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

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

(MARK ONE)

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

FOR THE FISCAL YEAR ENDED – March 31, 2010

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 001-15697

ELITE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

165 Ludlow Avenue, Northvale, New Jersey 07647
(Address of principal executive offices)

(201) 750-2646
(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Exchange on Which Registered
None	

Securities Registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act	Yes ¨	No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act	Yes ¨	No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrant was required to file such reports) and (2) has been subject to such filing requirements for at least the past 90 days.	Yes x	No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). The registrant is not yet subject to this requirement.	Yes ¨	No x

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

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

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

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

State the aggregate market value of the voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (for purposes of determining this amount, only directors, executive officers and, based on Schedule 13(d) filings as of September 30, 2009, 10% or greater stockholders, and their respective affiliates, have been deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes).

Title of Class	Aggregate Market Value	As of Close of Business on
Common Stock - $0.001 par value	$4,651,271	September 30, 2009

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated herein contain "forward-looking statements". Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Many of these risks and uncertainties are discussed in this report, particularly in the sections titled "Business", "Risk Factors" and "Management's Discussion and Analysis of Financial Conditions and Results of Operations". When used in this Annual Report, statements that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "plan", "intend", "may," "will," "expect," "believe", "could," "an "estimate," or "continue" or similar expressions or other variations or comparable terminology are intended to identify such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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

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PART I

ITEM 1. BUSINESS.

General

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

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

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

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

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

Business Overview and Strategy

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products, using proprietary technology. Our strategy includes improving off-patent drug products for life cycle management and developing generic versions of controlled-release drug products with high barriers to entry. Our technology is applicable to develop delayed-, sustained- or targeted-release pellets, capsules, tablets, granules and powders.

We have two products, Lodrane 24® and Lodrane 24D®, currently being sold commercially. We also have an approved generic methadone product developed with our partner, The PharmaNetwork. Elite is preparing for a commercial launch of this product. We are currently negotiating a sales and distribution agreement for this product. A sales and distribution agreement is a prerequisite for the launch of this product. Elite also purchased an approved generic to Dilaudid® (a product owned and sold by Purdue Pharma). The transfer of the process from the previous ANDA holder, Mikah Pharma, to our manufacturing facilities is currently in progress. The Company also has a pipeline of additional generic drug candidates under active development and the Company is developing ELI-216, an abuse resistant oxycodone product, and ELI-154, a once-a-day oxycodone product. Elite's facility in Northvale, New Jersey (the "Facility") operates under Good Manufacturing Practice ("GMP") and is a United States Drug Enforcement Agency ("DEA") registered facility for research, development and manufacturing.

Strategy

Elite is focusing its efforts on the following areas: (i) development of Elite's pain management products, (ii) manufacturing of Lodrane 24® and Lodrane 24D® products; (iii) set up and launch of the methadone generic and hydromorphone generic products; (iv) the development of the other products in our pipeline including the eight products pursuant to the Epic Strategic Alliance Agreement; (v) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of our formulations, and (vi) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

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

FDA Approval for generic Methadone tablets

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

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

Elite Purchased A Generic Hydromorphone HCl Product

On May 18, 2010, Elite executed an asset purchase agreement with Mikah Pharma LLC. Under that agreement we completed the acquisition from Mikah of an Abbreviated New Drug Application (Hydromorphone Hydrochloride Tablets USP, 8 mg) for aggregate consideration of $225,000, comprised of an initial payment of $150,000, which was made on May 18, 2010. A second payment of $75,000 is due to be paid to Mikah on June 15, 2010. The Company may, at its election, make this payment in cash or by issuing to Mikah 937,500 shares of the Company's common stock. Elite is transferring the process to the Facility in Northvale, NJ where it intends to manufacture the product. Elite will engage a third party to distribute and sell the product.

A current report on form 8-K was filed on May 24, 2010 in relation to this announcement, such filing being incorporated herein by this reference.

Research and Development

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

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

Commercial Products

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

Lodrane 24®, was first commercially offered in November 2004 and Lodrane 24D® was first commercially offered in December 2006. Elite's revenues for manufacturing these products and a royalty on sales for the years ended March 31, 2010 and 2009 aggregated $3,339,870 and, $2,274,825, respectively.

