ELITE PHARMACEUTICALS INC /DE/
Form 10-K
June 27, 2008

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, 2008

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission File Number: 001-15697

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

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

165 LUDLOW AVENUE, NORTHVALE, NEW JERSEY 07647
(Address of principal executive offices)

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

Securities registered pursuant to Section 12(b) of the Act: Common Stock - $.01 pa
The Common Stock is list
American Stock Exch

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K. [ ]

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

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [X]

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant as of June 18, 2008 was approximately $9,297,948.50 based upon the closing price of $0.50 of the Registrant's Common Stock on the American Stock Exchange, as of June 18, 2008. (For purposes of determining this amount, only directors, executive officers, and, based on Schedule 13(d) filings as of June 18, 2008, 10% or greater stockholders and their respective affiliates have been deemed affiliates).

Registrant had 23,232,207 shares of common stock, par value $0.01 per share, outstanding as of June 18, 2008.

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. The listed documents should be clearly described for identification purposes (e.g., annual report to security holders for fiscal year ended December 24, 1980). N/A

FORWARD LOOKING STATEMENTS

THIS ANNUAL REPORT ON FORM 10-K AND THE DOCUMENTS INCORPORATED HEREIN CONTAIN "FORWARD-LOOKING STATEMENTS" WITHIN THE MEANING OF THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995. SUCH FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS WHICH MAY CAUSE THE ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS OF THE COMPANY, OR INDUSTRY RESULTS, TO BE MATERIALLY DIFFERENT FROM ANY FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY SUCH FORWARD-LOOKING STATEMENTS. WHEN USED IN THIS ANNUAL REPORT, STATEMENTS THAT ARE NOT STATEMENTS OF CURRENT OR HISTORICAL FACT MAY BE DEEMED TO BE FORWARD-LOOKING STATEMENTS. WITHOUT LIMITING THE FOREGOING, THE WORDS "PLAN", "INTEND", "MAY," "WILL," "EXPECT," "BELIEVE", "COULD,"

"ANTICIPATE," "ESTIMATE," OR "CONTINUE" OR SIMILAR EXPRESSIONS OR OTHER VARIATIONS OR COMPARABLE TERMINOLOGY ARE INTENDED TO IDENTIFY SUCH FORWARD-LOOKING STATEMENTS. READERS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH SPEAK ONLY AS OF THE DATE HEREOF. EXCEPT AS REQUIRED BY LAW, THE COMPANY UNDERTAKES NO OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENTS, WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR OTHERWISE.

ANY REFERENCE TO "ELITE", THE "COMPANY", "WE", "US", "OUR" OR THE "REGISTRANT" MEANS ELITE PHARMACEUTICALS INC. AND ITS SUBSIDIARIES.

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PART I

ITEM 1. BUSINESS

GENERAL

Elite Pharmaceuticals, Inc. ("ELITE PHARMACEUTICALS") was incorporated on October 1, 1997 under the laws of the State of Delaware, and our 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. Elite Pharmaceuticals, Elite Labs, Elite Research and Novel, a variable interest entity, are referred to herein, collectively, as "ELITE", "WE", "US", "OUR" or the "COMPANY".

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, we acquired from Elan Corporation, plc and Elan International Services, Ltd. (together "ELAN") Elan's 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. 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 that file electronically with the SEC, including our filings.

BUSINESS OVERVIEW AND STRATEGY

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products. We develop 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(R) and Lodrane 24D(R), currently being sold commercially, and

a pipeline of five drug candidates under development in the therapeutic areas that include pain management, allergy and infection. Of the products under development, ELI-216, an abuse deterrent oxycodone product, and ELI-154, a once daily oxycodone product, are in clinical trials and we have completed pilot studies on two of our generic product candidates. The addressable market for the pipeline of products exceeds $6 billion. Our facility in Northvale, New Jersey also is a Good Manufacturing Practice ("GMP") and DEA registered facility for research, development and manufacturing.

STRATEGY

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

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

We intend to continue to collaborate in the development of additional products with our current partners. We also plan to seek additional collaborations to develop more drug products.

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

RESEARCH AND DEVELOPMENT

During each of the last three fiscal years, we have focused on research and development activities. We spent $5,795,779 for the fiscal year ended March 31, 2008, $5,777,865 for the fiscal year ended March 31, 2007 and $4,343,890 in the fiscal year ended March 31, 2006 on research and development activities. Our research and development spending has increased as we prepare for Phase III clinical trials for ELI-216 and ELI-154 and spend more on development costs including scale up and clinical studies.

Of our five products in the pipeline, three are for treatment or management of pain (ELI 216 is an abuse resistant oxycodone, ELI 154 is a once daily oxycodone and a third is for an analgesic indication), one is for anti-infective indications, and one is for gastrointestinal disorders

It is our general policy not to disclose products in our development pipeline or the status of such products until a product reaches a stage that we determine, for competitive reasons, in our discretion, to be appropriate for disclosure and because the disclosure of such information might suggest the occurrence of future matters or events that may not occur. In this instance, we believe that disclosure of the information in the following table is helpful for the description of the general nature, orientation and activity of the Company, and the disclosures are made for such purpose. No inference should be made as

to the occurrence of matters or events not specifically described. We may or may not disclose such information in the future based on competitive reasons and/or contractual obligations. We believe that the information is helpful on a one-time basis for the purpose described above.

The following table provides information concerning the controlled-release products that Elite is currently developing and to which we are devoting substantial resources and attention. None of these products has been approved by the United Stated Food and Drug Administration (the "FDA") and all are in development.

PRODUCT	APPROX. U.S. SALES FOR BRAND AND/OR GENERIC PRODUCTS (2006) $MM(A)	NDA/ ANDA (B)	PARTNER	IN
ELI 154 Once Daily oxycodone	N/A(c)	NDA	None	Pai
ELI 216 Once daily oxycodone with abuse resistant technology (ART(TM))	N/A(c)	NDA	None	Pai
Generic	$30	ANDA	None	
Generic	$3,300	ANDA	IntelliPharmaceutics (Toronto, Canada)	Gast di
Generic	$39	ANDA	The PharmaNetwork, LLC (Montvale, NJ)	Pai

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

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

(c) N/A means not applicable because there is no branded product on the market. There is neither a once-daily oxycodone nor an abuse resistant oxycodone on the market. The market for sustained release oxycodone was approximately $2 billion in 2007.

