ELITE PHARMACEUTICALS INC /DE/
Form S-3
June 01, 2007

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MAY 31, 2007
REGISTRATION NO. _____

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

DELAWARE	2834	22-3542636
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

BERNARD BERK, CHIEF EXECUTIVE OFFICER
ELITE PHARMACEUTICALS, INC.
165 LUDLOW AVENUE
NORTHVALE, NEW JERSEY 07647
(201) 750-2646
(Name, address, including zip code, and telephone number, including area code, of registrant's principal executive offices and agent for service)

With copies to:

SCOTT H. ROSENBLATT, ESQ.
GARY M. EMMANUEL, ESQ.
REITLER BROWN & ROSENBLATT, LLC
800 THIRD AVENUE, 21ST FLOOR
NEW YORK, NEW YORK 10022-4611
(212) 209-3050

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or reinvestment plans, please check the following box. |_|

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. |X|

If this Form is filed to register additional securities pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering. |_|

If this Form is a post-effective amendment filed pursuant to Rule

462(c) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering. |_|

If this form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.
|-|

If this form is a post-effective amendment to a registration statement pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. |_|

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Shares of common stock to be registered(1)	Proposed maximum offering price per share(2)	Prop aggr
Common Stock, par value $.01 per share	3,186,094(3)	$2.31	

(1) In accordance with Rule 416 under the Securities Act of 1933, as amended, this registration statement also registers the resale by the selling stockholders of any additional shares of our common stock which become issuable in connection with such shares because of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of outstanding shares of our common stock.

(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, and based on the average of the high and low sale price per share of shares of the common stock on the American Stock Exchange on May 24, 2007.

(3) Consists of (i) 957,396 shares of Common Stock; (ii) 478,698 shares of Common Stock issuable upon the exercise of warrants; and (iii) 1,750,000 shares of Common Stock issuable upon the exercise of options.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF

THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SECTION 8(A), MAY DETERMINE.

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. THE SELLING STOCKHOLDERS MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES, AND IT IS NOT SOLICITING OFFERS TO BUY THESE SECURITIES, IN ANY STATE WHERE THE OFFER OR SALE OF THESE SECURITIES IS NOT PERMITTED.

PROSPECTUS

SUBJECT TO COMPLETION, DATED MAY 31, 2007

ELITE PHARMACEUTICALS INC.

COMMON STOCK

This is an offering (the "OFFERING") of the following shares of common stock, par value $.01 per share, of Elite Pharmaceuticals, Inc. (the "COMPANY", "ELITE", "WE", "US" or "OUR"), by the selling stockholders named in this prospectus or by pledgees, donees, transferees or other successors in interest to the selling stockholders (the "SELLING STOCKHOLDERS"):

(i) 957,396 shares of Common Stock;

(ii) 478,698 shares of Common Stock issuable upon the exercise of warrants; and

(iii) 1,750,000 shares of Common Stock issuable upon the exercise of options.

The common stock is listed on the American Stock Exchange under the symbol "ELI." On May 30, 2007, the closing sales price of our common stock on the American Stock Exchange was $2.25 per share.

SEE "RISK FACTORS" BEGINNING ON 3 FOR A DISCUSSION OF FACTORS THAT YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR COMMON STOCK.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Other than receipt of the cash exercise price upon exercise of the warrants and options, we will receive no proceeds from the sale of the shares of

common stock sold by the Selling Stockholders.

The date of this prospectus is May ___, 2007.

TABLE OF CONTENTS

Page

WHERE YOU CAN FIND MORE INFORMATION ABOUT US.....1

PROSPECTUS SUMMARY.....1

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING INFORMATION.....2

RISK FACTORS.....3

USE OF PROCEEDS.....11

SELLING STOCKHOLDERS.....11

PLAN OF DISTRIBUTION.....13

LEGAL MATTERS.....14

EXPERTS.....14

INCORPORATION BY REFERENCE.....14

INFORMATION NOT REQUIRED IN PROSPECTUS.....II-1

SIGNATURES.....II-4

WHERE YOU CAN FIND MORE INFORMATION ABOUT US

We file reports, proxy statements, information statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy this information, for a copying fee, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information in its public reference rooms. Our SEC filings are also available to the public from commercial document retrieval services, from the American Stock Exchange and at the web site maintained by the SEC at http://www.sec.gov.