Approved Products

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

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

Products Under Development

ELI-154 and ELI-216

For ELI-154, Elite has developed a once-daily oxycodone formulation using its proprietary technology. An investigational new drug application, or IND, has been filed and Elite has completed two pharmacokinetic studies in healthy subjects that compared blood levels of oxycodone from dosing ELI-154 and the twice-a-day product that is on the market currently, OxyContin® marketed in the U.S. by Purdue Pharma LP. These studies confirmed that ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hour period and equivalent blood levels to the twice-a-day product at the end of 24 hours. Elite has successfully manufactured multiple batches on commercial scale equipment and we have discussions ongoing in Europe for this product. We are looking for a partner who can complete the clinical studies required for Europe and who can sell and distribute the product in key European territories. .

ELI-216 utilizes our patent-pending abuse-deterrent technology that is based on a pharmacological approach. ELI-216 is a combination of a narcotic agonist, oxycodone hydrochloride, in a sustained-release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, naltrexone hydrochloride, formulated to deter abuse of the drug. Both of these compounds, oxycodone hydrochloride and naltrexone hydrochloride, have been on the market for a number of years and sold separately in various dose strengths. Elite has filed an IND for the product and has tested the product in a series of pharmacokinetic studies. In single-dose studies for ELI-216, it was demonstrated

that no quantifiable blood levels of naltrexone hydrochloride were released at a limit of quantification ("LOQ") of 7.5 pg/ml. As described below, when crushed, naltrexone hydrochloride was released at levels that would be expected to eliminate the euphoria from the crushed oxycodone hydrochloride. This data is consistent with the premise of Elite's abuse resistant technology, or ART, that essentially no naltrexone is released and absorbed when administered as intended. Products utilizing the pharmacological approach to deter abuse such as Suboxone®, a product marketed in the United States by Reckitt Benckiser Pharmaceuticals, Inc., and Embeda®, a product marketed in the United States by King Pharmaceuticals, have been approved by the FDA and are being marketed in the United States.

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

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

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has currently chosen to develop these products itself but expects to license these products at a later date to a third party who could provide funding for the remaining clinical studies, including a Phase III study, and who could provide sales and distribution for the product. The drug delivery technology underlying ELI-154 was originally developed under a joint venture with Elan which terminated in 2002.

According to the Elan Termination Agreement, Elite acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture, including ELI-154. Upon licensing or commercialization of ELI-154, Elite will pay a royalty to Elan pursuant to the Termination Agreement. If Elite were to sell the product itself, Elite will pay a 1% royalty to Elan based on the product's net sales, and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite's net revenues from this product. (Elite's net product revenues would include license fees, royalties, manufacturing profits and milestones) Elite is allowed to recoup all development costs including research, process development, analytical development, clinical development and regulatory costs before payment of any royalties to Elan.

Epic Strategic Alliance Agreement

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

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

For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures under "Epic Strategic Alliance Agreement" in Item 7 of Part II of this Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which are incorporated herein by reference.

Novel Labs Investment

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

Patents

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

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

We have pending applications for four additional U.S. patents. The pending patent applications relate to two different controlled-release pharmaceutical products on which we are working. Three of these patents are for an opioid agonist and antagonist product that we are developing to be used with oxycodone and other opioids to minimize the abuse potential for the opioids. Another U.S. patent is for formulation of oral sustained-release opioids intended to improve the delivery of the opioids. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted. We have also filed corresponding foreign applications for key patents.

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

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

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

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

there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology.

Trademarks

We currently plan to license our products to marketing partners and not to sell under our own brand name and so we do not currently intend to register any trademarks related to our products.

Government Regulation and Approval

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

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

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

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

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

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

consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further delays may be encountered before the products become commercially available.

ANDAs

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

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

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

Controlled Substances

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

GMP

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

Compliance with Environmental Laws

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices

of corporations as to which we are the legal successor or in possession. We do not expect that compliance with such environmental laws will have a material effect on our capital expenditures, earnings or competitive position in the foreseeable future. There can be no assurance, however, that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on our capital expenditures, earnings or competitive position.

Competition

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

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

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

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

Sources and Availability of Raw Materials; Manufacturing

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

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

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

Please see the Risk Factor entitled “Even after regulatory approval, we will be subject to ongoing significant regulatory obligations and oversight” at Item 1A.

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

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

Dependence on One or a Few Major Customers

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have an agreement with ECR which sells and distributes two products that we manufacture: Lodrane 24® and Lodrane 24D®. We receive revenues to manufacture these products and also receive royalties based on in-market sales of the products. These are our only products that are being sold commercially now and are the primary source of our revenue currently.

Employees

As of June 15, 2010, we had 16 employees. Full-time employees are engaged in operations, administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

ITEM 1A. RISK FACTORS.

In addition to the other information contained in this report, the following risk factors should be considered carefully in evaluating an investment in us and in analyzing our forward-looking statements.

