone, hydromorphone, oxymorphone, or morphine (each a "Non-Generic Opioid Product") as to the first tranche and as to Elite's second Non-Generic Opioid Product for the second tranche. None of the Opioid Options vested as of the Separation Date and, therefore, all such Opioid Product Options terminated as of such Separation Date.

The Berk Agreement provided for the amendment of the vesting of options as to 400,000 shares of Common Stock which had been granted on September 2, 2005 to Mr. Berk at an exercise price of \$2.69 per share (the "Berk Milestone Options") with the Berk 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 Elite; (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 Product for which options were granted above; (C) 10,000 shares upon the filing by Elite (in Elite's name) with the FDA of either an ANDA or a 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 Elite's 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 Elite (in Elite's name); and (F) 25,000 shares upon the granting by the U.S. Patent and Trademark Office (the "PTO") of a patent to Elite filed in Elite's name or an approval of an ANDA or NDA; provided, however the foregoing options were to terminate upon Mr. Berk'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. Berk's employment by Elite without cause and the approval was made within 540 days of the filing of the ANDA, NDA or patent application. None of the Berk Milestone Options vested as of the Separation Date and, therefore, all such Berk Milestone Options terminated as of such Separation Date.

Elite also agreed that in the event that, as to Mr. Berk, all of the options to purchase the full 400,000 Berk Milestone Options have fully vested during the initial term of the agreement, Elite agreed to grant under the Stock Option Plan to Mr. Berk 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 Berk Milestone Options”): (a) to the extent not previously vested with respect to his comparable Berk 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 Elite; and (ii) up to an additional 125,000 shares as to such trial relating to the second Non-Generic Opioid Product developed by Elite, (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 Elite (in Elite’s name) with the FDA of either an ANDA or NDA for a product not covered by a previous FDA application for each of Elite’s drug product, other than the Non-Generic Opioid Products for which any Opioid Option was granted under the Berk Agreement; (d) 40,000 shares upon the approval by the FDA of any ANDA, NDA or 505(b)(2) application filed in Elite’s 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 Elite (filed in Elite’s name); and (f) 25,000 shares in the event of the granting by the PTO of the foregoing additional patent applications to Elite (filed in Elite’s name). No Additional Berk Milestone Options were issued to Mr. Berk under the Berk Agreement.

The Berk Agreement acknowledges that Mr. Berk holds previously granted incentive stock options to purchase 725,000 shares (the “Vested Berk Options”), of which 300,000 of the Vested Berk Options were exercisable at \$2.01 per share, 225,000 of the Vested Berk Options were exercisable at \$2.15 per share and 200,000 Vested Berk Options were exercisable at \$2.69 per share. Mr. Berk had 90 days following the Separation Date to exercise the Vested Berk Options. The Vested Berk Options terminated without exercise at the expiration of such 90-day period.

The Berk Agreement allowed Elite, at its discretion, to grant to Mr. Berk additional options under the Stock Option Plan and provides Mr. Berk the right to register at Elite’s expense for reoffering shares issued upon exercise of the options under the Securities Act in certain registration statements filed by Elite with respect to offerings of securities by Elite. Elite did not grant Mr. Berk any additional options prior to the Separation Date.

The Berk Agreement provided that if Elite terminated his employment due to his permanent disability, without Cause (as defined in the Berk Agreement) or Mr. Berk terminated his employment for Good Reason (as defined in the Berk Agreement), Mr. Berk would have been entitled to the following severance: (i) any earned but unpaid base salary plus any unpaid reimbursable expenses as of the effective date of termination of his employment, (ii) the then-current base salary and reimbursement of the cost to replace the life and disability insurance coverages afforded to Mr. Berk under Elite’s benefit plans with substantially similar coverages, following the effective date of termination of his employment, for a period equal to the greater of (x) the remainder of the then-current term, or (y) two years following the effective date of termination and (iii) payment by Elite of premiums for health insurance for the period during which Mr. Berk would have been entitled to continued health insurance coverage as specified in the Comprehensive Omnibus Budget Reconciliation Act. In the event that Elite terminated Mr. Berk’s employment because of his permanent disability, Mr. Berk would have been entitled to the severance specified above, less any amounts actually received by him under any disability insurance coverage provided for and paid by Elite. In the event that Elite terminated Mr. Berk’s employment for Cause or Mr. Berk terminates his employment with Elite without Good Reason, Mr. Berk would have been entitled to any earned but unpaid base salary plus any unpaid reimbursable expenses as of the effective date of termination of his employment.



The Berk Agreement provided that in the event of a change of control in lieu of any severance that may otherwise be payable to Mr. Berk if he elected to terminate his employment for any reason within 90 days thereof, or Elite elected to terminate his employment within 180 days thereof, other than for Cause, Mr. Berk would have been entitled to the following: (i) any earned but unpaid base salary plus any unpaid reimbursable expenses as of the effective date of termination of his employment, (ii) \$1,000,000, (iii) the then-current base salary for a period of 12 months following the effective date of termination, (iv) reimbursement of the cost, for a period of 12 months following the effective date of termination, of replacing the life and disability insurance coverage afforded to Mr. Berk under Elite's benefit plans with substantially similar coverage and (v) payment by Elite of premiums for health insurance for the period during which Mr. Berk would have been entitled to continued health insurance coverage as specified in the Comprehensive Omnibus Budget Reconciliation Act.

Except for the Cash Severance Amount, Elite did not pay Mr. Berk any severance as a result of his separation from Elite.

The Berk Agreement contained his non-solicitation covenant for a period of one year from termination. Pursuant to the Berk Release, Mr. Berk also agreed to customary negative covenants regarding confidentiality, return of corporate property and non-disparagement. Elite agreed to customary negative covenants regarding confidentiality of information relating to Mr. Berk (other than as may be required to be disclosed by applicable law or at the request of the SEC) and non-disparagement.

Pursuant to the Berk Agreement, Mr. Berk was entitled reimbursed for expenses (including business, travel and entertainment) reasonably incurred in the performance of his duties. Mr. Berk was also entitled to participate in such employee benefit and welfare plans and programs which were offered to Elite's senior executives, including life insurance, health and accident insurance, medical plans and programs and profit sharing and retirement plans.

For additional information regarding Mr. Berk's separation from Elite and the Berk Release, please see Elite's disclosures in the Annual Report on Form 10-K/A for the fiscal year ended March 31, 2008, filed with the SEC on January 16, 2009, as well as Elite's Current Reports on Form 8-K, filed with the SEC on October 21, 2008 and November 6, 2008, which such reports are incorporated herein by reference.

#### Veerappan Subramanian

Dr. Subramanian entered into an Advisory Services Agreement with Elite on December 6, 2006, the terms of which are summarized below, in Item 13 of this Annual Report on Form 10-K, under the caption "Certain Related Person Transactions," which is incorporated herein by reference. On April 24, 2008, Dr. Subramanian resigned as Elite's acting Chief Scientific Officer upon the appointment of Stuart Apfel to the office of Chief Scientific Officer.

### 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, 2009.

### 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

Please see the discussion under “Compensation Discussion and Analysis – Agreements with Named Executive Officers” above under this Item 13.

## COMPENSATION OF EXECUTIVE OFFICERS AND KEY EMPLOYEES

## Summary Compensation Table

The table below summarizes the compensation information in respect of the Named Executive Officers for the fiscal years ended March 31, 2009, 2008 and 2007.

Name and Principal Position	Year (1)	Salary (\$)	Bonus (2) (\$)	Stock Option Awards		Non-Equity Incentive Compensation (\$)	Deferred Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation (\$)	Other Compensation (\$)	Total (\$)
				(3) (\$)	(4) (\$)					
<b>Mark. Gittelman</b>										
Chief Financial Officer, Secretary and Treasurer	2008-09		—	—	—	—	—	—	—	—
	2007-08		—	—	—	—	—	—	—	—
	2006-07		—	—	83,293	—	—	—	—	83,293
<b>Chris C. Dick(5)</b>										
Chief Operating Officer, President and Acting Chief Executive Officer	2008-09	218,750	25,000	—	—	—	—	8,400(7)	—	252,150
	2007-08	200,000	25,000	—	—	—	—	8,400(7)	—	233,400
	2006-07	168,750	25,000	—	482,037	—	—	3,150(7)	—	678,937
<b>Stuart Apfel(6)</b>										
Chief Medical Officer and Chief Scientific Officer	2008-09	128,333	—	—	—	—	—	—	—	128,333
	2007-08	55,000	—	—	354,760	—	—	1,260(7)	—	411,020
	2006-07	—	—	—	—	—	—	—	—	—
<b>Charan Behl(8)</b>										
Consultant; Former Head of Technical Affairs	2008-09	179,362	—	—	—	—	—	—	—	—
	2007-08	250,000	25,000	—	—	—	—	—	—	275,000
	2006-07	344,135	25,000	—	482,037	—	—	—	—	851,172
<b>Bernard J. Berk(9)</b>										
Former President and Chief Executive Officer	2008-09	227,380	—	—	—	—	—	21,260(11)	—	248,640
	2007-08	330,140	165,070	—	—	—	—	21,260(11)	—	516,470
	2006-07	330,140	63,063	—	574,422	—	—	21,260(11)	—	988,885
<b>Veerappan Subramanian (10)</b>										
Former Chief Scientific Officer	2008-09	—	—	—	—	—	—	—	—	—
	2007-08	—	—	—	—	—	—	—	—	—
	2006-07	—	—	—	1,114,445	—	—	—	—	1,114,445