We have not authorized anyone to give any information or make any representation about the Offering that differs from, or adds to, the information

in this prospectus or in our documents that are publicly filed with the SEC and that are incorporated in this prospectus. Therefore, if anyone does give you different or additional information, you should not rely on it. The delivery of this prospectus does not mean that there have not been any changes in our condition since the date of this prospectus. If you are in a jurisdiction where it is unlawful to offer the securities offered by this prospectus, or if you are a person to whom it is unlawful to direct such activities, then the offer presented by this prospectus does not extend to you. This prospectus speaks only as of its date except where it indicates that another date applies. Documents that are incorporated by reference in this prospectus speak only as of their date, except where they specify that other dates apply.

THIS PROSPECTUS IS NOT AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY NOR SHALL THERE BE ANY SALE OF SECURITIES IN ANY STATE IN WHICH SUCH OFFER, SOLICITATION OR SALE WOULD BE UNLAWFUL PRIOR TO REGISTRATION OR QUALIFICATION UNDER THE SECURITIES LAWS OF ANY SUCH STATE.

PROSPECTUS SUMMARY

THE FOLLOWING SUMMARY HIGHLIGHTS SELECTED INFORMATION FROM, OR INCORPORATED BY REFERENCE INTO, THIS PROSPECTUS AND MAY NOT CONTAIN ALL THE INFORMATION THAT IS IMPORTANT TO YOU. TO UNDERSTAND OUR BUSINESS AND THIS OFFERING FULLY, YOU SHOULD READ THIS ENTIRE PROSPECTUS CAREFULLY, INCLUDING THE CONSOLIDATED FINANCIAL STATEMENTS AND THE RELATED NOTES AND THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS. REFERENCES IN THIS PROSPECTUS TO THE "COMPANY," "ELITE," "ELITE PHARMACEUTICALS," "WE," "OUR," AND "US" REFER TO ELITE PHARMACEUTICALS, INC., A DELAWARE CORPORATION, TOGETHER WITH OUR SUBSIDIARIES. PLEASE SEE "INCORPORATION BY REFERENCE" FOR A DESCRIPTION OF PUBLIC FILINGS DEEMED INCORPORATED BY REFERENCE INTO THIS PROSPECTUS.

THE COMPANY

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 and license these products. 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 seven 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 two generic product candidates that are undergoing pivotal studies. The addressable market for our 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.

At the end of 2006, we formed, together with VGS Pharma, LLC, Novel Laboratories, Inc. ("NOVEL"), a Delaware corporation as a separate specialty pharmaceutical company for the research, development, manufacturing, licensing and acquisition of specialty generic pharmaceuticals.

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.

CORPORATE INFORMATION

Elite Pharmaceuticals, Inc. was incorporated on October 1,1997 under the laws 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 Delaware.

On October 24, 1997, Elite Pharmaceuticals merged with and into our predecessor company, Prologica International, Inc. ("PROLOGICA"), an inactive publicly held corporation formed under the laws of Pennsylvania. At the same time, Elite Labs merged with a wholly-owned subsidiary of Prologica. Following these mergers, Elite Pharmaceuticals survived as the parent of 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., a Bermuda corporation ("ERL"), a joint venture formed between Elite and Elan in which our initial interest was 100% of the outstanding common stock which represented 80.1% of the outstanding capital stock. As a result of the termination of the joint venture, we owned 100% of ERL's capital stock. On December 31, 2002, ERL was merged into Elite Research, our wholly-owned subsidiary.

Our common stock is traded on the American Stock Exchange under the symbol "ELI". The market for our stock has historically been characterized generally by low volume and broad range of prices and volume volatility. We cannot give any assurance that a stable trading market will develop for our stock.