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RISKS RELATED TO OUR BUSINESS

We have a relatively limited operating history, which makes it difficult to evaluate our future prospects.

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and our presence in the generic pharmaceutical market. As a result, our potential for future profitability must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

- develop new products;
- obtain regulatory approval of our products;
- manage our growth, control expenditures and align costs with revenues;
- attract, retain and motivate qualified personnel; and
- respond to competitive developments.

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products.

We have not been profitable and expect future losses.

To date, we have not been profitable and we may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. For the past two years, we incurred net losses of $8,056,874 and $6,604,708, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

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

On June 21, 2010, we had cash reserves of approximately $400,000 which permits us to continue at our anticipated level of operations, including, but not limited to, the continued development of our pipeline products, through July 2011. The completion of all transactions contemplated by the Epic Strategic Alliance Agreement, including the consummation of the third closing thereof, will provide additional funds to permit us to continue development of our product pipeline for more than 2 years. Beyond 2 years, we are anticipating that, with growth of Lodrane; the launch of the ANDA for the methadone product that was approved last year with our co-development partner, The PharmaNetwork; and the launch of the generic hydromorphone product that we purchased, Elite could be profitable. In addition, the commercialization of the Epic products developed under the Epic Strategic Alliance Agreement will add a new revenue source for Elite. However, there can be no assurances as to the success of the development of such Epic products or the commercialization of such Epic products.

Despite the successful completion of the initial and second closings of the Epic Strategic Alliance Agreement, there can be no assurances that we will be able to consummate the third and quarterly payment closings pursuant to the terms and conditions of the Epic Strategic Alliance Agreement. If such transactions are consummated, we will receive additional cash proceeds of $1.6875 million. Even if we were able to successfully complete the third and quarterly payment closings of the Epic Strategic Alliance Agreement, we still may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain such additional capital on favorable terms, if at all. For additional information regarding the Epic Strategic Alliance Agreement, please see our disclosures

under “Epic Strategic Alliance Agreement” in Item 7 of Part II of this Annual Report on Form 10-K, and in our Current Reports on Form 8-K, filed with the SEC on March 23, 2009, May 6, 2009 and June 5, 2009, which are incorporated herein by reference.

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

We continue to require additional financing to ensure that we will be able to meet our expenditures to develop and commercialize our products. As of June 21, 2010 we had cash and cash equivalents of approximately $400,000. We believe that our existing cash and cash equivalents plus revenues from sale of our Lodrane 24® and Lodrane 24D® products will be sufficient to fund our anticipated operating expenses and capital requirements through July 2011. We will require additional funding in order to continue to operate thereafter. If the third and quarterly payment closings of the transactions contemplated by the Epic Strategic Alliance Agreement are not closed on a timely basis, or if another financing or strategic alternative providing sufficient resources to allow us to continue operations is not consummated upon exhaustion of our current capital, we will be required to cease operations and liquidate our assets. No assurance can be given that we will be able to consummate the third and quarterly payment closings under the Epic Strategic Alliance Agreement on a timely basis, or consummate such other financing or strategic alternative in the time necessary to avoid the cessation of our operations and liquidation of our assets. Moreover, even if we consummate the third and quarterly payment closings under the Epic Strategic Alliance Agreement, or such other financing or strategic alternative, we may be required to seek additional capital in the future and there can be no assurances that we will be able to obtain additional capital on favorable terms, if at all.

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

As a result of our determination not to fund our remaining contributions to Novel at the valuation set forth in the Novel Alliance Agreement and the resulting purchase from us of a portion of our shares of Class A Voting Common Stock of Novel by VGS Pharma, LLC, our remaining ownership interest in equity of Novel was reduced to approximately 10% of the outstanding shares of Novel. Novel may seek to raise additional operating capital in the future and may do so by the issuance of equity. If Novel issues additional equity, our future equity interest in Novel will decrease and we will be entitled to a decreased portion of any dividends or other distributions which Novel may issue in the future. Novel also has a company sponsored stock option plan and any equity issued from this stock plan will also reduce Elite's equity interest in Novel.

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

ELI-154 and ELI-216 are pre-Phase III and two of our generic products are still at an early stage of development. Other than Lodrane 24® and Lodrane 24D®, which are commercial drug products, and a generic drug product for which an ANDA was approved in 2009 and a generic drug product which Elite purchased in 2010, we will need to perform additional development work for the additional product candidates in our pipeline before we can seek the regulatory approvals necessary to begin commercial sales.

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

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

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

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

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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.