- (1) The information is provided for each fiscal year which begins on April 1 and ends on March 31.
- (2) Bonuses paid to Mr. Dick represent guaranteed bonuses.
- (3) No stock awards were granted to the Named Executive Officers in the fiscal years ended March 31, 2009, 2008 or 2007.
- (4) The amounts reflect the compensation expense in accordance with FAS 123® of these option awards. The assumptions used to determine the fair value of the option awards for fiscal year ended March 31, 2008 are set forth as follows: the per share weighted average of the above mentioned stock options was 0.8869 using the Black-Scholes options pricing model with the following weighted average assumptions: no dividend yield; expected volatility of 33%; risk free interest rate of 4.00% and expected lives of ten (10) years. The assumptions used to determine the fair value of the option awards for fiscal year ended March 31, 2007 are set forth in Note 3 of our financial statements included in our Quarterly Report on Form 10-Q for the quarter ended December 31, 2006.
- (5) Effective November 10, 2008, Mr. Dick's base salary was raised from \$200,000 per year to \$250,000 per year, pursuant to an amendment to the employment agreement, dated as of November 13, 2006, between the Company and Mr. Dick, so as to be commensurate with his increased responsibilities as the acting Chief Operating Officer of the Company.
- (6) Dr. Apfel has been Chief Medical Officer since January 3, 2008 and Chief Scientific Officer since April 24, 2008. Although Mr. Apfel's status as an employee of the Company terminated on October 20, 2008, pursuant to the employment termination agreement, dated as of October 20, 2008, between Mr. Apfel and the Company, he has agreed to continue to serve as the Company's Chief Medical Officer and Chief Scientific Officer pursuant to the consulting agreement, dated as of October 20, 2008, between Paralex and the Company as described in greater detail in this Item 11, above, under the heading "Agreements with Named Executive Officers and Key Employees." The 400,000 stock options granted to Mr. Apfel during the fiscal year ended March 31, 2008 expired without exercise in January 2008.
- (7) Represents amounts paid for auto and parking allowance.
- (8) As described in detail in this Item 11, above, under the heading "Agreements with Named Executive Officers and Key Employees," Dr. Behl was employed by Elite as Head of Technical Affairs pursuant to the Behl Agreement until November 3, 2008, at which point Dr. Behl's employment with Elite was terminated pursuant to the Behl Release.

- (9) As described in detail in this Item 11, above, under the heading “Agreements with Named Executive Officers and Key Employees”, Mr. Berk was employed by Elite as President and Chief Executive Officer pursuant to the Berk Agreement until November 6, 2008, at which point Mr. Berk’s employment with Elite was terminated pursuant to the Berk Release.
- (10) As described in detail in this Item 11, above, under the heading “Agreements with Named Executive Officers and Key Employees,” Dr. Subramanian served as Elite’s Chief Scientific Officer until April 24, 2008.
- (11) Represents \$16,345 for auto and parking allowance and \$4,915 for life insurance premiums.

Grants of Plan-Based Awards

No plan based awards were made to the Named Executive Officers during the fiscal year ended March 31, 2009.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock options and stock awards held by the Named Executive Officers as of March 31, 2009.

Name	Option Awards				Stock 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 (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock Held That Have Not Vested (#)	Market Value of Shares or Units of Stock Held That Have Not Vested (\$)	Equity Incentive Awards: Number of Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Awards: Market or Unearned Payout Value of Shares, Units or Other Rights That Have Not Vested (\$)
Mark I. Gittelman Chief Financial Officer	10,000(1)	—	—	\$ 2.34	03/08/14	—	—	—	—
	6,666(2)	—	—	\$ 2.80	07/14/15	—	—	—	—
	6,667(2)	—	—	\$ 2.80	07/14/15	—	—	—	—
	6,667(2)	—	—	\$ 2.80	07/14/15	—	—	—	—
	23,333(3)	—	—	\$ 2,26	05/03/16	—	—	—	—
	23,333(3)	—	—	\$ 2.26	05/03/16	—	—	—	—
	—	23,334(3)	—	\$ 2.26	05/03/16	—	—	—	—

Name	Option Awards			Stock Awards					
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock Held That Have Not Vested (#)	Market Value of Shares or Units of Stock Held That Have Not Vested (\$)	Unearned Shares or Units of Stock Held That Have Not Vested (#)	Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Chris Dick Chief Operating Officer, President and Acting CEO	10,000(4)	—	—	\$ 2.34	10/31/12	—	—	—	—
	10,000(4)	—	—	\$ 2.34	10/31/12	—	—	—	—
	10,000(4)	—	—	\$ 2.34	10/31/12	—	—	—	—
	10,000(5)	—	—	\$ 2.21	06/13/13	—	—	—	—
	10,000(5)	—	—	\$ 2.21	06/13/13	—	—	—	—
	10,000(5)	—	—	\$ 2.21	06/13/13	—	—	—	—
	40,000(6)	—	—	\$ 2.80	07/14/15	—	—	—	—
	250,000(7)	—	—	\$ 2.25	11/13/16	—	—	—	—
	—	—	150,000(8)	\$ 2.25	11/13/16	—	—	—	—
	—	—	150,000(9)	\$ 2.25	11/13/16	—	—	—	—
—	—	200,000(10)	\$ 2.25	11/13/16	—	—	—	—	
Charan Behl* Consultant; Former Head of Technical Affairs	50,000(11)	—	—	\$ 0.10	11/3/18	—	—	—	—

Name	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock Held That Have Not Vested (#)	Market Value of Shares or Units of Stock Held That Have Not Vested (\$)	Equity Incentive Awards: Number of Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)
Bernard Berk*	300,000(12)	—	—	—\$ 2.01	06/03/13	—	—	—	—
Former President and Chief Executive Officer	30,000(13)	—	—	—\$ 2.34	06/22/14	—	—	—	—
	10,000(14)	—	—	—\$ 2.75	08/30/15	—	—	—	—
	10,000(14)	—	—	—\$ 2.75	08/30/15	—	—	—	—
	10,000(14)	—	—	—\$ 2.75	08/30/15	—	—	—	—
	—	—	150,000	\$ 3.00	11/13/16	—	—	—	—
	—	—	150,000	\$ 3.00	11/13/16	—	—	—	—

\*See Item 11, above, under the heading “Executive Compensation – Named Executive Officers and Key Employees” for more information regarding such former officer of the Company.



- (1) These options vested on June 22, 2004.
- (2) These options vest in annual increments over a three year period on July 14, 2006, July 14, 2007 and July 14, 2008, respectively.
- (3) These options vest in annual increments over a three year period on May 3, 2007, May 3, 2008 and May 3, 2009, respectively.
- (4) These options vested on November 1, 2003, 2004 and 2005, respectively.
- (5) These options vested on June 13, 2004, 2005 and 2006, respectively.
- (6) These options vested on July 14, 2005.
- (7) These options vested on November 3, 2006.
- (8) 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.
- (9) 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.
- (10) 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.
- (11) These options vested as of November 3, 2008.
- (12) These options vested as of June 3, 2003.
- (13) These options vested as of June 22, 2004.
- (14) These options vested in annual increments over a three year period on August 30, 2006, August 30, 2007 and August 30, 2008, respectively.

## DIRECTOR COMPENSATION

The following table sets forth director compensation for the year ended March 31, 2009:

Name	Fees Paid or Earned in Cash (\$)	Stock Awards (\$)	Option Awards (\$)	Non Equity Incentive Compensation (\$)	Change in Pension Value and Non-qualified Deferred Compensation (\$)	Other Compensation (\$)	Total (\$)
Jerry Treppel	8,750	—	180,000(1)	—	—	8,333	17,083
Barry Dash	33,000	—	—	—	—	—	33,000
Robert J. Levenson	37,000	—	—	—	—	—	37,000
Melvin Van Woert	35,750	—	—	—	—	—	32,000

(1) Represents 180,000 options of which 60,000 vest during the period commencing on December 1, 2008 and ending December 1, 2009; 60,000 vest during the period commencing on December 1, 2009 and ending on December 1, 2010 and 60,000 vest during the period commencing on December 1, 2010 and ending on December 1, 2011; provided, however, that the options shall fully vest upon the director's death, disability, retirement as a director or removal as a director without cause at the request of the Board of Directors.

## Fee Compensation

Prior to January 1, 2008, each Director received \$2,000 per meeting attended by such Director. As of January 1, 2008, the Company's policy regarding director fees has been revised 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 a compensation agreement, dated as of December 1, 2008, between Mr. Treppel and the Company.

## Equity Compensation

Members of the Board of Directors during the fiscal years ended March 31, 2008 and March 31, 2009 did not receive any options or equity compensation for serving as directors other than the grant of 90,000 options to each of the independent directors in January 2008 and the grant of 180,000 options to the Chairman of the Board in December 2008.