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

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

In the table, Pilot Phase I studies for the NDA products are generally preliminary studies done in healthy human subjects to assess the tolerance/safety and pharmacokinetics of the product. The Phase II

study listed below was done in recreational drug users and a visual analog scale for euphoria was measured in the study. Additional larger studies in humans will be required prior to submission of the product to the FDA for review. Pilot bioequivalence studies are initial studies done in humans for generic products and are used to assess the likelihood of achieving bioequivalence for generic products. Larger pivotal bioequivalence studies will be required prior to submission of the product to the FDA for review.

DEVELOPMENT STAGE	NUMBER OF PRODUCTS	NDA/ANDA
Preclinical	1	ANDA
Pilot bioequivalence study	2	ANDA
Pilot Phase I study	1	NDA
Phase II	1	NDA

COMMERCIAL PRODUCTS

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

Lodrane 24(R), was first commercially offered in November 2004, and Elite's revenues for manufacturing the product and a royalty on sales for the years ended March 31, 2008, 2007 and 2006 aggregated $1,413,119, $1,143,841 and $550,697 respectively. Lodrane 24D(R) was first commercially offered in December, 2006 and Elite's revenues for manufacturing the product and a royalty on sales for the years ended March 31, 2008 and March 31, 2007 aggregated $498,144 and $555,221 respectively.

PRODUCTS UNDER DEVELOPMENT

ELI-154 AND ELI-216

For ELI-154, Elite has developed a once-daily oxycodone formulation using its proprietary technology. An investigational new drug application or IND has been filed and Elite has completed two pharmacokinetic studies in healthy subjects that compared blood levels of oxycodone from dosing ELI-154 and the twice-a-day product that is on the market currently. ELI-154, when compared to twice-daily delivery, demonstrated an equivalent onset, more constant blood levels of the drug over the 24 hours and equivalent blood levels to the twice-a-day product at the end of 24 hours. We are now scaling up that product using commercial size equipment for manufacture of batches. Elite submitted a proposed clinical plan and received guidance from the FDA for this product. Elite has also requested a special protocol assessment ("SPA") for the ELI-154 Phase III protocol but has not yet received a final agreement for it. Elite is also evaluating developing this product for markets outside the U.S.

ELI-216 utilizes our patent-pending abuse deterrent technology that is based on a pharmacological intervention approach. ELI-216 is a combination of a narcotic agonist, oxycodone hydrochloride, in a sustained release formulation intended for use in patients with moderate to severe chronic pain, and an antagonist, naltrexone hydrochloride, formulated to deter abuse of the drug. Both of these compounds, oxycodone hydrochloride and naltrexone hydrochloride, have been on the market for a number of years and sold separately in various dose strengths. Elite has filed an IND for the product and has tested the product in a series of pharmacokinetic studies. In single dose studies for ELI-216, it was demonstrated that no quantifiable blood levels of naltrexone hydrochloride were released at a limit of quantification ("LOQ") of 7.5 pg/ml. When crushed, however, naltrexone hydrochloride was released at levels that would be expected to eliminate the euphoria from the crushed oxycodone hydrochloride. This data is consistent with the premise of Elite's abuse resistant technology or ART, that essentially no naltrexone is released and absorbed when administered as intended.

In further studies, ELI-216 demonstrated the euphoria-blocking effect of ELI-216 when the product is crushed. This study was designed to determine the optimal ratio of oxycodone hydrochloride and the opioid antagonist, naltrexone hydrochloride, to significantly block the euphoric effect of the opioid if the product is abused by physically altering it, (i.e., crushing). The study also helped determine the appropriate levels of naltrexone hydrochloride required to reduce or eliminate the euphoria experienced by subjects who might take crushed product to achieve a "high". Elite intends to complete and submit to the FDA a second stage of this study that will be a double blinded, cross-over pivotal study.

Elite met with the FDA in October 2006 for a Type C clinical guidance meeting regarding the NDA development program for ELI-216. Elite has

incorporated the FDA's guidance into its developmental plan. Elite has begun scale up of ELI-216 to commercial size batches and Elite has obtained an SPA with the FDA for the ELI-216 Phase III protocol. Elite will conduct additional Phase I studies including, but not limited to, food effect, ascending dose and a multi-dose studies.

Elite has developed ELI-154 and ELI-216 and retains the rights to these products. Elite has currently chosen to develop these products itself but expects to license these products at a later date to a third party for sales and distribution. The drug delivery technology underlying ELI-154 was originally developed under a joint venture with Elan which terminated in 2002.

According to the termination agreement, Elite acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture including ELI-154. Upon licensing or commercialization of ELI-154, Elite will pay a royalty to Elan pursuant to

the termination agreement with Elan. If Elite were to sell the product itself, Elite would pay a 1% royalty to Elan based on the product's net sales and if Elite enters into an agreement with another party to sell the product, Elite will pay a 9% royalty to Elan based on Elite net revenues from this product (Elite 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.

MANUFACTURING, CO-DEVELOPMENT AND LICENSE AGREEMENTS

On March 30, 2005, Elite entered into a three party agreement with Tish Technologies, Inc. and Harris Pharmaceuticals, Inc. ("HARRIS") for the co-development and license of a controlled-release generic product. The innovator has now received approval for an alternative dose form (a tablet rather than capsule) and has discontinued the original dose form. While a reference product remains for the capsule, the market opportunity has changed and this affects how we might commercialize the capsule dosage form. On June 19, 2006, we received written notice from Harris of Harris' intent to terminate the agreement in accordance with Section 9.3 of the agreement and therefore Elite is not currently going forward with the development of this product. As of the date hereof, Elite has received $29,700 for this development work.

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

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

On June 22, 2005, Elite entered into a Product Development and License Agreement with PLIVA, Inc. ("PLIVA"), now a subsidiary of Barr Pharmaceuticals, Inc. providing, for the development and license of a controlled-released generic product. On June 28, 2007, shortly after the acquisition of Pliva by Barr Pharmaceuticals, Inc., Elite and Pliva terminated the Product Development and License Agreement and entered into a termination agreement according to which it was agreed that Elite owns all intellectual property rights relating to the controlled-released generic product under development and Pliva agreed to pay Elite $100,000 in discharge of outstanding payments under the Product Development and License Agreement.