Our executive offices are located at 165 Ludlow Avenue, Northvale, New Jersey 07647. Phone No.: (201) 750-2646; Facsimile No.: (201) 750-2755.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING INFORMATION

Certain information contained in or incorporated by reference into this prospectus includes forward-looking statements (as defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934) that reflect our current views with respect to future events and financial performance. Certain factors, such as unanticipated technological difficulties, the volatile and competitive environment for drug delivery products and the development of generic drug products, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the degree of success, if any, in concluding business partnerships or licenses with viable pharmaceutical companies, instabilities arising from terrorist actions and responses thereto, and other considerations described as "RISK FACTORS" in this prospectus could cause actual results to differ materially from those in the forward-looking statements. When used in this registration statement, 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, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

RISK FACTORS

IN ADDITION TO THE OTHER INFORMATION CONTAINED IN THIS PROSPECTUS, INCLUDING THE OTHER DOCUMENTS INCORPORATED HEREIN BY REFERENCE AND REFERRED BELOW, 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 $7,750,174, $6,883,914, $5,906,890, $6,514,217 and $4,061,422, for the nine months ended December 31, 2006 and the years ended March 31, 2006, 2005,

2004 and 2003, 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.

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. In particular, we have committed to make a substantial investment in our joint venture, Novel, of up to $25,000,000 upon Novel meeting certain milestones and if we fail to meet this obligation, VGS Pharma, LLC, our co-venturer in Novel, may exercise a purchase right that would result in either the elimination or significant dilution of our interest in Novel.

We do not have committed external sources of funding and may not be able to obtain any additional funding, especially if volatile market conditions persist for biotechnology companies. We believe our existing cash resources, including the $15 million raised in the private placement of our Series C Preferred Stock that closed on April 24, 2007, is sufficient to meet our cash requirements for the next 14 months.

Other possible sources of the required financing are income from product sales or sales of market rights, distributions from Novel, 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. Our inability to obtain additional financing when needed would impair our ability to continue our business.

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.

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-216 and ELI-254, which are in clinical trial development, our five 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 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 applications for approval 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 LICENSE 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 licensee 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; and

- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant and costly litigation or arbitration.

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. With our expansion into the generic pharmaceutical market through our joint venture, Novel, our risk of litigation has increased. 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 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 through our joint venture, Novel, its 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 inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, could have a material adverse effect on us.

The delay or unavailability of raw materials 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, 2007.

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, pursuant hereto, we are registering the resale of:

- 957,396 shares of Common Stock;
- 478,698 shares of Common Stock issuable upon the exercise of warrants; and
- 1,750,000 shares of Common Stock issuable upon the exercise of options.

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 May 21, 2007, the closing sale price on the American Stock Exchange of our common stock fluctuated from a high of $2.60 per share to a low of $1.75 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 EFFECT ON THE MARKET FOR OUR COMMON STOCK AND OUR MARKET PRICE.

On January 4, 2006, we received a letter from the American Stock Exchange ("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 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.

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 in opposing a takeover bid that the Board 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 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.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares by the Selling Stockholders pursuant to this prospectus.

A portion of the shares covered by this prospectus are issuable upon exercise of warrants and options to purchase our common stock. Upon any exercise of the warrants and options for cash, the Selling Stockholders would pay us the exercise price of the warrants and options, as applicable. Any proceeds from the exercise of the warrants and options will be used for working capital.

SELLING STOCKHOLDERS

On December 6, 2006, we entered into a strategic alliance agreement with Veerappan Subramanian and VGS Pharma pursuant to which we issued to VGS Pharma LLC ("VGS Pharma") 957,396 shares of our common stock and a warrant to acquire 478,698 shares of our common stock. In addition, on December 6, 2006, we entered into an advisory agreement with Veerappan Subramanian pursuant to which we granted him a stock option to purchase 1,750,000 shares of our common stock. Pursuant to the registration rights agreement related to such transactions, we agreed to file, at our expense, a registration statement, of which this prospectus is a part, with the Securities Exchange Commission to register for resale, from time to time, the 957,396 shares of common stock and the 478,698 shares of common stock issuable upon the exercise of warrants issued to VGS Pharma pursuant to the strategic alliance agreement and 1,750,000 shares of

common stock issuable upon exercise of options issued to Veerappan Subramanian pursuant to the advisory agreement. The terms of the strategic alliance agreement, advisory agreement and registration rights agreement were disclosed in our Current Report on Form 8-K which we filed with the Securities Exchange Commission on December 12, 2006 and which is incorporated by reference herein.