## 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.

## Compensation Committee Report

The Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis set forth above with management and, based on such review and discussion, has recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Barry Dash (Chairman of the Compensation Committee)  
Robert J. Levenson  
Melvin Van Woert

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 23, 2009 (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 23, 2009, we had 69,969,781 shares of Common Stock outstanding (exclusive of 100,000 treasury shares). The 1,000 shares of Series E Preferred Stock outstanding as of June 23, 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). The 895.5590 shares of Series B Preferred Stock, 5,418 shares of Series C Preferred Stock and 9,059.4410 shares of Series D Preferred Stock outstanding as of June 23, 2009 are nonvoting. As of June 23, 2009, 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) 1,000 shares of Series E Preferred Stock were beneficially owned by Messrs. Ashok G. Nigalaye, Jeenarine Narine and Ram Potti, (b) 3,986 shares of Series D Preferred Stock were beneficially owned by Midsummer Capital LLC and (c) 2,084.4410 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 23, 2009. 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, Chief Operating Officer and Acting Chief Executive Officer*	(1) 885,287	1.25
Robert J. Levenson, Director*	90,000(2)	*
Melvin Van Woert, Director*	120,000(3)	*
Barry Dash, Director*	163,761(4)	*
Jerry Treppel, Chairman of the Board and Director*	1,856,172(5)	2.60
Ashok G. Nigalaye*	60,000,000(6)	46.16
Jeenarine Narine*	60,000,000(6)	46.16
Ram Potti*	60,000,000(6)	46.16
Mark I. Gittelman, Chief Financial Officer*	76,666(7)	*
Stuart Apfel, Chief Scientific Officer and Chief Medical Officer*	0(8)	*
Epic Pharma, LLC 227-15 North Conduit Ave. Laurelton, NY 11413	60,000,000(6)	46.16
Trellus Management Company Adam Usdan 350 Madison Avenue, 9th Floor New York, New York 10017	28,672,715(9)	30.52
Davidson Kempner Partners 65 East 55th Street, 19th Floor New York, NY 10022	4,948,447(10)	6.61
Midsummer Capital LLC Scott D. Kaufman 295 Madison Ave., 38th Floor New York, NY 10017	24,687,310(11)	26.08
Bushido Capital Partners Ronald S. Dagar 145 E. 57th St., 11th Floor New York, NY 10022	14,328,847(12)	17.02

All Directors and Officers as a group***	63,191,886(13)	47.62
--	----------------	-------

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

\*\* Less than 1%

\*\*\* As of June 23, 2009

(1) Includes options to purchase 850,000 shares of Common Stock and warrants held by Mr. Dick and Hedy Rogers as joint tenants to purchase 10,479 shares of Common Stock.

(2) Represents options to purchase shares of Common Stock.

(3) Represents options to purchase shares of Common Stock.

(4) Based on information contained in the Form 4 filed with the SEC on January 28, 2008 and the Company's records as of June 23, 2009. Includes options to purchase 120,000 shares of Common Stock, warrants to purchase 15,009 shares of Common Stock, and 28,932 shares of Common Stock.

(5) Based on information contained in the Form 3 filed with the SEC on November 6, 2008 and the Company's records as of June 23, 2009. Includes an option to purchase up to 180,000 shares of Common Stock held by Mr. Treppel; also includes warrants to purchase up to 1,257,113 shares of Common Stock and 419,059 shares of Common Stock held by Wheaton HealthCare Partners, LP, of which Mr. Treppel is a general partner.

(6) 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 1,000 shares of Series E Preferred Stock convertible into 20,000,000 shares of Common Stock and a warrant to purchase 40,000,000 shares of Common Stock held by Epic Investments, LLC, a Delaware limited liability company. Messrs. Nigalaye, Narine and Potti are executive officers and equity owners of Epic Pharma, LLC, a Delaware limited liability company, and Epic Investments, LLC, a Delaware limited liability company. Epic Pharma, LLC is an equity owner of Epic Investments, LLC. Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti share voting and investment control over, and are indirect beneficial owners of, the shares. The interest of Epic Pharma LLC and Messrs. Nigalaye, Narine and Potti in the shares is limited, and each disclaims beneficial ownership of such shares except to the extent of its pecuniary interest in Epic Investments, LLC.

(7) Represents options to purchase shares of Common Stock.

(8) Mr. Apfel's options to purchase 400,000 shares of Common Stock expired on January 16, 2009.

(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"), Trellus Small Cap Opportunity Fund L.P. ("TSC"), Trellus Small Cap Offshore Opportunity Fund Ltd. ("TSCOOF") and Adam Usdan ("Usdan" and, together with TMC, TPLP, TPLP II, TOF, TSC and TSCOOF, the "Trellus Entities") in the Schedule 13D filed jointly by the Trellus Entities with the SEC on March 6, 2009, and on information provided to the Company in connection with the Company's Current Report on Form 8-K, dated March 23, 2009, and filed with the SEC on March 27, 2009. Includes an aggregate of 23,969,652 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" and, together with TPLP and TPLP II, 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, TOF, TSC, and TSCOOF. 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) Based on information provided to the Company as of June 26, 2009 and contained in the Schedule 13G/A filed with the SEC on February 17, 2009 jointly by Davidson Kempner Healthcare International Ltd. ("DKHI") and its affiliates, Davidson Kempner Partners ("DKP"), Davidson Kempner Institutional Partners, L.P. ("DKIP"), M.H. Davidson & Co. ("CO"), Davidson Kempner International, Ltd. ("DKIL"), Davidson Kempner Healthcare Fund LP ("DKHF" and, together with DKHI, DKP, DKIP, CO and DKIL, the "DK Entities"), MHD Management Co. ("MHD"), Davidson Kempner Advisors Inc. ("DKAI"), Davidson Kempner International Advisors, L.L.C. ("DKIA"), DK Group LLC ("DKG"), DK Management Partners LP ("DKMP"), DK Stillwater GP LLC ("DKS"), Thomas L. Kempner, Jr., Marvin H. Davidson, Stephen M. Dowicz, Scott E. Davidson, Michael J. Leffell, Timothy I. Levart, Robert J. Brivio, Jr., Eric P. Epstein, Anthony A. Yoseloff, Avram Z. Friedman and Conor Bastable. Includes warrants to purchase an aggregate of 4,948,447 shares of Common Stock held collectively by the DK Entities. Messrs. Thomas L. Kempner, Jr., Marvin H. Davidson, Stephen M. Dowicz, Scott E. Davidson, Michael J. Leffell, Timothy I. Levart, Robert J. Brivio, Jr., Eric P. Epstein, Anthony A. Yoseloff, Avram Z. Friedman and Conor Bastable (collectively, the "Principals," and together with the DK Entities, the "DK Reporting Persons"), are the general partners of CO and MHD, the sole managing members of DKIA and DKG and the sole stockholders of DKAI. Messrs. Thomas L. Kempner, Jr. and Timothy I. Levart are Executive Managing Member and Deputy Executive Managing Member, respectively, of DKS. Each of Messrs. Kempner and Levart, together with Messrs. Marvin H. Davidson, Stephen M. Dowicz, Scott E. Davidson, Michael J. Leffell, Robert J. Brivio, Jr., Anthony A. Yoseloff, Eric P. Epstein, Avram Z. Friedman and Conor Bastable are limited partners of DKMP. The partners, members or stockholders of each of the DK Reporting Persons, including the Principals, have the right to participate in the receipt of proceeds from the sale of the shares held for the account of such DK Reporting Person in accordance with their ownership interests in such DK Reporting Person. The DK Reporting Persons disclaim all beneficial ownership as affiliates of a registered investment adviser, and, in any case, disclaim beneficial ownership except as to the extent of their pecuniary interest in the shares. Each of the Reporting Persons certified in the aforesaid Schedule 13G/A that, to the best of its knowledge and belief, the securities referred to were not acquired and are not held for the purpose of or with the effect of changing or influencing the control of the Company and were not acquired and are not held in connection with or as a participant in any transaction having that purpose or effect. 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 DK 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 DK Entities to 9.99% upon at least 61 days' prior notice to the Company.



(11) Includes 3,986 shares of Series D Preferred Stock convertible into an aggregate of 19,930,000 shares of Common Stock and warrants to purchase up to 4,757,310 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.

(12) Includes 2,084.4410 shares of Series D Preferred Stock convertible into an aggregate of 10,422,205 shares of Common Stock and warrants to purchase up to 3,802,236 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.

(13) Includes options to purchase an aggregate of 1,399,999 shares of Common Stock, warrants to purchase an aggregate of 41,282,601 shares of Common Stock, 1,000 shares of Series E Preferred Stock convertible into 20,000,000 shares of Common Stock and 472,799 shares of Common Stock.

#### 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 23, 2009, Epic held 1,000 shares of Series E Preferred Stock convertible into 20,000,000 shares of Common Stock and a warrant to purchase up to 40,000,000 shares of Common Stock, representing its beneficial ownership of approximately 46% of the Company’s outstanding Common Stock as of such date (calculated in accordance with Rule 13d-3 of the Exchange Act). Further, the 1,000 shares of Series E Preferred Stock held by Epic as of June 23, 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 2,000 shares of Series E Preferred Stock and warrants to purchase up to 80,000,000 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 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 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, 2009, 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 Paralex Clinical Research

For a description of the consulting agreement between Elite and Paralex Clinical Research, please see Item 11 of this Annual Report on Form 10-K, under the heading “Compensation Discussion Analysis – Agreements with Named Executive Officers and Key Employees”, which is incorporated herein by reference. Stuart Apfel, our Chief Scientific Officer and Chief Medical Officer, is the founder and current president of Paralex.