On January 10, 2006, Elite entered into an agreement with Orit Laboratories LLC ("ORIT"), an affiliate of Tish Technologies LLC, providing that Elite and Orit will co-develop and commercialize an extended-release drug product for treatment of anxiety, and, upon completion of development, may license it for manufacture and sale. Orit has been providing formulation and analytical resources for the development work. Elite's facility has been used for manufacture of development batches. There have been a number of generic approvals on this product and Elite has determined that it no longer is

economically desirable to complete the development and to file this product. We are in discussion with Orit about terminating the agreement.

On November 10, 2006, Elite entered into a product collaboration agreement with The PharmaNetwork, LLC ("TPN") for the development of the generic product equivalent of a synthetic narcotic analgesic drug product. TPN is to perform development services and prepare and file an ANDA in the name of TPN with the FDA. Elite is to provide development support, including the purchase of active pharmaceutical ingredients and materials and supplies to manufacture the batch, provide adequate facilities to TPN for use in its development work and following ANDA approval, Elite will manufacture the drug product developed. Elite is to pay TPN for the development services rendered upon the attainment of certain milestones. The out-of-pocket costs are to be shared by TPN and Elite, with TPN's obligation to be payable from the royalty compensation. We have completed the formulation development work and compilation of the ANDA submission is currently underway.

JOINT VENTURE WITH NOVEL

Under the terms of the Strategic Alliance Agreement (the "ALLIANCE AGREEMENT"), dated as of December 6, 2006, between us, Dr. Veerappan S. Subramanian and VGS Pharma, LLC, a Delaware limited liability company ("VGS"), we and VGS jointly formed Novel Laboratories, Inc., a Delaware corporation ("NOVEL"), a specialty pharmaceutical company for the research, development, manufacturing, licensing and acquisition of specialty generic pharmaceuticals. Under the Alliance Agreement, we acquired 49% and VGS acquired 51% of Novel's Class A Voting Common Stock, for $9,800 and $10,200 respectively. In order to maintain our full 49% interest in Novel, we had agreed to provide additional cash contributions to Novel upon achievement by Novel of certain performance milestones. While the contributions were not mandatory obligations of Elite, under the Stockholders Agreement, dated as of December 6, 2006, between Elite and VGS, if we did not fund an agreed upon contribution after the occurrence of the related performance milestone, VGS would have the right to purchase from us a pre-defined portion of our shares of Class A Voting Common Stock, resulting in a decrease in our ownership interest in Novel.

Subsequent to the entry into the Alliance Agreement, we and VGS agreed that the performance milestones relating to the funding of our remaining

$20,000,000 of cash contributions would be (i) $10,000,000 upon the submission to the FDA of three abbreviated new drug applications (ANDAs) related to three different prospective products developed by Novel and (ii) $10,000,000 upon the submission to the FDA of three ANDAs related to at least three additional different prospective products developed by Novel. In October 2007, we were notified by Novel of the submission to the FDA of its third ANDA and, pursuant to the terms of the Alliance Agreement, we requested and received, in November 2007, written evidence verifying that such ANDA filings related to prospective products developed by Novel.

At the end of 2007, we elected not to fund our remaining contributions to Novel upon the terms set forth in the Alliance Agreement because we had reached agreement with the FDA under a Special Protocol Assessment on the Phase III clinical trial of ELI-216, our abuse deterrent oxycodone product, and determined that our funds would be better used to support the clinical trials for ELI-216. We and VGS negotiated alternative structures that would permit investments by us at valuations which differed from those set forth in the

Alliance Agreement, however VGS and we were unable to agree upon an alternative acceptable to both parties. Accordingly, upon our determination not to fund our remaining contributions to Novel at the valuation set forth in the Alliance Agreement, VGS exercised its rights to purchase from us our shares of Class A Voting Common Stock of Novel proportionate to the amount of remaining contributions which were not funded by us. As a result, our remaining ownership interest in Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel.

PATENTS

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

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

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

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

priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price 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. The benefits of this 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 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 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 can begin. In some instances this process could result in substantial delay and expense. These 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 Act, which do

not require certain studies that would otherwise be necessary; accordingly, the development timetable should be shorter. While the FDA is required to review applications within a certain timeframe, during the review process, the FDA frequently requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. It is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product.

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

ANDAS

The FDA approval procedure for an ANDA differs from the procedure for a NDA in that the FDA waives the requirement of conducting complete clinical studies, although it normally requires bioavailability and/or bioequivalence studies. "Bioavailability" indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce

a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of the active drug substance in the body are equivalent for the generic drug and the previously approved drug. An ANDA may be submitted for a drug on the basis that it is the equivalent of a previously approved drug or, in the case of a new dosage form, is suitable for use for the indications specified.

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

In May 1992, Congress enacted the Generic Drug Enforcement Act of 1992, which allows the FDA to impose debarment and other penalties on individuals and companies that commit certain illegal acts relating to the generic drug approval process. In some situations, the Generic Drug Enforcement Act requires the FDA to not accept or review ANDAs for a period of time from a company or an individual that has committed certain violations. It also provides for temporary denial of approval of applications during the investigation of certain violations that could lead to debarment and also, in more limited circumstances, provides for the suspension of the marketing of approved drugs by the affected company. Lastly, the Generic Drug Enforcement Act allows for civil penalties and withdrawal of previously

approved applications. Neither we nor any of our employees have ever been subject to debarment. We do not believe that we receive any services from any debarred person.

CONTROLLED SUBSTANCES

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

GMP

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

COMPLIANCE WITH ENVIRONMENTAL LAWS

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation

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

COMPETITION

We have competition with respect to our two principal areas of operation. We develop and manufacture products using controlled-release drug technology for other pharmaceutical companies, and we develop and market (either on our own or by license to other companies) proprietary controlled-release pharmaceutical products. In both areas, our competition consists of those companies which develop controlled-release drugs and alternative drug delivery systems.