As a result of entering into the strategic alliance agreement, Veerappan Subramanian was appointed to our Board of Directors and became Chief Executive Officer of Novel Laboratories, Inc., our newly established joint venture with VGS Pharma. In addition, on February 14, 2007, Veerappan Subramanian was appointed as our new Chief Scientific Officer. VGS Pharma is a wholly-owned subsidiary of Kali Capital, L.P., which is controlled by Kali Management, LLC ("KALI MANAGEMENT"), its general partner, and Kali Management is controlled by Anu Subramanian, its managing member and daughter of Veerappan Subramanian.

We are registering the shares to permit the Selling Stockholders to offer these shares for resale from time to time. The Selling Stockholders may sell all, some or none of the shares covered by this prospectus. For more information, see the section of this prospectus entitled "PLAN OF DISTRIBUTION."

The table below presents information as of May 25, 2007, regarding the Selling Stockholders and the shares of our common stock that they may offer and sell from time to time under this prospectus. The information is based on information provided by or on behalf of the Selling Stockholders. Except as noted above, no Selling Stockholder has had, within the past three years, any position, office, or material relationship with us or any of our predecessors or affiliates. The table has been prepared on the assumption that all shares offered under this prospectus will be sold to parties unaffiliated with the Selling Stockholders. Except as indicated below the Selling Stockholders have sole voting and investment power with their respective shares.

NAME OF SELLING STOCKHOLDER(1)	NUMBER OF SHARES BENEFICIALLY OWNED PRIOR TO OFFERING	NUMBER OF SHARES OFFERED	SHARES B NUMBER OF
VGS Pharma, LLC	1,436,094(4)	1,436,094	0
Veerappan Subramanian	1,776,800(5)	1,750,000	26,80

* Less than 1%

(1) Selling Stockholders means the persons listed in the table above, as well as the pledgees, assignees or other successors in interest to the selling stockholders.

(2) Assumes that the Selling Stockholders dispose of all the shares of common stock covered by this prospectus and do not acquire or dispose of any additional shares of common stock. The Selling Stockholders are not representing, however, that any of the shares covered by this prospectus will be offered for sale, and the Selling Stockholders reserve the right to accept or reject, in whole or in part, any proposed sale of shares.

(3) The percentage of common stock beneficially owned is based on 20,820,048 shares of common stock (excluding 100,000 treasury shares) outstanding on May 25, 2007.

(4) Represents 957,396 shares of common stock and 478,698 shares of common stock issuable upon the exercise of warrants.

(5) Represents 26,800 shares of common stock and 1,750,000 shares of common stock issuable upon exercise of options.

PLAN OF DISTRIBUTION

OFFER AND SALE OF SHARES

Each Selling Stockholder has or its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on the American Stock Exchange or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A Selling Stockholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of

the block as principal to facilitate the transaction;

- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "SECURITIES ACT"), if available, rather than under this prospectus.

In connection with sales of the shares of common stock or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The Selling Stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The Selling Stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The Selling Stockholders may pledge or grant a security interest in some or all of the warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The Selling Stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners.

Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440.

The Selling Stockholders and any broker-dealers or agents involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or

discounts under the Securities Act. Each Selling Stockholder has informed us that it does not have any written or oral agreement or understanding, directly or

indirectly, with any person to distribute the common stock. In no event shall any broker-dealer receive fees, commissions and markups which, in the aggregate, would exceed eight percent (8%).

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because Selling Stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the Selling Stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be sold by the Selling Stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

Reitler Brown & Rosenblatt LLC, New York, New York, as our counsel will pass upon whether the shares of common stock which are being registered under the Securities Act of 1933, as amended, by the registration statement of which this prospectus is a part are fully paid, nonassessable and validly issued.

EXPERTS

Miller, Ellin & Company, LLP, independent certified public accountants, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended March 31, 2006 as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Miller Ellin's report, given on their authority as experts in accounting and auditing.