##### Transactions with Mark Gittelman and Gittelman & Co. P.C.

For a description of the agreement between Elite and Gittelman & Co., P.C., please see Item 11, under the heading “Compensation Discussion Analysis – Agreements with Named Executive Officers and Key Employees”, which is incorporated herein by reference. Mark Gittelman, our Chief Financial Officer is the principal of Gittelman & Co., P.C.

##### Transactions with Dr. Subramanian and VGS Pharma LLC

Elite entered into a strategic alliance agreement, dated December 6, 2006 (the “VGS Alliance Agreement”), with Dr. Subramanian and VGS Pharma LLC (“VGS”), under which (i) Dr. Subramanian was appointed to Elite’s Board of Directors, (ii) VGS made a \$2,000,000 equity investment in Elite, (iii) Elite engaged Dr. Subramanian to serve as its strategic advisor on the research, development and commercialization of its existing pipeline and (iv) Elite, together with VGS formed Novel, as a separate specialty pharmaceutical company for the research, development, manufacturing, licensing and acquisition of specialty generic pharmaceuticals. VGS is wholly-owned subsidiary of Kali Capital, L.P., which is controlled by Kali Management, LLC (“Kali”), its general partner, and Kali is controlled by Anu Subramanian, its managing member and daughter of Dr. Subramanian.



The specialty pharmaceutical product initiative of the strategic alliance between Elite and Dr. Subramanian is to be conducted by Novel, of which Elite acquired 49% and VGS acquired 51% of its Class A Voting Common Stock for \$9,800 and \$10,200, respectively. Pursuant to the VGS Alliance Agreement, VGS acquired for \$2,000,000: (i) 957,396 shares of Common Stock at approximately \$2.089 per share and (ii) a five-year warrant to purchase 478,698 shares of Common Stock, for cash, at an exercise price of \$3.00 per share, subject to adjustment upon the occurrence of certain events.

Elite contributed \$5,000,000 to Novel. During the three months ended December 31, 2007, Elite elected not to fund its remaining contributions to Novel upon the terms set forth in the VGS Alliance Agreement because it had reached agreement with the FDA under an SPA on the Phase III clinical trial of ELI-216, Elite's abuse-deterrent oxycodone product and determined that its funds would be better used to support the clinical trials for ELI-216.

Elite and VGS negotiated alternative structures that would permit investments by Elite at valuations which differed from those set forth in the VGS Alliance Agreement, however Elite was unable to agree upon an alternative acceptable to both parties. Accordingly, upon Elite's determination not to fund its remaining contributions to Novel at the valuation set forth in the VGS Alliance Agreement, VGS exercised its rights under the Stockholders Agreement to purchase from Elite shares of Class A Voting Common Stock of Novel proportionate to the amount of remaining contributions which were not funded by Elite. As a result, Elite's remaining ownership interest in Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel.

Pursuant to an advisory agreement, effective as of December 6, 2006 (the "Subramanian Advisory Agreement"), between Elite and Dr. Subramanian, Dr. Subramanian had agreed to provide advisory services to Elite, including but not limited to, assisting in the implementation of current and new drug product development projects of Elite and assisting in the recruitment of additional R&D staff members. As an inducement to enter into the Subramanian Advisory Agreement, Elite granted Dr. Subramanian a non-qualified stock option to purchase up to 1,750,000 shares of Common Stock, at a price of \$2.13 per share, pursuant to a stock option agreement, dated as of December 6, 2006, between Elite and Dr. Subramanian. On April 24, 2008, upon Dr. Subramanian's resignation as the Chief Scientific Officer of Elite, 1,000,000 shares of Common Stock underlying Dr. Subramanian's option were vested, however, such options expired without exercise on August 24, 2008 in accordance with the terms of the stock option agreement.

#### 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 on Form 10-K under Item 7, 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.

## 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.

The following table presents fees, including reimbursements for expenses, for professional audit services rendered by 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, 2009 and March 31, 2008 and fees billed for other services rendered by Rosen Seymour and Miller Ellin during those periods.

	2009	2008
Audit Fees(1)	\$ 90,315	\$ 52,847
Audit-Related Fees	—	—
Tax Fees	—	—
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.
- 3.2 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 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 IntelliPharmaceuticals, Corp., incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K, dated June 21, 2005 and originally filed with the SEC on June 27, 2005, as amended on the Current Report on Form 8-K/A filed September 7, 2005, as further amended by the Current Report on Form 8-K/A filed December 7, 2005 (Confidential Treatment granted with respect to portions of the Agreement).
- 10.12 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 Wilstar Consultants, Inc., incorporated by reference as Exhibit 10.1 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.



- 10.40 Consulting Agreement, dated as of September 4, 2007, between the Registrant, Bridge Ventures, Inc. and Saggi Capital, Inc., incorporated by reference as Exhibit 10.2 to the Quarterly Report on Form 10-Q for the period ending September 30, 2007 and filed with the SEC on November 14, 2007.
- 10.41 Employment Agreement, dated as of January 3, 2008, by and between the Registrant and Dr. Stuart Apfel, incorporated by reference as Exhibit 10.1 to the Current Report on Form 8-K dated January 3, 2008 and filed with the SEC on January 9, 2008.
- 10.42 Form of Securities Purchase Agreement, between the Company and the signatories thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 10.43 Form of Placement Agent Agreement, between the Company, ROTH Capital Partners, LLC and Boenning & Scattergood, Inc., incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, dated September 15, 2008 and filed with the SEC on September 16, 2008.
- 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.
- 21 Subsidiaries of the Company.\*
- 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.\*

---

\* 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/ Chris Dick  
Chris Dick  
Chief Executive Officer

Dated: June 29, 2009

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/ Chris Dick Chris Dick	Acting Chief Executive Officer (Principal Executive Officer)	June 29, 2009
/s/ Mark Gittelman Mark I. Gittelman	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	June 29, 2009
/s/ Jerry Treppel Jerry Treppel	Director and Chairman of the Board	June 29, 2009
/s/ Barry Dash Barry Dash	Director	June 29, 2009
/s/ Melvin Van Woert Melvin Van Woert	Director	June 29, 2009
/s/ Robert J. Levenson Robert J. Levenson	Director	June 29, 2009

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED MARCH 31, 2009, 2008 AND 2007

CONTENTS

	PAGE
REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F - 1
CONSOLIDATED BALANCE SHEETS	F - 2
CONSOLIDATED STATEMENTS OF OPERATIONS	F - 4
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY	F - 5
CONSOLIDATED STATEMENTS OF CASH FLOWS	F - 8
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS	F - 9 to F - 29

---

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

---

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, 2008, and the related consolidated statements of operations, shareholders' equity and cash flows for the years ended March 31, 2008 and 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and subsidiaries as of March 31, 2008, and the consolidated results of their operations and their cash flows for the years ended March 31, 2008 and 2007 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/ MILLER, ELLIN & COMPANY LLP  
CERTIFIED PUBLIC ACCOUNTANTS

New York, New York  
June 27, 2008



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
MARCH 31, 2009 AND 2008

ASSETS

	2009	2008
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 282,578	\$ 3,702,615
Accounts receivable	1,177	148,484
Inventories	1,703,766	2,124,420
Prepaid expenses and other current assets	331,622	177,972
<b>Total current assets</b>	<b>2,319,143</b>	<b>6,153,491</b>
PROPERTY AND EQUIPMENT- net of accumulated depreciation and amortization	4,575,487	5,008,701
INTANGIBLE ASSETS - net of accumulated amortization	27,743	35,276
<b>OTHER ASSETS:</b>		
Accrued interest receivable	8,539	4,744
Deposit on equipment	14,073	14,073
Investment in Novel Laboratories Inc.	3,329,322	3,329,322
Security deposit	13,488	13,488
Restricted cash - debt service	327,435	432,079
EDA bond offering costs, net of accumulated amortization of \$49,534 and \$35,356, respectively	304,918	319,096
<b>Total other assets</b>	<b>3,997,775</b>	<b>4,112,802</b>
<b>TOTAL ASSETS</b>	<b>\$ 10,920,148</b>	<b>\$ 15,310,270</b>

The accompanying notes are an integral part of the Consolidated Financial Statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS  
MARCH 31, 2009 AND 2008  
(CONTINUED)