In recent years, an increasing number of pharmaceutical companies have become interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will significantly increase in the future since smaller specialized research and development companies are beginning to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many of these companies have greater financial and other resources as well as more experience than we do in commercializing

pharmaceutical products. Certain companies have a track record of success in developing controlled-release drugs. Significant among these are Alpharma, Inc., Sandoz (a Novartis company), Durect Corporation, Mylan Laboratories, Inc., Par Pharmaceuticals, Inc., Teva Pharmaceuticals Industries Ltd., Biovail Corporation, Ethypharm S.A., Eurand, Impax Laboratories, Inc., K-V Pharmaceutical Company and Penwest Pharmaceuticals Company. Each of these companies has developed expertise in certain types of drug delivery systems, although such expertise does not carry over to developing a controlled-release version of all drugs. Such companies may develop new drug formulations and products or may improve existing drug formulations and products more efficiently than we can. In addition, almost all of our competitors have vastly greater resources than we do. While our product development capabilities and, if obtained, patent protection may help us to maintain our market position in the field of advanced drug delivery, there can be no assurance that others will not be able to develop such capabilities or alternative technologies outside the scope of our patents, if any, or that even if patent protection is obtained, such patents will not be successfully challenged in the future.

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

Inc.

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

SOURCES AND AVAILABILITY OF RAW MATERIALS; MANUFACTURING

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

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

DEPENDENCE ON ONE OR A FEW MAJOR CUSTOMERS

Each year we have had one or a few customers that have accounted for a large percentage of our limited revenues therefore the termination of a contract with a customer may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar or material revenue. We have an agreement with ECR which sells and distributes two products that we manufacture: Lodrane 24(R) and Lodrane 24D(R). 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. We receive development fees or milestone payments under some of the co-development agreements with partners, but these fees are currently small compared to the Lodrane 24(R) and Lodrane 24D(R) revenues.

EMPLOYEES

As of June 18, 2008, we had 34 full-time employees and no part-time employees. Full-time employees are engaged in administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the

continued service of our senior management and key personnel.

ITEM 1A. RISK FACTORS

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

RISKS RELATED TO OUR BUSINESS

WE HAVE A RELATIVELY LIMITED OPERATING HISTORY, WHICH MAKES IT DIFFICULT TO EVALUATE OUR FUTURE PROSPECTS.

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

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

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

WE HAVE NOT BEEN PROFITABLE AND EXPECT FUTURE LOSSES.

To date, we have not been profitable, and since our inception in 1990, we have not generated any significant revenues. We may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. We incurred net losses of $13,893,060, $11,803,512, $6,883,914, $5,906,890 and $6,514,217 for the years ended March 31, 2008, 2007, 2006, 2005 and 2004, respectively. We expect to realize significant losses for the current year of operation and to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

THERE IS DOUBT AS TO OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our condensed consolidated unaudited financial statements were prepared on the assumption that we will continue as a going concern. We estimate that our cash reserves will be sufficient to permit us to continue at our anticipated level of operations until September 30, 2008. During 2008, we will require additional funding to continue our research and development programs, including clinical testing of our product candidates, for operating expenses and to pursue regulatory approvals for our product candidates. We intend to use our cash reserves, as well as other funds in the event that they shall be available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If

sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See "RISK FACTORS -- 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".

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 March 31, 2008, we had cash and cash equivalents of $3.7 million. We believe that our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses and capital requirements until September 30, 2008. We will require additional funding to continue our research and development programs, including clinical testing of our product candidates, for operating expenses and to pursue regulatory approvals for our product candidates. We are considering a number of different financing alternatives and we intend to seek additional capital in 2008 through private financing or collaborative agreements. However, no assurance can be given that we will consummate a financing or that any material cash will be generated to us therefrom. Other possible sources of the required financing are income from product sales or sales of market rights, income from co-development or partnering arrangements and the cash exercise of warrants and options that are currently outstanding. No representation can be made that we will be able to obtain such revenue or additional financing or if obtained it will be on favorable terms, or at all. No assurance can be given that any offering if undertaken will be successfully concluded or that if concluded the proceeds will be material. If adequate funds are not available to us as we need them, we will be required to curtail significantly or delay or eliminate one or more product development programs which would impair our ability to meet our business objectives.

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 REVENUE AND CASH FLOW GENERATED BY NOVEL.

As a result of our determination not to fund our remaining contributions to Novel at the valuation set forth in the 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 revenue and cash flow which Novel may generate in the future.

SUBSTANTIALLY ALL OF OUR PRODUCT CANDIDATES ARE AT AN EARLY STAGE OF DEVELOPMENT AND ONLY A PORTION OF THESE ARE IN CLINICAL DEVELOPMENT.

Other than ELI-154 which is in Phase III clinical development and ELI-216 which is in Phase III clinical development, our three other product candidates are still at an early stage of development. We do not have any

products that are commercially available other than Lodrane 24(R) and Lodrane 24D(R). We will need to perform additional development work for all of our 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 file our application for substantive review or may form the opinion after review of our data that our application is insufficient to allow approval of our product candidates. If the FDA does not file or approve our application, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that 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, which might cause us to cease operations.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products. Whether or not 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 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 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 successfully, our business, financial condition, and results of operations may be materially harmed.

IF OUR COLLABORATION OR LICENSING ARRANGEMENTS ARE UNSUCCESSFUL, OUR REVENUES AND PRODUCT DEVELOPMENT MAY BE LIMITED.

We have entered into several collaboration 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 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; and
- 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.

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS AND 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, have two patents pending and we intend to file further patent applications in the future. With respect to our pending patents, we cannot be certain that these applications will result in the issuance of patents. If patents are issued, third parties may sue us to challenge such 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. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

We rely particularly on trade secrets, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by entering into

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

LITIGATION IS COMMON IN OUR INDUSTRY, PARTICULARLY THE GENERIC PHARMACEUTICAL INDUSTRY, AND CAN BE PROTRACTED AND EXPENSIVE AND COULD DELAY AND/OR PREVENT ENTRY OF OUR PRODUCTS INTO THE MARKET, WHICH, IN TURN, COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

Litigation concerning patents and proprietary rights can be protracted and expensive. Companies that produce brand pharmaceutical products routinely bring litigation against applicants that seek FDA approval to manufacture and market generic forms of their branded products. These companies allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an applicant. 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, par value $0.01 per share (the "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, it 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 such specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

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

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

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

IF OUR PRODUCT CANDIDATES DO NOT ACHIEVE MARKET ACCEPTANCE AMONG PHYSICIANS, PATIENTS, HEALTH CARE PAYORS AND THE MEDICAL COMMUNITY, THEY WILL NOT BE COMMERCIALLY SUCCESSFUL AND OUR BUSINESS WILL BE ADVERSELY AFFECTED.

