ELITE PHARMACEUTICALS INC /DE/
Form 424B3
July 13, 2007

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Registration No. 333-143246

PROSPECTUS

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) 10,653,147 shares of common stock issuable upon conversion of outstanding shares of our Series C PreferredH Stock, par value $.01 per share issued in a private placement that closed on April 24, 2007 and shares of common stock issuable in satisfaction of certain Series C Preferred Stock dividend obligations;

(ii) 2,133,606 shares of common stock issuable upon exercise of warrants issued in the private placement;

The common stock is listed on the American Stock Exchange under the symbol "ELI." On May 21, 2007, the closing sales price of our common stock on the American Stock Exchange was $2.30 per share.

SEE "RISK FACTORS" BEGINNING ON PAGE 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 issued in the private placement, 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 July 11, 2007.

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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 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 NDAs 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, 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 are 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:

- 10,653,147 shares of common stock issuable upon conversion of outstanding shares of our Series C Preferred Stock issued in the private placement that closed on April 24, 2007 and shares of common stock issuable in satisfaction of certain Series C Preferred Stock dividend obligations;

- 2,133,606 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 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 to purchase our common stock. Upon any exercise of the warrants for cash, the Selling Stockholders would pay us the exercise price of the warrants, as applicable. Under certain conditions set forth in the warrants, the warrants are exercisable on a cashless basis. If the warrants are exercised on a cashless basis, we would not receive any cash payment from the Selling Stockholder upon any exercise of the warrants. Any proceeds from the exercise of the warrants will be used for working capital.

SELLING STOCKHOLDERS

On April 24, 2007 we issued 15,000 shares of Series C Preferred Stock convertible into 6,465,504 shares of our common stock and warrants to purchase 2,133,606 shares of our common stock in a private placement. Pursuant to the registration rights agreement related to such private placement, we agreed to file, at our expense, a registration statement, of which this prospectus is a part, with the SEC to register for resale, from time to time, the 6,465,504 shares of our common stock issuable upon conversion of the shares of Series C Preferred Stock, 4,187,643 shares of our common stock issuable in satisfaction of certain Series C Preferred Stock dividend obligations, and 2,133,606 shares of our common stock issuable upon exercise of the warrants issued in the private placement.

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 April 24, 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 in the footnotes, 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.

			SHARES BENEFICIALLY O AFTER OFFERING	
NAME OF SELLING STOCKHOLDER(1)	NUMBER OF SHARES BENEFICIALLY OWNED PRIOR TO OFFERING	NUMBER OF SHARES OFFERED	NUMBER OF SHARES(2)	PERCEN OF CLA
M.H. Davidson & Co.**	27,404(4)	27,404	0	0
Davidson Kempner Healthcare Fund LP**	1,729,413(5)	1,729,413	0	0
				0
Davidson Kempner Healthcare International Ltd.**	2,547,106(6)	2,547,106	0	0
Serena Limited**	16,790(7)	16,790	0	0
Davidson Kempner International, Ltd.**	677,492(8)	677,492	0	0
Davidson Kempner Institutional0 Partners, L.P.**	386,178(9)	386,178	0	0
Davidson Kempner Partners**	212,398(10)	212,398	0	0
CAMOFI Master LDC	839,520(11)	839,520	0	0
The Gabelli Convertible and Securities Fund Inc. +	83,951(12)	83,951	0	0
Sphera Global Healthcare Master Fund	293,832(13)	293,832	0	0
Cotswold Foundation	251,856(14)	251,856	0	0
Martha H. Morris+	209,879(15)	209,879	0	0
I. Wistar Morris III IRA+	335,806(16)	335,806	0	0

Eleventh Generation LP	209,879(17)	209,879	0	0

Trellus Partners, LP	2,195,257(18)	629,639	1,565,618	7%
Trellus Partners II, LP	33,975(19)	25,185	8,790	*
Trellus Offshore Fund Limited	1,373,215(20)	1,024,215	349,000	1.7%
Otago Partners, LLC+	209,879(21)	209,879	0	0
Capital Ventures International+	839,520(22)	839,520	0	0
Iroquois Master Fund Ltd.	419,760(23)	419,760	0	0
Rockmore Investment Master Fund Ltd.	839,520(24)	839,520	0	0
BridgePointe Master Fund Ltd.	503,712(25)	503,712	0	0
Benyamin Mandel	125,927(26)	125,927	0	0
Reitler Brown & Rosenblatt LLC	10,912(27)	10,912	0	0
Rose Millennium Investments Ltd.	41,975(28)	41,975	0	0
Eurocom Capital Finance Ltd.	92,356(29)	92,356	0	0
Barry H. Dash	33,790(30)	16,790	17,000	*
Oppenheimer & Co., Inc.	184,238(31)	133,998	50,240	*
Ledgemont Capital Group, LLC+	270,637(32)	36,045	234,592	1.1%
Boenning & Scattergood, Inc.	15,517(34)	15,517	0	0