LIABILITIES AND STOCKHOLDERS' EQUITY

	2009	2008
<b>CURRENT LIABILITIES:</b>		
Current portion of EDA bonds	\$ 210,000	\$ 200,000
Current portion of long-term debt	10,788	9,864
Accounts payable and accrued expenses	981,058	850,442
Dividends payable	358,621	63,255
<b>Total current liabilities</b>	<b>1,560,467</b>	<b>1,123,561</b>
<b>LONG TERM DEBT:</b>		
EDA bonds - net of current portion	3,385,000	3,595,000
Long-term debt, less current portion	31,600	42,388
<b>Total long-term liabilities</b>	<b>3,416,600</b>	<b>3,637,388</b>
<b>Total liabilities</b>	<b>4,977,067</b>	<b>4,760,949</b>
<b>COMMITMENTS AND CONTINGENCIES:</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock - \$.01 par value;		
Authorized - 4,483,442 (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, 2009 and 2008, respectively	—	—
Authorized - 10,000 Convertible Series B Preferred Stock - issued and outstanding – 1,046 shares and 8,410 shares, respectively	11	84
Authorized 20,000 Series C Convertible Preferred Stock - issued and outstanding – 13,705 and 19,155 shares, respectively	137	192
Authorized 30,000 Series D Convertible Preferred Stock - issued and outstanding – 9,154 shares at March 31, 2009	91	—
Common Stock - \$.01 par value;		
Authorized – 210,000,000 as of March 31, 2009 and 150,000,000 shares at March 31, 2008 Issued and outstanding – 60,839,374 and 23,131,035 shares in 2009 and 2008, respectively	608,394	231,310
Additional paid-in capital	95,718,082	91,889,978
Accumulated deficit	(90,001,793)	(81,190,402)
<b>Treasury stock, at cost (100,000 shares)</b>	<b>6,324,922</b>	<b>10,931,162</b>
	<b>(306,841)</b>	<b>(306,841)</b>
	<b>6,018,081</b>	<b>10,624,321</b>

Subscription receivable	(75,000)	(75,000)
Total stockholders' equity	5,943,081	10,549,321
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 10,920,148</b>	<b>\$ 15,310,270</b>

The accompanying notes are an integral part of the Consolidated Financial Statements.

F-3

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

	YEARS ENDED		
	MARCH 31,		
	2009	2008	2007
<b>REVENUES:</b>			
Manufacturing fees	\$ 1,927,062	\$ 1,173,890	\$ 1,038,916
Royalties	347,763	239,229	104,925
<b>Total revenues</b>	<b>2,274,825</b>	<b>1,413,119</b>	<b>1,143,841</b>
Cost of Revenues	1,464,568	1,024,511	831,250
<b>Gross Profit</b>	<b>810,257</b>	<b>388,608</b>	<b>312,591</b>
<b>OPERATING EXPENSES:</b>			
Research and development	3,631,425	5,795,779	5,777,865
General and administrative	2,146,895	2,434,803	2,196,154
Non-cash compensation satisfied by issuance of stock options and warrants	921,442	2,607,470	3,479,070
Depreciation and amortization	500,817	524,893	408,814
	7,200,579	11,362,945	11,861,903
<b>LOSS FROM OPERATIONS</b>	<b>(6,390,322)</b>	<b>(10,974,337)</b>	<b>(11,549,312)</b>
<b>OTHER INCOME (EXPENSES):</b>			
Interest income	40,917	356,274	286,603
Sale of New Jersey tax losses	—	—	377,259
Interest expense	(252,183)	(292,277)	(275,030)
	(211,266)	63,997	388,832
<b>LOSS BEFORE PROVISION FOR INCOME TAXES</b>	<b>(6,601,588)</b>	<b>(10,910,340)</b>	<b>(11,160,480)</b>
Provision for Income Taxes	(3,120)	(3,120)	(1,000)
Loss from continuing operations	(6,604,708)	(10,913,460)	(11,161,480)
Loss from discontinued operations	—	(2,979,600)	(642,032)
<b>NET LOSS</b>	<b>(6,604,708)</b>	<b>(13,893,060)</b>	<b>(11,803,512)</b>
Preferred Stock Dividends	(2,206,683)	(2,104,797)	(791,181)
<b>NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS</b>	<b>\$ (8,811,391)</b>	<b>\$ (15,997,857)</b>	<b>\$ (12,594,693)</b>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<b>\$ (.27)</b>	<b>\$ (.73)</b>	<b>\$ (.64)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>	<b>32,047,421</b>	<b>21,801,042</b>	<b>19,815,780</b>

The accompanying notes are an integral part of the Consolidated Financial Statements.

F-4

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	PREFERRED		ADDITIONAL				TREASURY STOCK		ACCUMULATED		TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	COMMON SHARES	STOCK SUBSCRIPTION RECEIVABLE	PAID-IN CAPITAL	SHARES	AMOUNT	DEFICIT			
<b>BALANCES</b>											
<b>AT APRIL 1, 2006</b>	10,000	\$ 100	19,190,159	\$ 191,902	\$ —	60,105,107	(100,000)	\$ (306,841)	\$ (50,216,623)	\$	9,773,641
Investment in equity of subsidiary											
Investment in company	—	—	957,396	9,574	—	1,990,426	—	—	—	—	2,000,000
Conversion of preferred to common	(305)	(3)	135,555	1,356	—	(1,353)	—	—	—	—	
Conversion of warrants to common	—	—	84,430	844	—	(844)	—	—	—	—	
Exercise of Stock Options	—	—	59,000	590	—	87,910	—	—	—	—	88,500
Non-cash compensation through issuance of stock options and warrants	—	—	—	—	—	3,479,070	—	—	—	—	3,479,070
Amortization of costs associated with Raising Capital	—	—	—	—	—	(26,347)	—	—	—	—	(26,347)
Net loss	—	—	—	—	—	—	—	—	(11,803,512)	(11,803,512)	
Dividends	—	—	372,562	3,725	—	786,649	—	—	(791,182)	(80,000)	
<b>BALANCES</b>											
<b>AT MARCH 31, 2007</b>	9,695	\$ 97	20,799,102	\$ 207,991	\$ (75,000)	\$ 66,495,618	(100,000)	\$ (306,841)	\$ (62,811,317)	\$	(3,510,541)

The accompanying notes are an integral part of the Consolidated Financial Statements.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series B Preferred Stock		Series C Preferred Stock		Common Stock		Subscription Receivable	Additional Paid-In Capital	Treasury Stock		Accumulated Deficit	Stock
	Shares	Amount	Shares	Amount	Shares	Amount			Shares	Amount		
ELITE PHARMACEUTICALS, INC.	9,695	\$ 97	—	\$ —	20,799,102	\$ 207,991	\$ (75,000)	\$ 66,495,618	(100,000)	\$ (306,841)	\$ (62,811,317)	\$ 3,111,111
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	20,000	200	—	—	—	19,999,800	—	—	—	20,000
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	(1,285)	(13)	(845)	(8)	937,992	9,380	—	(9,359)	—	—	—	—
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	280,424	2,804	—	371,701	—	—	—	—
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	—	—	—	2,607,470	—	—	—	2,607,470
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	—	—	—	2,384,609	—	—	(2,384,609)	—
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	—	—	—	(1,576,055)	—	—	—	(1,576,055)
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	—	—	—	—	—	—	(13,893,060)	(13,893,060)
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	—	—	—	—	1,113,517	11,135	—	1,616,194	—	—	(2,101,416)	(2,101,416)
ELITE PHARMACEUTICALS, INC. SUBSIDIARIES	8,410	\$ 84	19,155	\$ 192	23,131,035	\$ 231,310	\$ (75,000)	\$ 91,889,978	(100,000)	\$ (306,841)	\$ (81,190,402)	\$ (10,000,000)

The accompanying notes are an integral part of the Consolidated Financial Statements.

F-6

---



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Series B Preferred Stock		Series C Preferred Stock		Series D Preferred Stock		Common Stock		Additional Subscription Paid in Receivable Capital		Treasury Stock	Accumulated Deficit	
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			Shares	Amount	
8,410	84	19,155	192			23,131,035	231,310	(75,000)	91,889,978	(100,000)	(306,841)	(81,190,402)
				1,777	18				1,776,982			
(7,139)	(71)	(4,898)	(49)	12,037	120							
(225)	(2)	(552)	(6)	(4,660)	(47)	23,682,161	236,822		(236,767)			
						125,000	1,250		100,000			
												(342,454)
									921,442			

(6,604,708)

13,901,178 139,012

1,608,901

(2,206,683)

1,046 11 13,705 137 9,154 91 60,839,374 608,394 (75,000) 95,718,082 (100,000) (306,841) (90,001,793)

The accompanying notes are an integral part of the Consolidated Financial Statements.