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

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

If we are unable to achieve market acceptance for our product

candidates, then such product candidates will not be commercially successful and our business will be adversely affected.

WE ARE DEPENDENT ON A SMALL NUMBER OF SUPPLIERS FOR OUR RAW MATERIALS AND ANY DELAY OR UNAVAILABILITY OF RAW MATERIALS CAN MATERIALLY ADVERSELY AFFECT OUR ABILITY TO PRODUCE PRODUCTS.

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

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

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

- restrictions on the transfer of funds, or fluctuations in currency exchange rates; and
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

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

EVEN AFTER REGULATORY APPROVAL, WE WILL BE SUBJECT TO ONGOING SIGNIFICANT REGULATORY OBLIGATIONS AND OVERSIGHT.

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

or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

IF KEY PERSONNEL WERE TO LEAVE US OR IF WE ARE UNSUCCESSFUL IN ATTRACTING QUALIFIED PERSONNEL, OUR ABILITY TO DEVELOP PRODUCTS COULD BE MATERIALLY HARMED.

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

IF WE WERE SUED ON A PRODUCT LIABILITY CLAIM, AN AWARD COULD EXCEED OUR INSURANCE COVERAGE AND COST US SIGNIFICANTLY.

The design, development and manufacture of our products involve an inherent risk of product liability claims. We have procured product liability insurance; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. The amount of our insurance coverage, which has been limited due to our limited financial resources, may be materially below the coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of

March 31, 2008.

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 SEC Rule 144 subject in some cases to volume and other limitations. In addition, we filed a registration statement for the resale of 6,465,504 shares of Common Stock issuable upon conversion of outstanding shares of our Series C 8% Convertible Preferred Stock, par value $0.01 per share (the "SERIES C PREFERRED STOCK") issued in the private placement that closed on April 24, 2007, 4,187,643 shares of Common Stock issuable in satisfaction of certain Series C Preferred Stock dividend obligations and 2,133,606 shares of Common Stock issuable upon exercise of warrants issued in the private placement; and a registration statement for the resale of 957,396 shares of Common Stock and 478,698 shares of Common Stock issuable upon the exercise of warrants issued to VGS Pharma, an affiliate of Veerappan Subramanian, one of our directors and former acting Chief Scientific Officer and 1,750,000 shares of Common Stock issuable upon the exercise of options granted to Dr. Subramanian of which 750,000 options have since expired; and a registration statement for the resale of 1,313,747 shares of Common Stock issuable upon conversion of outstanding shares of our Series C Preferred Stock issued in a private placement that closed on July 17, 2007 and in satisfaction of certain Series C Preferred Stock dividend obligations and 242,068 shares of Common Stock issuable upon exercise of warrants issued in the private placement.

Due to the foregoing factors sales of a substantial number of shares of our Common Stock in the public market could occur at any time. 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.

There has been significant volatility in the market prices for publicly traded shares of pharmaceutical companies, including ours. For the twelve months ended March 31, 2008, the closing sale price on the American Stock Exchange ("AMEX") of our Common Stock fluctuated from a high of $2.75 per share to a low of $0.78 per share. The per share price of our Common Stock may not remain at or exceed current levels. The market price for our Common Stock, and for the stock of pharmaceutical companies generally, has been highly volatile. The market price of our Common Stock may be affected by:

- Results of our clinical trials;
- Approval or disapproval of abbreviated new drug applications or new drug applications;
- 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; and
- Fluctuations in our operating results.

THE FAILURE TO MAINTAIN THE AMERICAN STOCK EXCHANGE LISTING OF THE COMMON STOCK WOULD HAVE A MATERIAL ADVERSE AFFECT ON THE MARKET FOR OUR COMMON STOCK AND OUR MARKET PRICE.

On January 4, 2006, we received a letter from the AMEX notifying us that, based on our unaudited financial statements as of September 30, 2005, we were not in compliance with the continued listing standards set forth in the AMEX Company Guide in that under one listing standard our shareholders' equity is less than $4,000,000 and we had losses from continuing operations and/or net losses in three of our four most recent fiscal years and under another listing standard our shareholders' equity is less than $6,000,000 and we had losses from continuing operations and/or net losses in our five most recent fiscal years. At the request of AMEX, we submitted a plan on February 3, 2006 advising AMEX of action, we had taken and will take, to bring ourselves in compliance with the continued listing standards within a maximum of 18 months from January 4, 2006. On March 15, 2006, we completed a private placement of our Series B 8% Convertible Preferred Stock, par value $0.01 per share (the "SERIES B PREFERRED STOCK") and warrants to purchase Common Stock. We received $10,000,000 in gross proceeds from the private placement. On March 21, 2006, we submitted an update to the plan we had previously submitted on February 6, 2006. Upon notice of the March 2006 private placement and the acceptance of the updated plan, AMEX allowed us to maintain our AMEX listing, subject to periodic review of the our progress by the AMEX staff. If we are not in compliance with the continued listing standards, AMEX may then initiate delisting proceedings. The failure to maintain listing of our Common Stock on AMEX will have an adverse effect on the market and the market price for our Common Stock.

IF WE RAISE ADDITIONAL FUNDING THROUGH SALES OF OUR SECURITIES, OUR EXISTING

STOCKHOLDERS WILL LIKELY EXPERIENCE SUBSTANTIAL DILUTION.

If any future financing involves the further sale of our securities, our then-existing stockholders' equity could be substantially diluted. 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 SHARES OF OUR COMMON STOCK OR OUR PREFERRED STOCK COULD MAKE A CHANGE OF CONTROL MORE DIFFICULT TO ACHIEVE.

The issuance of additional shares of our Common Stock or the issuance of shares of an additional series of preferred stock could be used to make a change of control of us more difficult and expensive. Under certain circumstances, such shares could be used to create impediments to or frustrate persons seeking to cause a takeover or to gain control of us. Such shares could be sold to purchasers who might side with the Board of Directors in opposing a takeover bid that the Board of Directors determines not to be in the best interests of our stockholders. It might also have the effect of discouraging an attempt by another person or entity through the acquisition of a substantial number of shares of our Common Stock to acquire control of us with a view to consummating a merger, sale of all or part of our assets, or a similar transaction, since the issuance of new shares could be used to dilute the stock ownership of such person or entity.