* Less than 1%

** Messrs Thomas L. Kempner, Jr., Marvin H. Davidson, Stephen M. Dowicz, Scott E. Davidson, Michael J. Leffell, Timothy I. Levart, Robert H. Brivio, Jr., Anthony A. Yoseloff, Eric P. Epstein and Avram Z Friedman (collectively, the "PRINCIPALS"), are

the general partners of M. H. Davidson & Co. and MHD Management Co. ("MHD"), the general partner of Davidson Kempner Partners, the sole managing members of Davidson Kempner International Advisors, L.L.C. ("DKIA"), the investment manager of each of Davidson Kempner International, Ltd. and Serena Limited, the sole stockholders of Davidson Kempner Advisers Inc. ("DKAI"), the general partner of Davidson Kempner Institutional Partners, L.P., the managing members of DK Group LLC ("DKG"), the general partner of Davidson Kempner Healthcare Fund LP, and the limited partners of DK Management Partners LP ("DKMP"), the investment manager of Davidson Kempner Healthcare International Ltd. Each of the Principals, MHD, DKIA, DKAI, DKG and DKMP disclaim all beneficial ownership as affiliates of a registered investment adviser, and, in any case disclaim all beneficial ownership except as to the extent of their pecuniary interest in the shares.

\+ The Selling Stockholder has identified itself as an affiliate of a registered broker-dealer. The Selling Stockholder has represented to us

that it purchased the shares in the ordinary course of its business and, at the time of purchase, had no agreements or understandings, directly or indirectly, with any person to distribute the shares.

(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 20,904,592 shares of common stock outstanding on April 24, 2007.

(4) Includes 14,224 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 9,213 dividend shares and 4,267 shares of common stock issuable upon exercise of warrants.

(5) Includes 887,931 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 575,103 dividend shares and 266,379 shares of common stock issuable upon exercise of warrants.

(6) Includes 1,307,758 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 847,021 dividend shares and 392,327 shares of common stock issuable upon exercise of warrants.

(7) Includes 8,620 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 5,584 dividend shares and 2,586 shares of common stock issuable upon exercise of warrants.

(8) Includes 347,844 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 225,295 dividend shares and 104,353 shares of common stock issuable upon exercise of warrants.

(9) Includes 198,275 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 128,421 dividend shares and 59,482 shares of common stock issuable upon exercise of warrants.

(10) Includes 109,051 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 70,632 dividend shares and 32,715 shares of common stock issuable upon exercise of warrants.

(11) Includes 431,034 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 279,176 dividend shares and 129,310 shares of common stock issuable upon exercise of warrants. Mr. Richard Smithine has the power to vote or dispose of the shares.

(12) Includes 43,103 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 27,918 dividend shares and 12,930 shares of common stock issuable upon exercise of warrants. Mr. Bruce Alpert has the power to vote or dispose of the shares.

(13) Includes 150,862 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 97,712 dividend shares and 45,258 shares of common stock issuable upon exercise of warrants. Doron Breen has the power to vote or dispose of the shares.

(14) Includes 129,310 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 83,753 dividend shares and 38,793 shares of common stock issuable upon exercise of warrants. I Wistar Morris and Martha H. Morris, Co-Trustees have the power to vote or dispose of the shares.

(15) Includes 107,758 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 69,794 dividend shares and 32,327 shares of common stock issuable upon exercise of warrants.

(16) Includes 172,413 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 111,670 dividend shares and 51,723 shares of common stock issuable upon exercise of warrants. I. Wistar Morris III has the power to vote or dispose of the shares.

(17) Includes 107,758 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 69,794 dividend shares and 32,327 shares of common stock issuable upon exercise of warrants. Martha H. Morris, Agent has the power to vote or dispose of the shares.

(18) Includes 323,275 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 888,889 shares of common stock issuable upon conversion of shares of Series B Preferred Stock, 209,382 dividend shares and 541,426 shares of common stock issuable upon exercise of warrants. Adam Usdan has the power to vote or dispose of the shares.

(19) Includes 12,931 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 8,375 dividend shares and 3,879 shares of common stock issuable upon exercise of warrants. Adam Usdan has the power to vote or dispose of the shares.

(20) Includes 525,862 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 340,595 dividend shares and 157,758 shares of common stock issuable upon exercise of warrants. Adam Usdan has the power to vote or dispose of the shares.

(21) Includes 107,758 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 69,794 dividend shares and 32,327 shares of common stock issuable upon exercise of warrants. Lindsay A. Rosenwald, M.D. is the managing member of Otago Partners, LLC. Dr. Rosenwald is also the sole shareholder and Chairman of Paramount BioCapital, Inc., an NASD member broker-dealer, and Paramount BioCapital Asset Management, Inc., an investment adviser registered with the SEC.