F-7

---

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

	YEARS ENDED MARCH 31,		
	2009	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Loss from Continuing Operations	\$ (6,604,708)	\$ (10,913,460)	\$ (11,161,480)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	500,817	413,701	408,814
Non-cash compensation satisfied by issuance of stock, options and warrants	921,442	2,607,470	3,479,070
Changes in assets and liabilities:			
Accounts receivable	147,307	67,353	(215,837)
Accrued interest receivable	(3,795)	(3,795)	(949)
Inventories	420,654	(1,311,451)	(485,964)
Prepaid expenses and other current assets	(52,400)	128,423	(162,767)
Security Deposit	—	(6,508)	—
Accounts payable, accrued expenses and other current liabilities	130,615	(867,016)	(22,805)
<b>NET CASH USED IN CONTINUING OPERATING ACTIVITIES</b>	<b>(4,540,068)</b>	<b>(9,885,283)</b>	<b>(8,161,918)</b>
<b>Discontinued Operations</b>			
Loss from Discontinued Operations	—	(2,979,600)	(642,032)
Equity in loss of discontinued operations	—	2,979,600	642,032
<b>NET CASH PROVIDED BY DISCONTINUED OPERATIONS</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,540,068)</b>	<b>(9,834,277)</b>	<b>(8,161,918)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Increase in intangible assets due to patent costs	—	—	(5,470)
Deposits to restricted cash	—	(17,080)	—
Release of restricted cash	104,644	—	1,174,397
Payment of deposit for manufacturing equipment	—	(14,703)	(32,880)
Purchases of property and equipment	(45,892)	(505,580)	(925,150)
Investment in Novel Laboratories, Inc.	—	(4,992,160)	(2,009,800)
<b>NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES</b>	<b>58,752</b>	<b>(5,529,523)</b>	<b>(1,798,903)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Repayments of bank loans	(9,864)	(5,752)	—
Dividends paid	(163,403)	(410,832)	(34,141)
Proceeds from issuance of Common Stock and warrants	—	—	2,000,000
Principal repayments of NJEDA bonds	(200,000)	(185,000)	(175,000)
Proceeds from issuance of Series C 8% Convertible Preferred Stock and Warrants	—	20,000,000	—
Costs associated with raising capital	(342,454)	(1,576,055)	(26,347)
Proceeds from bank loan	—	58,004	—
	1,777,000	—	—

## Proceeds from issuance of Series D 8% Convertible Preferred Stock and Warrants

Proceeds from exercise of stock options	—	61,500	88,500
Proceeds from exercise of stock warrants	—	313,005	—
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>1,061,279</b>	<b>18,254,870</b>	<b>1,853,012</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(3,420,037)</b>	<b>2,891,070</b>	<b>(8,107,809)</b>
<b>CASH AND CASH EQUIVALENTS - beginning of period</b>	<b>3,702,615</b>	<b>811,545</b>	<b>8,919,354</b>
<b>CASH AND CASH EQUIVALENTS - end of period</b>	<b>\$ 282,578</b>	<b>\$ 3,702,615</b>	<b>\$ 811,545</b>

## SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:

Cash paid for interest	\$ 253,402	\$ 293,404	\$ 275,554
Cash paid (received) for income taxes	3,120	3,120	(376,259)

## SCHEDULES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:

Preferred Stock dividends of \$2,106,535 , \$1,627,328, and \$791,182 paid by issuance of 13,901,178, 1,113,517 and 372,562 shares of Common Stock	\$	\$	—\$	—
Utilization of equipment deposit towards purchase of equipment			32,880	—
Dividends accrued on preferred stock			—	—
Beneficial Conversion Dividend			2,384,609	—
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, 2009, 2008 AND 2007

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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, 2009, 2008 and 2007 and its variable interest entity, Novel Laboratories, Inc. ("Novel"). During the quarter ended December 31, 2007, Novel ceased to be a variable interest entity of Elite. Accordingly, the information in this 10K has been prepared as if Elite divested of Novel as a wholly owned subsidiary on October 1, 2007 and the operations are being reflected as a discontinued operation. Our Company consolidates all entities that we control by ownership of a majority voting interest. As of March 31, 2009, 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.

F-9

---

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.

F-10

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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, 2009 are \$77,435. 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 collectability 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 generally accepted accounting principles 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 and stock-based awards.

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, 2007. Additionally, no adjustments related to uncertain tax positions were recognized during the year ended March 31, 2009.



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, 2009.

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 statues of limitation expire. As of March 31, 2009, a summary of the tax years that remain subject to examination in our major tax jurisdictions are: United States – Federal and State – 2004 and forward. The Company does not expect to have a material change to unrecognized tax positions within the next twelve months.

F-11

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 MARCH 31, 2009, 2008 AND 2007

## NOTE 3 – FAIR VALUE DISCLOSURES

On April 1, 2008, the Company adopted SFAS No. 157, which defines fair value, establishes a frame work for measuring fair value in accordance with GAAP and expands disclosures about fair value measurements. SFAS No. 157 defines fair value as the exchange price that would be received to sell an asset or paid to transfer a liability, based upon an exit price in an orderly transaction between market participants at the measurement date.

FAS No. 157 establishes a three-level valuation hierarchy of valuation techniques that is based on observable and unobservable inputs:

Level 1 – observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2 – quoted prices for similar instruments in active markets or inputs that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs based on the Company’s own assumptions.

In accordance with SFAS 157, the following table presents the Company’s valuation hierarchy for its financial asset in Novel Laboratories, Inc. measured at fair value on a recurring basis as of March 31, 2009:

“FAIR VALUE MEASUREMENT AT MARCH 31, 2009”

	Balance at March 31, 2009	Quoted Price in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Investment in Novel Laboratories, Inc.	\$ 3,329,322	\$ —	\$ —	3,329,322

Significant unobservable inputs have been based on projected discounted cash flows for 2009-2012 on sales of currently filed ANDA products and future filings with a 60% risk adjustment and using a 12.50% discount rate. Each product assumes a net income of \$75,000 per year.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment at March 31, 2009 and 2008 consists of the following:

	2009	2008
Laboratory manufacturing, and warehouse equipment	\$ 5,089,540	\$ 5,075,215
Office equipment	56,961	53,607
Furniture and fixtures	62,406	62,406
Transportation equipment	66,855	66,855
Land, building and improvements	2,492,152	2,463,939
Equipment under capital lease	168,179	168,179
	7,936,093	7,890,201
Less: Accumulated depreciation and amortization	(3,360,606)	(2,881,500)
	\$ 4,575,487	\$ 5,008,701

Depreciation and amortization expense amounted to \$479,106, \$413,701 and \$403,698 for the years ended March 31, 2009, 2008 and 2007, respectively.

## NOTE 5 - INTANGIBLE ASSETS

Intangible assets at March 31, 2009 and 2008, consist of the following:

	2009	2008
Patents	\$ 151,300	\$ 151,300
Trademarks	8,120	8,120
	159,420	159,420
Less: Accumulated amortization	(131,677)	(124,144)
	\$ 27,743	\$ 35,276

Amortization of intangible assets amounted to \$21,711, \$21,711 and \$22,118 for the years ended March 31, 2009, 2008 and 2007, respectively.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 6 - 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, 2009, 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 \$14,178, \$14,178 and \$14,178 for the years ended March 31, 2009, 2008 and 2007, respectively.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 MARCH 31, 2009, 2008 AND 2007

## NOTE 6 - LONG TERM DEBT (CONTINUED)

Bond financings consisted of the following at March 31:

	2009	2008
Refinanced NJEDA Bonds	\$ 3,595,000	\$ 3,795,000
	3,595,000	3,795,000
Current portion	(210,000)	(200,000)
Long term portion, net of current maturities	\$ 3,385,000	\$ 3,595,000

Maturities of Bonds for the next five years follow:

YEAR ENDING MARCH 31,	AMOUNT
2010	\$ 210,000
2011	225,000
2012	245,000
2013	260,000
2014	185,000
Thereafter	2,470,000
	\$ 3,595,000

F-15

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 6 - LONG TERM DEBT (CONTINUED)

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

	2009	2008
Note payable to First Niagara Bank in 60 monthly installments of \$1,180 including interest at 9.00%; final payment September, 2012; secured by vehicle purchased.	\$ 42,388	\$ 52,252
	42,388	52,252
Less Current Portion	(10,788)	(9,864)
Long-term debt, less current portion	\$ 31,600	\$ 42,388

Maturities of long-term debt in each of the next five years are as follows:

Year Ended March 31,	Amount
2010	\$ 10,788
2011	11,798
2012	12,904
2013	6,898
	\$ 42,388

## NOTE 7 - INCOME TAXES

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

	YEAR ENDED MARCH 31,		
	2009	2008	2007
Federal:			
Current	\$ —	\$ —	\$ —
Deferred	—	—	—
State:			
Current	3,120	3,120	1,770
Deferred	—	—	—
	3,120	3,120	1,770
	\$ 3,120	\$ 3,120	\$ 1,770

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 7 - INCOME TAXES (CONTINUED)

During the year ended March 31, 2007 the Company received approval for the sale of an additional \$4,818,122 of New Jersey net-operating losses under the Technology Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority (NJEDA). The total tax benefits received during the year ended March 31, 2007 was \$377,259 and is recorded as other income in the statement of operations.

The major components of deferred tax assets at March 31, 2009 and 2008 are as follows:

	2009	2008
Net operating loss carry forwards	\$ 17,048,800	\$ 15,128,722
Valuation allowance	(17,048,800)	(15,128,722)
	\$ —	\$ —

At March 31, 2009 and 2008, 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 2009, 2008 and 2007 by \$1,920,078, \$3,394,838 and \$948,084, respectively.