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

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

- collaborations and licensing arrangements may be terminated, in which case we will experience increased operating expenses and capital requirements if we elect to pursue further development of the related product candidate;
- collaborators and licensees may delay clinical trials and prolong clinical development, under-fund a clinical trial program, stop a clinical trial or abandon a product candidate;
- expected revenue might not be generated because milestones may not be achieved and product candidates may not be developed;
- collaborators and licensees could independently develop, or develop with third parties, products that could compete with our future products;
- the terms of our contracts with current or future collaborators and licensees may not be favorable to us in the future;
- a collaborator or licensee with marketing and distribution rights to one or more of our products may not commit enough resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of a product;
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration;
- one or more third-party developers could obtain approval for a similar product prior to the collaborator or licensee resulting in unforeseen price competition in connection with the development product; and
- Epic may decide that the further or continuing development of one or more of the eight designated drug products being developed by Epic at our facility is no longer commercially feasible, delaying a potential source of revenue to us pursuant to the Epic Strategic Alliance Agreement. In addition, there can be no assurance that any drug product designated by the parties as a replacement would be as strong a candidate for commercial viability as the drug product that it replaced.

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

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

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

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

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

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

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

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

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

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

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, the pharmaceutical industry is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on

this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

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

- obtaining new patents on drugs whose original patent protection is about to expire;
- filing patent applications that are more complex and costly to challenge;
- filing suits for patent infringement that automatically delay approval from the FDA;
- filing citizens' petitions with the FDA contesting approval of the generic versions of products due to alleged health and safety issues;
- developing controlled-release or other "next-generation" products, which often reduce demand for the generic version of the existing product for which we may be seeking approval;
- changing product claims and product labeling;
- developing and marketing as over-the-counter products those branded products which are about to face generic competition; and
- making arrangements with managed care companies and insurers to reduce the economic incentives to purchase generic pharmaceuticals.

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

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

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

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

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

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

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

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

- greater possibility for disruption due to transportation or communication problems;

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

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

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

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

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

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

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

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

The design, development and manufacture of our products involve an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could

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

RISKS RELATED TO OUR COMMON STOCK

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

Sales of substantial amounts of our shares in the public market could harm the market price of our Common Stock, even if our business is doing well. A significant number of shares of our Common Stock are eligible for sale in the public market under Rule 144, promulgated under the Securities Act of 1933, as amended (the "Securities Act"), subject in some cases to volume and other limitations. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

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

The market price for the publicly traded stock of pharmaceutical companies is generally characterized by high volatility. There has been significant volatility in the market prices for our Common Stock. For the twelve months ended March 31, 2010, the closing sale price on the OTC Bulletin Board ("OTC-BB") of our Common Stock fluctuated from a high of $0.20 per share to a low of $0.06 per share. The price per share of our Common Stock may not exceed or even remain at current levels in the future. The market price of our Common Stock may be affected by a number of factors, including:

- Results of our clinical trials;
- Approval or disapproval of our ANDAs or NDAs;
- Announcements of innovations, new products or new patents by us or by our competitors;
- Governmental regulation;
- Patent or proprietary rights developments;
- Proxy contests or litigation;
- News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- Economic and market conditions, generally and related to the pharmaceutical industry;
- Healthcare legislation;
- Changes in third-party reimbursement policies for drugs;
- Fluctuations in our operating results;
- Commercial success of the eight drug products of Epic identified under the Epic Strategic Alliance Agreement; and
- Our ability to consummate the third closing of the transactions contemplated by the Epic Strategic Alliance Agreement

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

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

other securities.

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

The Over-the-Counter Bulletin Board (the "OTCBB") is a regulated quotation service that displays real-time quotes, last sale prices and volume limitations in over-the-counter securities. Because trades and quotations on the OTCBB involve a manual process, the market information for such securities cannot be guaranteed. In addition, quote information, or even firm quotes, may not be available. The manual execution process may delay order processing and intervening price fluctuations may result in the failure of a limit order to execute or the execution of a market order at a significantly different price. Execution of trades, execution reporting and the delivery of legal trade confirmations may be delayed significantly. Consequently, one may not be able to sell shares of our common stock at the optimum trading prices.

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

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

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

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

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

If Elite and Epic consummate the third closing and the quarterly payment closings under the Epic Strategic Alliance Agreement, Elite will issue to Epic an aggregate of 1,750 shares of Series E Preferred Stock, convertible into an aggregate of approximately 61.8 million shares of Common Stock, based on a conversion price as of June 30, 2010, and warrants to purchase an additional 40 mil