(22) Includes 431,034 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 279,176 dividend shares and 129,310 shares of common stock issuable upon exercise of warrants. Heights Capital Management, Inc., the authorized agent of Capital Ventures International ("CVI"), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, Investment Manager of Heights Capital Management, Inc. may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any beneficial ownership of such shares and warrants, except to the extent of any pecuniary interest therein.

(23) Includes 215,517 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 139,588 dividend shares and 64,655 shares of common stock issuable upon exercise of warrants. Joshua Silverman has

voting and investment control over the shares held by Iroquois Master Fund Ltd. Mr. Silverman disclaims beneficial ownership of these shares.

(24) Includes 431,034 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 279,176 dividend shares and 129,310 shares of common stock issuable upon exercise of warrants. Rockmore Capital, LLC ("Rockmore Capital") and Rockmore Partners, LLC ("Rockmore Partners"), each a limited liability company formed under the laws of the State of Delaware, serve as the investment manager and general partner, resectively, to Rockmore Investments (US) LP, a Delaware limited partnership, which invests all of its assets through Rockmore Investment Master Fund Ltd., an exempted company formed under the laws of Bermuda ("Rockmore Master Fund"). By reason of such relationships, Rockmore Capital and Rockmore Partners may be deemed to share dispositive power over the shares of common stock owned by Rockmore Master Fund.

Rockmore Capital and Rockmore Partners disclaim beneficial ownership of such shares of common stock. Rockmore Partners has delegated authority to Rockmore Capital regarding the portfolio management decisions with respect to the shares of common stock owned by Rockmore Master Fund and, as of May 22, 2007 Mr. Bruce T. Bernstein and Mr. Brian Daly, as officers of Rockmore Capital are responsible for the portfolio and management decisions of the shares of common stock owned by Rockmore Master Fund. By reason of such authority, Messrs. Bernstein and Daly may be deemed to share dispositive power over the shares of common stock owned by Rockmore Master Fund. Messrs. Bernstein and Daly disclaim beneficial ownership of such shares of common stock and neither of such persons has any legal right to maintain such authority. No other person has sole or shared voting or dispositive power with respect to the shares of common stock as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. No person or "group" (as that term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Rockmore Master Fund.

(25) Includes 258,620 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 167,506 dividend shares and 77,586 shares of common stock issuable upon exercise of warrants. Eric S. Swartz has the power to vote or dispose of the shares.

(26) Includes 64,655 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 41,876 dividend shares and 19,396 shares of common stock issuable upon exercise of warrants.

(27) Includes 5,603 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 3,629 dividend shares and 1,680 shares of common stock issuable upon exercise of warrants. Reitler Brown & Rosenblatt LLC are counsel to us. Mr. Scott Rosenblatt, John Watkins, Robert Brown and Edward Reitler have the power to vote or dispose of the shares.

(28) Includes 21,551 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 13,959 dividend shares and 6,465 shares of common stock issuable upon exercise of warrants. Mr. Ohad Rozen has the power to vote or dispose of the shares.

(29) Includes 43,103 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 27,918 dividend shares and 21,335 shares of

common stock issuable upon exercise of warrants. Mr. Shaul Elovitch and Mr. Rabinovitch Alex have the power to vote or dispose of the shares.

(30) Includes 8,620 shares of common stock issuable upon conversion shares of Series C Preferred Stock, 5,584 dividend shares and 2,586 shares of common stock issuable upon exercise of warrants and 10,000 options to purchase our shares of common stock. Mr. Dash is a member of our Board of Directors.

(31) Consists of shares of common stock issuable upon exercise of warrants. Oppenheimer & Co. Inc. is a broker-dealer who acquired 133,998 warrants to purchase our common stock as compensation for serving as our placement agent in the private placement.

(32) Includes 270,637 shares of common stock issuable upon exercise of warrants. Ledgemont Capital Group, LLC ("Ledgemont") was assigned these shares by Indigo Securities LLC ("Indigo"). Indigo acquired 36,045 warrants to purchase our common stock for serving as a selected dealer to our placement agent in the private placement. Mr. Edward Neugeboren, a member of our Board of Directors, was a consultant of Indigo and is currently managing director of Ledgemont.

(33) Consists of shares of common stock issuable upon exercise of warrants. Boenning & Scattergood, Inc. is a broker-dealer who acquired its warrants as compensation for serving as a selected dealer to our placement agent in the private placement.

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. Reitler Brown & Rosenblatt LLC is also a Selling Stockholder of 10,912 shares of common stock.

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, 2007, filed with the Commission on June 28, 2007;

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 with 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.