At March 31, 2009, for federal income tax purposes, the Company has unused net operating loss carryforwards of approximately \$50,143,530 expiring in fiscal years ending in 2010 through 2024. For state tax purposes, the Company has \$28,838,064 of unused net operating losses, which are net of the \$19,784,360 of the New Jersey net-operating losses sold, as discussed above.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 8 - COMMITMENTS AND CONTINGENCIES

EMPLOYMENT AGREEMENTS

As a result of the Company continuing efforts to reorganize its workforce and decrease its operating expenses the Company requested that Dr. Stuart Apfel, the Company Chief Scientific Officer and Chief Medical Officer, change the status of his relationship with the Company from employee to consultant. Dr. Apfel agreed to such change in status and will continue to provide his services as the Company Chief Scientific Officer and Chief Medical Officer on an hourly basis, thereby reducing the Company expenses as they relate to Dr. Apfel. In his continuing service as the Company Chief Scientific Officer and Chief Medical Officer, Dr. Apfel will be compensated pursuant to a consulting agreement, dated as of October 20, 2008, between the Company and Paralex Clinical Research ("Paralex"). Dr. Apfel is the founder and current president of Paralex. Pursuant to the consulting agreement, Paralex is to provide the Company consulting services for its opioid abuse-resistant product, controlled-release opioid product and other such products that the Company may request assistance with. Dr. Apfel will be the primary person providing such consulting services for which he will be paid on an hourly basis. The Company may terminate the consulting agreement at any time upon written notice to Paralex. Paralex and Dr. Apfel are subject to covenants not to disclose confidential information and assignment of intellectual property and a one year from termination non-competition covenant and non-solicitation covenant.

The Company also requested that Dr. Charan Behl, the Company Head of Technical Affairs, change the status of his relationship with the Company from employee to consultant. Dr. Behl agreed to such change in status and will continue to provide his services as a consultant to the Company on an hourly basis, thereby reducing the Company expenses as they relate to Dr. Behl. In his continuing service to the Company as a consultant, Dr. Behl will be compensated pursuant to a consulting agreement, dated as of November 3, 2008, between the Company and Dr. Behl. Pursuant to the consulting agreement, Dr. Behl is to provide the Company consulting services for its opioid abuse-resistant product, controlled-release opioid product and other such products that the Company may request assistance with. Dr. Behl will be paid for such consulting services on an hourly basis. The Company may terminate the consulting agreement at any time upon written notice to Dr. Behl. Dr. Behl is subject to covenants not to disclose confidential information and assignment of intellectual property and a one year from termination non-competition covenant and non-solicitation covenant.

CHIEF SCIENTIFIC OFFICER

On April 24, 2008, Dr. Subramanian resigned as the Acting Chief Scientific Officer of the Company and Dr. Apfel was appointed the Chief Scientific Officer of the Company. The appointment of Dr. Apfel did not modify his employment agreement in any way.



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 8 - COMMITMENTS AND CONTINGENCIES (CONTINUED)

CONSULTING AGREEMENTS

On April 14, 2008, the Company entered into a consulting agreement with New Castle Consulting, LLC ("New Castle") whereby New Castle was to provide consulting services to the Company for a six month term. Services included, but were not necessarily limited to analyzing, the Company's needs with respect to investor relations, consulting, assisting and advising the Company with respect to its needs for investor relations, oversee and facilitate investor relations, assist the Company in developing and implementing appropriate means for presenting the Company and its business plans, strategy and personnel to financial community and advising the Company with respect to its relations with brokers, dealers, analysts and other investment professionals. For its services New Castle received \$8,000 per month in addition to 125,000 shares of the Company's restricted Common Stock.

COLLABORATIVE 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.

F-19

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 9 - STOCKHOLDERS' EQUITY

During 2005, the Certificate of Incorporation was amended to increase the number of authorized shares of capital stock from 25,000,000 shares of Common Stock to 65,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, each with a par value of \$.01 per share.

On June 26, 2008, at the annual meeting of the stockholders of the Company, the stockholders approved (i) an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 65,000,000 shares to 150,000,000 shares and (ii) an amendment to the Company's Stock Option Plan to increase the number of shares of Common Stock reserved for issuance under the Stock Option Plan from 7,000,000 shares to 10,000,000 shares.

On December 19, 2008, at a special meeting of the stockholders of the Company, the stockholders approved an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 150,000,000 to 210,000,000 shares.

As of March 23, 2009, holders of a majority of, in number, of shares of the Company's outstanding Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock approved by written consent the creation and issuance of the Company's Series E Convertible Preferred Stock, par value \$0.01 per share, including the filing of the Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock with the Secretary of State of the State of Delaware, in connection with the transactions contemplated by the Epic Strategic Alliance Agreement.

## 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 three years ended March 31, the following potentially dilutive securities were not included in the computation of diluted loss per share:

	2009		2008		2007	
	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Stock options	2,554,900	\$ 1.87	5,543,300	\$ 2.16	6,622,500	2.28
Convertible						
Preferred Stock	54,971,921	\$ 0.43	11,994,243	\$ 2.25	4,308,885	\$ 2.25
Warrants	39,667,853	\$ 0.63	9,216,736	\$ 2.59	6,640,446	\$ 2.31
	97,194,674		26,754,279		17,571,831	

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 9 - STOCKHOLDERS' EQUITY (CONTINUED)

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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

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.

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 \$0.01 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.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

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.

COMMON STOCK TRANSACTIONS

The following grants were made under the Company's 2004 Stock Option Plan in the year ended March 31, 2009:

On December 1, 2008, the Company granted options to 3 employees to purchase an aggregate of 28,000 shares of common stock with an exercise price of \$.06 to vest over a period of three years from grant date.

On December 1, 2008, the Board granted 180,000 options to an independent board member, who serves as Chairman of the Board, under the Company's option plan. The options vest in equal thirds on December 1, 2009, 2010 and 2011, assuming the board member continues to serve on the Company's board. The options are exercisable at \$.06 per option and are subject to the Company's customary stock option agreements and the Company's Stock Option Plan.

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.

The following grants were made under the Company's 2004 Stock Option Plan in the year ended March 31, 2008:

On July 27, 2007, the Company entered into a consulting agreement with Willstar Consultants, Inc. ("Willstar") whereby Willstar is to provide advice pertaining to overall strategic planning, business opportunities, acquisition policy, investment and banking relationships and stockholders matters in consideration of the grant of options to purchase 90,000 shares of Common Stock, at a price of \$2.50 per share. One third of options vest on each of July 27, 2008, July 27, 2009 and July 27, 2010.

On January 24, 2008, the Company granted options to 29 employees to purchase an aggregate of 148,800 shares of Common Stock with an exercise price of \$1.08 to vest over a period of three years from grant date.

Additionally under an employment agreement dated January 3, 2008 with Dr. Stuart Apfel, the Company granted options to purchase 400,000 shares of Company Stock with an exercise price of \$1.75 per share. 120,000 options vested immediately and 280,000 will vest upon successful completion of Company sponsored Phase III clinical trials

of Company's developmental drug products and strategic events or milestones.

F-23

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

On January 24, 2008, the Board granted 90,000 options to each of its three non-executive independent Board members under the Company's option plan. The options vest in equal thirds on June 26, 2008, 2009 and 2010, assuming each Director continues to serve on the Company's Board; provided, however that, the options shall fully vest upon such Director's death, disability, retirement as a director on the Board or such Director's removal as a director, without cause, at the request of the Board. The options are exercisable at \$1.08 per option. The options are subject to the Company's customary stock option agreements and the Company's Stock Option Plan.

On March 7, 2008, the Company granted The Investor Relations Group, Inc. an option to purchase up to 75,000 shares of the Company's Common Stock at \$1.12 pursuant to Stipulation of Settlement dated March 7, 2008. The option vested immediately.

During the year ended March 31, 2008, there were cashless exercises of 100,633 warrants issued in our October, 2004 Private Placement, which resulted in the issuance of 36,174 shares of Common Stock.

During the year ended March 31, 2008, \$313,005 was received and 203,250 shares of Common Stock were issued upon the exercise of 203,250 Long-Term Warrants granted at an exercise price of \$1.54, as part of the Company's private placement in October, 2004.

During the year ended March 31, 2008, 1,285 shares of Series B 8% preferred Stock were converted into 571,112 shares of Common Stock.

Dividends accrued on Series B Stock through conversion date and March 31, 2008 were satisfied by the issuance of 1,631 and 454,923 shares of Common Stock, respectively.

On April 20, 2007 \$61,500 was received from the exercise of stock options previously granted to purchase 41,000 shares of Common Stock at \$1.50 per share. During the year ended March 31, 2008, 470,000 options expired and 1,552,000 were forfeited.



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

During the year ended March 31, 2008, 845 shares of Series C Preferred Stock were converted into 364,224 shares of Common Stock.

Dividends accrued on Series C Stock through conversion date and March 31, 2008 were satisfied by the issuance of 1,025 and 658,594 shares of Common Stock, respectively.

On July 12, 2006, the Company sold to Indigo Ventures, LLC ("Indigo") for \$150,000 a warrant to purchase up to 600,000 shares of Common Stock at \$3.00 per share pursuant to the Financial Advisory Agreement with Indigo (the "Advisory Agreement"), of which 100,000 shares of Common Stock have vested. The Advisory Agreement has been amended and the warrant reduced from 600,000 to 300,000 shares of common stock.

## 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 \$2.00 to \$3.74 per warrant. The warrants expire at various times through March 15, 2013.

