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.