IF PENNY STOCK REGULATIONS BECOME APPLICABLE TO OUR COMMON STOCK THEY WILL IMPOSE RESTRICTIONS ON THE MARKETABILITY OF OUR COMMON STOCK AND THE ABILITY OF OUR STOCKHOLDERS TO SELL SHARES OF OUR STOCK COULD BE IMPAIRED.

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

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

- Control of the market for the security by one or a few broker-dealers;
- "Boiler room" practices involving high-pressure sales tactics;
- Manipulation of prices through prearranged matching of purchases and sales;
- The release of misleading information;
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and

- Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer loss.

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

SECTION 203 OF THE DELAWARE GENERAL CORPORATION LAW MAY DETER A THIRD PARTY FROM ACQUIRING US.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

Our facility, which we own, is located at 165 Ludlow Avenue, Northvale, New Jersey, and contains approximately 20,000 square feet of floor space. This real property and the improvements

thereon are encumbered by a mortgage in favor of the New Jersey Economic Development Authority ("NJEDA") as security for a loan through tax-exempt bonds from the NJEDA to Elite. The mortgage contains certain customary provisions including, without limitation, the right of NJEDA to foreclose upon a default by Elite.

On July 15, 2005, we entered into a lease for two years commencing on July 1, 2005 for a portion of a one-story warehouse for the storage of finished and raw material of pharmaceutical products and equipment. We have exercised an option to rent the property through July 1, 2008.

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

ITEM 3. LEGAL PROCEEDINGS.

In the ordinary course of business we may be subject to litigation from time to time. There is no past, pending or, to our knowledge, threatened litigation or administrative action (including litigation or action involving our officers, directors or other key personnel) which in our opinion has or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the three months ended March 31, 2008.

Stockholders at the Company's Annual Meeting of Stockholders held on June 26, 2008 took the following actions:

1. Elected its four Directors.

	No. of Votes For	No. of Votes Against
Bernard Berk	16,460,240	3,161,806
Barry Dash	17,692,942	1,931,104
Robert Levensen	17,692,942	1,931,104
Melvin Van Woert	16,937,460	2,684,586

2. Approved the proposal to approve and ratify the amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 65,000,000 to 150,000,000 by a vote of a majority of the shares of Common Stock outstanding: 16,774,807 shares for, 2,843,614 shares against and 28,854 shares abstaining.

3. Approved the proposal to approve and ratify the amendment to the Company's Certificate of Incorporation to provide that holders of Common Stock are not entitled to vote on any amendment to the Company's Certificate of Incorporation (including any Preferred Stock certificate of designation) that relates solely to the terms of one or more outstanding series of the Company's Preferred Stock if the holders of such affected series are entitled to vote on such amendment by a vote of a majority of the shares of Common Stock outstanding: 13,645,843 shares for, 5,946,664 shares against and 29,537 shares abstaining.

4. Did not approve the proposal to ratify certain amendments made to the Company's Certificate of Incorporation which relate solely to the Series B Preferred Stock which were previously approved by a majority of the holders of the Series B Preferred Stock by a vote of less than a majority of the Common Stock outstanding: 4,393,575 shares for, 1,492,691 shares against and 61,450 shares abstaining.

5. Approved the proposal to approve and ratify the amendment to the Company's Stock Option Plan to increase the number of shares of Common Stock reserved for issuance under the Stock Option Plan from 7,000,000 shares to 10,000,000 shares by a vote of a majority of the shares voting in person or proxy: 4,057,474 shares for, 209,460 shares against and 219,313 shares abstaining.

6. Approved the engagement of Miller, Ellin & Company LLP as the Company's independent auditors for the year ended March 31, 2008 by a vote of a majority of the shares voting in person or by proxy: 19,193,274 shares for, 209,460 shares against and 219,313 shares abstaining.

PART II

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

Our Common Stock is quoted on the American Stock Exchange under the symbol "ELI". The following table shows, for the periods indicated, the high and

low sales prices per share of our Common Stock as reported by the American Stock Exchange.

COMMON STOCK

QUARTER ENDED	HIGH	LOW
FISCAL YEAR ENDING MARCH 31, 2008:		
March 31, 2008	$1.80	$0.72
December 31, 2007	$2.75	$1.45
September 30, 2007	$2.77	$1.95
June 30, 2007	$2.70	$2.08
FISCAL YEAR ENDING MARCH 31, 2007:		
March 31, 2007	$2.40	$1.94
December 31, 2006	$2.49	$2.02
September 30, 2006	$2.46	$2.03
June 30, 2006	$2.54	$2.02

On June 18, 2008, the last reported sale price of our Common Stock, as reported by the American Stock Exchange, was $0.50 per share.

As of June 18, 2008, there were approximately 115 holders of record and, we believe, approximately 2,482 are beneficial owners of our Common Stock. We are informed and believe that as of June 18, 2008, Cede & Co. held 20,756,593 shares of our Common Stock as nominee for Depository Trust Company, 55 Water Street, New York, New York 10004. It is our understanding that Cede & Co. and Depository Trust Company both disclaim any beneficial ownership therein and that such shares are held for the account of numerous other persons.

We have never paid cash dividends on our Common Stock. During the fiscal year ended March 31, 2008, we have paid dividends in the aggregate principal amount of $2,104,797 on our Series B Preferred Stock and Series C Preferred Stock. Such amount reflects $474,087 paid in cash and 1,116,173 shares of Common Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business.

Please see our Quarterly Reports on Form 10-Q for the three month periods ending June 30, 2007, September 30, 2007 and December 31, 2007 and our Current Reports on Form 8-K dated April 25, 2007, July 17, 2007 and January 3, 2008, for information concerning our issuances of unregistered securities during the 12 months ended March 31, 2008.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth certain information regarding Elite's equity compensation plans as of March 31, 2008.