INCORPORATION BY REFERENCE

The Securities and Exchange Commission (the "COMMISSION") allows us to incorporate by reference the information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference into this registration statement is considered to be part of this registration statement, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (including those filed by us prior to the termination of the offering) we make with the Commission under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act:

a. our annual report on Form 10-K for the year ended March 31, 2006, filed with the Commission on June 29, 2006;

b. our quarterly report on Form 10-Q for the quarter ended June 30, 2006, filed with the Commission on August 11, 2006;

c. our quarterly report on Form 10-Q for the quarter ended September 30, 2006, filed with the Commission on November 14, 2006;

d. our quarterly report on Form 10-Q for the quarter ended December 31, 2006, filed with the Commission on February 14, 2007;

e. our current report on Form 8-K filed on July 18, 2006;

f. our current report on Form 8-K filed on August 21, 2006;

g. our current report on Form 8-K filed on September 8, 2006;

h. our current report on Form 8-K filed on September 12, 2006;

i. our current report on Form 8-K filed on October 30, 2006;

j. our current report on Form 8-K filed on November 15, 2006;

k. our current report on Form 8-K filed on December 12, 2006;

l. our current report on Form 8-K filed on February 14, 2007; and

m. our current report on Form 8-K filed on April 25, 2007;

n. the description of our capital stock which is contained in our registration statement on Form 8-A filed on February 16, 2000 including any subsequent amendments and reports filed for the purpose of updating that description.

You may request a copy of these filings, at no cost, by written or oral request to us at the following address:

Mark I. Gittelman
Corporate Secretary
Elite Pharmaceuticals, Inc.
165 Ludlow Avenue
Northvale, New Jersey 07647
(201) 750-2646

No person has been authorized to give any information or to make any representation other than those contained in this prospectus in connection with the offering of the shares of our common stock by the Selling Stockholders. If information or representations other than those contained in this prospectus are given or made, you must not rely on it as if we authorized it. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create an implication that the information contained or incorporated by reference herein is correct as of any time subsequent to its date or that there has been no change in our affairs since such date. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered hereby in any jurisdiction in which such offer or solicitation is not permitted, or to anyone whom it is unlawful to make such offer or solicitation. The information in this prospectus is not complete and may be changed.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following is a statement of the estimated expenses incurred by us in connection with the distribution of the securities registered under this registration statement:

	AMOUNT TO BE PAID *
SEC Registration Fee	$ 225.96
Legal Fees and Expenses	$ 5,000.00*
Accounting Fees and Expenses ...	$ 1,000.00
Printing Expenses	$ 2,000.00*
Miscellaneous	$ 2,000.00*
Total	$10,225.96*

* Estimated

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Pursuant to authority conferred by Section 102 of the Delaware General Corporation Law (the "DGCL"), our Certificate of Incorporation, as amended, contains a provision providing that the personal liability of a director is eliminated to the fullest extent provided by the DGCL. The effect of this provision is that none of our directors is personally liable to us or our

stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for (i) any breach of the director's duty of loyalty to us or our stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) unlawful payment of dividends as provided in Section 174 of the DGCL and (iv) any transaction from which the director derived an improper personal benefit. This provision is intended to eliminate the risk that a director might incur personal liability to us or our stockholders for breach of duty of care. The Certificate of Incorporation, as amended, also provides that if the Delaware Law is amended to eliminate or limit further the liability of directors, then the liability of our directors shall be eliminated or limited, without further stockholder action.

Section 145 of the DGCL contains provisions permitting and, in some situations, requiring Delaware corporations, such as Elite, to provide indemnification to their officers and directors for losses and litigation expenses incurred in connection with their service to the corporation in those capacities. Our Certificate of Incorporation, as amended, and by-laws contain such a provision requiring that we indemnify our directors and officers to the fullest extent permitted by law, as the law may be amended from time to time.

In our registration rights agreement with each of the Selling Stockholders, we have agreed to indemnify the purchaser against damages or losses and expenses arising from any losses or expenses incurred in connection with a loss or alleged loss arising from a material misstatement in or a material omission from the registration statement or any violation of the Securities Act except for a material misstatement or omission based on written information provided to us by the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions or otherwise, it has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

ITEM 16. EXHIBITS

4.1 Form of Common Stock certificate, incorporated by reference to Exhibit 4.1 to the Registration Statement on Form SB-2, Registration No. 333-90633, made effective on February 28, 2000.

5.1 Opinion of Reitler Brown & Rosenblatt LLC.

10.1 Form of Strategic Alliance Agreement between the Registrant, VGS Pharma, LLC and Veerappan Subramanian, incorporated by reference to Exhibit 10A to the Current Report on Form 8-K dated December 12, 2006, 2007 and filed with the Commission on December 12, 2006.