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

	2009		2008		2007	
	Average Weighted Exercise Price		Average Weighted Exercise Price		Average Weighted Exercise Price	
Balance at beginning of year:	9,281,391	\$ 2.64	6,640,445	\$ 2.53	6,079,199	\$ 2.50
Warrants issued	—		150,000	3.00	778,698	3.00
Warrants issued pursuant to Placement Agent Agreements	355,400	0.25	258,620	3.00	—	
Warrants issued pursuant to Private Placement	17,770,000	0.25	2,586,209	3.00	—	
Exchange Warrants issued	12,261,062	(0.33)	—	—	—	
Warrants exercised, forfeited or expired	—		(353,883)	3.50	(217,452)	3.50
Ending balance	39,667,853	\$ 0.63	9,281,391	\$ 2.64	6,640,445	\$ 2.53

## CLASS B WARRANTS

The Company's Class B Warrants originally issued in a private placement in September 1998 expired on November 30, 2005, their amended expiration date.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

## NOTE 10 - STOCK OPTION PLANS

## STOCK-BASED COMPENSATION

During the years ended March 31, 2007, 2008 and 2009 the Company issued 3,779,500, 983,800 and 208,000, 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 except 750,000 issued for year ending March 31, 2007 which vested upon grant date, and 250,000 which vested in 6 months and 1,025,000 which vest based upon strategic events or accomplishments of certain milestones. For the year ending March 31, 2008, 195,000 options vested upon grant date and 280,000 vest based upon strategic events or accomplishments of certain milestones. The options expire between five and ten years from the date of grant. The Company has recorded compensation expense of \$3,479,070, \$2,607,470 and \$921,422 for the years ended March 31, 2007, 2008 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:

	2009		2008		2007	
	OPTIONS	AVERAGE WEIGHTED EXERCISE PRICE	OPTIONS	AVERAGE WEIGHTED EXERCISE PRICE	OPTIONS	AVERAGE WEIGHTED EXERCISE PRICE
Outstanding at beginning of year	5,543,300	\$ 2.16	6,622,500	2.28	2,971,250	\$ 2.36
Granted	258,000	.07	983,800	1.49	3,779,500	2.20
Exercised	—	—	(41,000)	1.50	(59,000)	1.50
Expired	(3,246,400)	(2.40)	(2,022,000)	(2.23)	(69,250)	2.31
Outstanding at end of year	2,554,900	\$ 1.87	5,543,300	2.16	6,622,500	\$ 2.28

The following table summarizes information about stock options outstanding at March 31, 2009:

RANGE OF EXERCISE PRICE	OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	WEIGHTED-AVERAGE EXERCISE PRICE	OPTIONS EXERCISABLE	WEIGHTED AVERAGE EXERCISABLE PRICE
\$ .01 – 1.00	258,000	9.75	\$ 0.06	—	—
1.01 - 2.00	402,900	8.50	1.29	195,000	1.51
2.01 - 3.00	1,894,000	6.50	2.33	2,858,928	2.24
\$ .01 - 3.00	2,554,900	6.82	\$ 2.16	3,053,928	\$ 2.19



ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 MARCH 31, 2009, 2008 AND 2007

## NOTE 10 - STOCK OPTION PLANS (CONTINUED)

## STOCK-BASED COMPENSATION (CONTINUED)

During the fiscal year ended March 31, 2009, options granted were of an insignificant value. The per share weighted-average fair value of each option granted during such fiscal year was \$0.0156 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 128%; risk-free interest rate of 3.00%; and expected life of 10 years. The per share weighted-average fair value of each option granted during fiscal years ended March 31, 2008 and March 31, 2007 ranged from \$.56 to \$1.20 during fiscal 2008 and \$1.36 to \$1.39 during fiscal 2007 on the date of grant using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 33.0% for fiscal 2008 and ranging from 46.12% to 57.95% for fiscal 2007; risk-free interest rates of 4.00% in 2008 and 5.00% in 2007. Expected lives range from 5 to 10 years.

There are 7,520,100 options available for future grant under our Stock Option Plan.

## NOTE 11 - MAJOR CUSTOMERS

For the years ended March 31, revenues from its major customers are as follows:

	2009	2008	2007
Customer A -	100%	100%	100%

## NOTE 12 - SUBSEQUENT EVENTS

## EPIC TRANSACTION DISCUSSION

On March 18, 2009, the Company entered into a Strategic Alliance Agreement (as amended on April 30, 2009 (the "First Amendment") and June 1, 2009 (the "Second Amendment), the "Epic Strategic Alliance Agreement") with Epic Pharma, LLC (the "Parent") and Epic Investments, LLC, a subsidiary controlled by the Parent (the "Purchaser", and collectively with the Parent, "Epic"), pursuant to which the Company commenced a strategic relationship with Epic, a pharmaceutical company that operates a business synergistic to that of the Company in the research and development, manufacturing, sales and marketing of oral immediate and controlled-release drug products.

Pursuant to the Epic Strategic Alliance Agreement, on June 3, 2009 (the "Initial Closing Date"), the Company and Epic conducted the initial closing (the "Initial Closing"), and Epic and its employees and consultants commenced use of a portion of the Company'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 (other than Facility-related expenses), for a period of at least three years (the "Initial Term"). In addition to the use of the Facility, Epic will use the Company'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.

At the Initial Closing, on June 3, 2009, the Company issued and sold to Epic, in a private placement, 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 20,000,000 shares of Common Stock, par value \$0.01 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 the Purchaser'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 the Company's dividend obligations on outstanding shares of its Series B Preferred Stock, Series C Preferred Stock, and/or

F-27

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 12 - SUBSEQUENT EVENTS (CONTINUED)

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 the Company to redeem all of such holder's shares of Series D Preferred Stock pursuant to the terms thereof. The Purchaser also acquired a warrant to purchase 40,000,000 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 the Purchaser'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. The Purchaser 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 the Company to the Purchaser at the Initial Closing, of which \$250,000 was received by the Company, 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 the Company by the Purchaser at the Initial Closing.

A Second Closing must occur within 180 days of the Initial Closing Date, upon which, Epic will pay to the Company a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, into 20,000,000 shares of Common Stock, and a warrant (the "Second Warrant") to purchase an additional 40,000,000 shares of Common Stock. The Second Warrant will be exercisable until the date that is the seventh anniversary of the Second Closing Date and will have a per share exercise price equal to \$0.0625, subject to adjustments for certain events.

On the first trading day following the first anniversary of the Initial Closing Date, the Company and Epic will conduct a third closing (the "Third Closing"), 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. The Third Closing must occur within thirty days following the first anniversary of the Initial Closing Date. At the Third Closing, Epic will pay to the Company a sum of \$1,000,000 in exchange for an additional 1,000 shares of Series E Preferred Stock, which such shares of Series E Preferred Stock will be convertible, at the Conversion Price, subject to adjustment, 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 will be exercisable until the date that is the seventh anniversary of the Third Closing Date and will have a per share exercise price equal to \$0.0625, subject to adjustments for certain events.

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 the Company 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.

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 the Company 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 the Company 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.

The Company 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 the Company 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 a Identified Controlled Release Products (as defined in the Epic Strategic Alliance Assignment) and/or Additional Controlled Release Products (as defined in the Epic Strategic Alliance Assignment), 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 the Company will issue and deliver to Epic 7,000,000 shares of Common Stock following the receipt by the Company from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified Controlled Release Products and/or Additional Controlled Release Products, up to a maximum of an aggregate of 28,000,000 shares of Common Stock (such shares, the "CR Related Shares").

F-28

---

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2009, 2008 AND 2007

NOTE 12 - SUBSEQUENT EVENTS (CONTINUED)

The Company 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 the Company 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 a Identified Immediate Release Products (as defined in the Epic Strategic Alliance Assignment) and/or Additional Identified Immediate Release Products (as defined in the Epic Strategic Alliance Assignment), 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 Controlled Release Related Warrants, the "Milestone Warrants"), and (ii) the Company will issue and deliver to Epic 3,000,000 shares of Common Stock following the receipt by the Company from Epic of each written notice of Epic's receipt from the FDA of approval for such Identified Immediate Release Products and/or Additional Identified Immediate Release Products, up to a maximum of an aggregate of 12,000,000 shares of Common Stock. The Milestone Warrants may only be exercised by payment of the applicable cash exercise price.

COMMON STOCK TRANSATIONS

During the first quarter of the fiscal year ending March 31, 2010, 150 shares of Series B Preferred Stock were converted into 96,154 shares of Common Stock. In connection with such conversion, the Registrant issued 22,857 shares of Common Stock in satisfaction of dividend obligations on such shares of Series B Preferred Stock accrued through the date of conversion

During the first quarter of the fiscal year ending March 31, 2010, 8,287 shares of Series C Preferred Stock were converted into 5,147,206 shares of Common Stock. In connection with such conversion, the Registrant issued 131,281 shares of Common Stock in satisfaction of dividend obligations on such shares of Series C Preferred Stock accrued through the date of conversion.

During the first quarter of the fiscal year ending March 31, 2010, 95 shares of Series D Preferred Stock were converted into 475,000 shares of Common Stock. In connection with such conversion, the Registrant issued 15,835 shares of Common Stock in satisfaction of dividend obligations on such shares of Series D Preferred Stock accrued through the date of conversion.

On June 3, 2009, upon the consummation of the initial closing of the Epic Strategic Alliance Agreement, the Company issued warrants to certain investors, pursuant to individual conversion agreements between the Company and each such investor, to purchase an aggregate of 6,518,360 shares of Common Stock, at an exercise price per share of \$0.25, in consideration of such investors' conversion of the shares of the Company's preferred stock held by the respective investors in accordance with the terms of the Epic Strategic Alliance Agreement.