	Number of securities to be issued upon exercise of	Weighted-average exercise price per	secur avail is equit

Plan Category	outstanding options, warrants and rights	share of outstanding options, warrants and rights	pla secur in
	(a)	(b)	
Equity compensation plans approved by security holders	4,468,300(1)	$2.18	
Equity compensation plans not approved by security holders	1,075,000(2)	$2.06	
Total:	5,543,300	$2.16	

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

(2) Represents 1,000,000 non-qualified options issued to Veerappan Subramanian and 75,000 non-qualified options to The Investor Relations Group.

2004 STOCK OPTION PLAN

Our 2004 Stock Option Plan (the "STOCK OPTION PLAN") permits us to grant both incentive stock options ("INCENTIVE STOCK OPTIONS" or "ISOS") within the meaning of Section 422 of the Internal Revenue Code (the "CODE"), and other options which do not qualify as Incentive Stock Options (the "NON-QUALIFIED OPTIONS") to employees, officers, Directors of and consultants to Elite.

Unless earlier terminated by the Board of Directors, the Stock Option Plan (but not outstanding options issued thereunder) terminates on March 1, 2014, after which no further awards may be granted under the Stock Option Plan. The Stock Option Plan is administered by the full Board of Directors or, at the Board of Directors' discretion, by a committee of the Board of Directors consisting of at least two persons who are "disinterested persons" as defined under Rule 16b-2(c)(ii) under the Securities Exchange Act of 1934, as amended (the "Committee").

Recipients of options under the Stock Option Plan ("OPTIONEES") are selected by the Board of Directors or the Committee. The Board of Directors or Committee determines the terms of each option grant including (1) the purchase price of shares subject to options, (2) the dates on which options become exercisable and (3) the expiration date of each option (which may not exceed ten years from the date of grant). The minimum per share purchase price of options granted under the Stock Option Plan for Incentive Stock Options is the fair market value (as defined in the Stock Option Plan) or for Nonqualified Options is 85% of fair market value of one share of the Common Stock on the date the option is granted.

Optionees have no voting, dividend or other rights as stockholders with respect to shares of Common Stock covered by options prior to becoming the holders of record of such shares. The purchase price upon the exercise of options may be paid in cash, by certified bank or cashier's check, by tendering stock held by the Optionee, as well as by cashless exercise either through the surrender of other shares subject to the option or through a broker. The total number of shares of Common Stock available under the Stock Option Plan, and the

number of shares and per share exercise price under outstanding options will be appropriately adjusted in the event of any stock dividend, reorganization, merger or recapitalization or similar corporate event. Subject to limitations set forth in the Stock Option Plan, the terms of option agreements will be determined by the Board of Directors or Committee, and need not be uniform among Optionees.

The Board of Directors may at any time terminate the Stock Option Plan or from time to time make such modifications or amendments to the Stock Option Plan as it may deem advisable and the Board of Directors or Committee may adjust, reduce, cancel and regrant an unexercised option if the fair market value declines below the exercise price except as may be required by any national stock exchange or national market association on which the Common Stock is then listed. In no event may the Board of Directors, without the approval of stockholders, amend the Stock Option Plan to increase the maximum number of shares of Common Stock for which options may be granted under the Stock Option Plan or change the class of persons eligible to receive options under the Stock Option Plan.

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

INCENTIVE OPTIONS

No taxable income is realized by the Optionee upon the grant or exercise of an Incentive Option, except as noted below with respect to the alternative minimum tax. If Common Stock is issued to an Optionee pursuant to the exercise of an Incentive Option, and if no disqualifying disposition of such shares is made by such Optionee within two years after the date of grant or within one year after the

transfer of such shares to such Optionee, then (1) upon sale of such shares, any amount realized in excess of the option price will be taxed to such Optionee as a long-term capital gain and any loss sustained will be a long-term capital loss, and (2) no deduction will be allowed to the Optionee's employer for Federal income tax purposes.

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

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

For purposes of determining whether an Optionee is subject to any

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

NON-QUALIFIED OPTIONS

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

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

COMPLIANCE WITH SECTION 409A OF THE CODE

To the extent that the Board of Directors or Committee determines that any option granted under the Stock Option Plan is subject to Section 409A of the Code, the award agreement evidencing such option shall incorporate the terms and conditions required by Section 409A. To the extent applicable, the Stock Option Plan and award agreements shall be interpreted in accordance with Section 409A. Notwithstanding any provision of the Stock Option Plan to the contrary, in the event that, following the effective date of this amendment to the Stock Option Plan, the Board of Directors or Committee

determines that any option may be subject to Section 409A of the Code, the Board of Directors or Committee may adopt such amendments to the Stock Option Plan and the applicable award agreement or adopt such other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions that the Board of Directors or Committee determines are necessary or appropriate to (a) exempt the option from Section 409A and/or preserve the intended tax treatment of the benefits provided with respect to the option or (b) comply with the requirements of Section 409A of the Code.

SPECIAL RULES APPLICABLE TO CORPORATE INSIDERS

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

COMPARATIVE STOCKHOLDER RETURN

The graph that follows compares the yearly percentage change in Elite's cumulative total stockholder return on its Common Stock for the five year period ended March 31, 2008 with the cumulative total stockholder return of (1) all United States companies traded on the American Stock Exchange (where Elite's Common Stock is now traded) and (2) all companies traded on the American Stock Exchange which carry the Standard Industrial Classification (SIC) code 283 (Pharmaceuticals). The table was prepared by the Research Data Group, Inc.