10.2 Form of Advisory Agreement between the Registrant and Veerappan Subramanian, incorporated by reference to Exhibit 10B to the Current Report on Form 8-K dated December 12, 2006, 2007 and filed with the Commission on December 12, 2006.

10.3 Form of Registration Rights Agreement between the Registrant, VGS Pharma, LLC and Veerappan Subramanian, incorporated by reference to Exhibit 10C to the Current Report on Form 8-K dated December 12, 2006, 2007 and filed with the Commission on December 12, 2006.

10.4 Form of Warrant issued to VGS Pharma, LLC, incorporated by reference to Exhibit 3A to the Current Report on Form 8-K dated December 12, 2006, 2007 and filed with the Commission on December 12, 2006.

10.5 Form of Non Qualified Stock Option Agreement with Veerappan Subramanian, incorporated by reference to Exhibit 3B to the Current Report on Form 8-K dated December 12, 2006, 2007 and filed with the Commission on December 12, 2006.

23.1 Consent of Miller, Ellin & Company LLP.

23.2 Consent of Reitler Brown & Rosenblatt LLC (included in Exhibit 5.1 above).

24.1 Power of Attorney (included on Signature page).

ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

(a)(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement; notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of the securities offered would not exceed that which was registered) may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if the change in volume represents no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant

to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(b) INSOFAR AS INDEMNIFICATION FOR LIABILITIES ARISING UNDER THE SECURITIES ACT OF 1933 MAY BE PERMITTED TO DIRECTORS, OFFICERS AND CONTROLLING PERSONS OF THE REGISTRANT PURSUANT TO THE FOREGOING PROVISIONS, OR OTHERWISE, THE REGISTRANT HAS BEEN ADVISED THAT IN THE OPINION OF THE SECURITIES AND EXCHANGE COMMISSION SUCH INDEMNIFICATION IS AGAINST PUBLIC POLICY AS EXPRESSED IN THE SECURITIES ACT OF 1933 AND IS, THEREFORE, UNENFORCEABLE. IN THE EVENT THAT A CLAIM FOR INDEMNIFICATION AGAINST SUCH LIABILITIES (OTHER THAN THE PAYMENT BY THE REGISTRANT OF EXPENSES INCURRED OR PAID BY A DIRECTOR, OFFICER OR CONTROLLING PERSON OF THE REGISTRANT IN THE SUCCESSFUL DEFENSE OF ANY ACTION, SUIT OR PROCEEDING) IS ASSERTED AGAINST THE REGISTRANT BY SUCH DIRECTOR, OFFICER OR CONTROLLING PERSON IN CONNECTION WITH THE

SECURITIES BEING REGISTERED, THE REGISTRANT WILL, UNLESS IN THE OPINION OF ITS COUNSEL THE MATTER HAS BEEN SETTLED BY CONTROLLING PRECEDENT, SUBMIT TO A COURT OF APPROPRIATE JURISDICTION THE QUESTION WHETHER SUCH INDEMNIFICATION BY IT IS AGAINST PUBLIC POLICY AS EXPRESSED IN THE SECURITIES ACT OF 1933 AND WILL BE GOVERNED BY THE FINAL ADJUDICATION OF SUCH ISSUE.

(c)(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(b) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Borough of Northvale, State of New Jersey, on May 31, 2007.

ELITE PHARMACEUTICALS, INC.

/s/ Bernard Berk

Bernard Berk

President and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bernard Berk and Mark I. Gittelman as his attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign and file Registration Statement(s) and any and all pre- or post-effective amendments to such Registration Statement(s), with all exhibits thereto and hereto, and other documents with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Dated: May 31, 2007 /s/ Bernard Berk

Bernard Berk
Chief Executive Officer and
Chairman of the Board of Directors

Dated: May 31, 2007 /s/ Mark Gittelman

Mark I. Gittelman
Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: May 31, 2007 /s/ Edward Neugeboren

Edward Neugeboren
Director

Dated: May 31, 2007 /s/ Barry Dash

Barry Dash
Director

Dated: May 31, 2007 /s/ Melvin Van Woert

Melvin Van Woert
Director

Dated: May 31, 2007 /s/ Veerappan Subramanian

Veerappan Subramanian
Chief Scientific Officer and Director