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

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Elite Pharmaceuticals Inc, The AMEX Composite Index
And Amex Stocks (SIC 2830-2839 US Companies)

[DATA BELOW REPRESENTS A LINE GRAPH IN PRINTED PIECE]

	ELITE PHARMACEUTICALS INC	AMEX COMPOSITE	AMEX STOCKS (SIC 2830-2839 US COMPANIES)
3/03	100.00	100.00	100.00
4/03	98.69	102.41	112.88
5/03	137.25	112.28	132.93
6/03	186.27	116.45	157.11
7/03	160.13	114.15	159.02
8/03	182.35	117.99	162.88
9/03	189.54	122.38	172.66
10/03	209.80	130.63	188.07
11/03	209.15	134.87	194.84
12/03	196.08	143.10	209.13
1/04	241.83	146.38	213.78
2/04	163.40	153.00	211.93
3/04	194.12	154.59	213.21
4/04	212.42	146.95	198.59
5/04	196.08	145.51	190.77
6/04	150.98	150.55	190.49
7/04	143.79	148.89	153.66
8/04	85.62	149.57	142.78
9/04	78.43	154.14	151.15
10/04	114.38	159.18	158.23
11/04	212.42	171.27	175.06
12/04	239.87	175.85	187.83
1/05	271.24	175.10	172.45
2/05	313.07	185.97	164.87
3/05	287.58	181.53	151.12
4/05	232.03	178.70	148.43
5/05	196.08	181.88	154.59
6/05	201.31	192.51	152.30
7/05	189.54	197.64	156.91
8/05	179.74	206.60	143.43
9/05	194.77	217.10	133.66
10/05	160.13	202.71	129.66
11/05	118.30	207.56	136.48
12/05	120.26	216.73	134.48
1/06	132.68	229.93	162.36
2/06	152.29	227.67	171.00

3/06	162.75	240.62	176.01
4/06	149.02	247.53	178.18
5/06	143.79	237.77	167.33
6/06	150.33	237.15	160.31
7/06	143.79	239.39	154.96
8/06	156.86	248.53	166.57
9/06	156.21	238.63	162.92
10/06	133.33	245.10	169.23
11/06	139.22	259.72	176.88
12/06	142.48	258.04	181.77
1/07	130.72	263.15	189.32
2/07	131.37	262.94	179.35
3/07	153.59	271.66	181.62
4/07	144.44	275.04	176.80
5/07	150.33	294.64	191.49
6/07	167.32	293.49	190.72
7/07	153.59	282.71	179.56
8/07	156.86	278.18	174.71
9/07	150.33	299.45	190.97
10/07	179.74	312.46	203.12
11/07	137.25	293.16	192.66
12/07	135.95	299.65	181.77
1/08	59.48	277.04	154.24
2/08	101.31	290.81	123.74
3/08	60.13	281.78	120.79

ITEM 6. SELECTED FINANCIAL DATA

The following consolidated selected financial data, at the end of and for the last five fiscal years, should be read in conjunction with our Consolidated Financial Statements and related Notes thereto appearing elsewhere in this Annual Report on Form 10-K. The consolidated selected financial data are derived from our audited Consolidated Financial Statements. The audit report of Miller, Ellin & Company, LLP, our independent auditors, for the three years ended March 31, 2008, 2007 and 2006 is included herein. The selected financial data provided below is not necessarily indicative of our future results of operations or financial performance.

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

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

GENERAL

The following discussion and analysis should be read with the financial statements and accompanying notes, included elsewhere in this Annual Report on Form 10-K. It is intended to assist the reader in understanding and evaluating our financial position.

OVERVIEW

We are a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled-release products. We develop 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(R) and Lodrane 24D(R), currently being sold commercially, and a pipeline of five drug candidates under development in the therapeutic areas that include pain management, allergy and infection. Of the products under development, ELI-216, an abuse deterrent oxycodone product, and ELI-154, a once daily oxycodone product, are in clinical trials and we have completed pilot studies on two of our generic product candidates. The addressable market for the pipeline of products exceeds $6 billion. Our facility in Northvale, New Jersey also is a Good Manufacturing Practice ("GMP") and DEA registered facility for research, development and manufacturing.

In January 2006, the FDA accepted our IND for ELI-154, our once-a-day oxycodone painkiller. We completed a second pharmacokinetic study to evaluate ELI-154's sustained release formation in 2006. In December 2007, we submitted to the FDA a Special Protocol Assessment ("SPA") for the Phase III protocol for ELI-154. We are currently scaling up the product and expect to wait until we reach agreement with the FDA on this SPA before beginning the Phase III. Currently there is no once-daily oxycodone available. We estimate that the U.S. market for sustained release, twice-daily oxycodone was about $1.6 billion as of September, 2006.

In May 2005, the FDA accepted our IND for ELI-216, our once-a-day, abuse resistant oxycodone painkiller. After the acceptance of the IND, we completed two pharmacokinetic studies and a euphoria study in recreational drug users to assess the abuse deterrent properties of ELI-216. In November 2007, we reached agreement with the FDA on a Special Protocol Assessment for the Phase III protocol for ELI-216. We are currently scaling up the product and preparing for additional studies including a multi-dose study in opioid dependent patients, a food effect study and the Phase III study for ELI-216, Currently there is no abuse deterrent oxycodone product available.

At the end of 2006, we 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.

At the end of 2007, we elected not to fund our remaining contributions to Novel upon the terms set forth in the Alliance Agreement because we had reached agreement with the FDA under a SPA on the Phase III clinical trial of ELI-216, our abuse deterrent oxycodone product and determined that our funds would be better used to support the clinical trials for ELI-216. Upon our

determination not to fund our remaining contributions to Novel at the valuation set forth in the Alliance Agreement, VGS exercised its rights to purchase from us our shares of Class A Voting Common Stock of Novel proportionate to the amount of remaining contributions which were not funded by us. As a result, our remaining ownership interest in Class A Voting Common Stock of Novel is approximately 10% of the outstanding shares of Class A Voting Common Stock of Novel.

Until VGS purchased our shares of Class A Voting Common Stock of Novel, Novel was consolidated into our financial statements as a "variable interest entity" because of the extent of its dependence on the Company. Since then, Novel is no longer considered a "variable interest entity" of the Company and therefore is not consolidated into our financial statements. Accordingly, the information in our Quarterly Report on Form 10-Q consolidates the results of operations of Novel for the six months ended September 30, 2007. As of October 1, 2007, Elite deconsolidated its financial statements from that of Novel. Our investment in Novel was decreased from $7,009,800 to $3,329,322 to recognize the cumulative losses of $3,672,638 from Novel from inception through September 30, 2007 and the return of 80% of our initial investment of $9,800.

STRATEGY

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

We are focusing on the development of various types of drug products, including branded drug products (which require NDAs) under Section 505(b)(1) or 505(b)(2) of the Drug Price

Competition and Patent Term Restoration Act of 1984 as well as generic drug products (which require ANDAs).

We intend to continue to collaborate in the development of additional products with our current partners. We also plan to seek additional collaborations to develop more drug products.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion addresses our Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those

related to bad debts, intangible assets, income taxes, workers compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policie