ELITE PHARMACEUTICALS INC /DE/
Form 424B1
April 26, 2006

Filed Pursuant to Rule 424B1
Registration No. 333-133304

PROSPECTUS

ELITE PHARMACEUTICALS

COMMON STOCK

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This is an offering (the "OFFERING") of up to 246,175 shares of Common Stock, $.01 par value (the "COMMON STOCK"), of Elite Pharmaceuticals, Inc. (the "COMPANY" or "ELITE"), by the selling stockholders named in this prospectus (the "SELLING STOCKHOLDERS") acquired upon exercise of warrant to purchase Common Stock, expiring on or prior to December 14, 2010 (the "REPLACEMENT WARRANTS"), issued by the Company in a private placement.

The Common Stock is listed on the American Stock Exchange under the symbol "ELI." On April 13, 2006, the closing sales price of our Common Stock on the American Stock Exchange was $2.20 per share.

SEE "RISK FACTORS" BEGINNING ON PAGE 5 FOR A DISCUSSION OF FACTORS THAT YOU SHOULD CONSIDER BEFORE BUYING SHARES OF OUR COMMON STOCK.

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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.

We will receive no proceeds from the sale of the shares of Common Stock sold by the Selling Stockholders.

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The date of this prospectus is April 25, 2006.

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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.

Elite has 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 its 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 Elite's 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

Elite is a specialty pharmaceutical company principally engaged in the development and manufacture of oral, controlled release products. Elite develops controlled release products using proprietary technology and licenses these products. The Company's strategy includes developing generic versions of controlled release drug products with high barriers to entry and assisting partner companies in the life cycle management of products to improve off-patent drug products. Elite's technology is applicable to develop delayed, sustained or targeted release pellets, capsules, tablets, granules and powders. Elite has one product currently being sold commercially and a pipeline of eight drug products under development in the therapeutic areas that include cardiovascular, pain management, allergy and infection. The addressable market for Elite's pipeline of products exceeds $6 billion. Elite's facility in Northvale, New Jersey also is a Good Manufacturing Practice (GMP) and DEA registered facility for research, development, and manufacturing.

We have concentrated on developing orally administered controlled release drug products. These products include drugs that cover therapeutic areas for pain, angina, hypertension, allergy and infection. One of our products, Lodrane24(R), has been commercially developed and is being marketed by ECR Pharmaceuticals, our partner for this product.

In an effort to reduce costs, improve focus and enhance efficiency, we reduced the number of products that we are actively developing from fifteen to nine. The nine products, one of which has been commercially developed and eight that are in development, are deemed by us to be the most suitable for development given our limited resources.

STRATEGY

We are focusing our efforts on the following areas: (i) manufacturing of Lodrane 24(R) product, (ii) the development of the other products in our pipeline, (iii) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of tablets and capsules using our formulations, and (iv) development of new products and the



expansion of our licensing agreements with other pharmaceutical companies, including co-development projects, joint ventures and other collaborations.

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

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

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

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 and Section 21E of the Securities Exchange Act) that reflect Elite's 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, 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, the Company undertakes 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 ELITE AND IN ANALYZING OUR FORWARD-LOOKING STATEMENTS.

OUR CONTINUING LOSSES ENDANGER OUR VIABILITY AS A GOING-CONCERN AND HAVE CAUSED OUR AUDITORS TO ISSUE "GOING CONCERN" ANNUAL AUDIT REPORTS.

We reported net losses of $4,648,549, $5,906,890, $6,514,217 and $4,061,422 for the nine months ended December 31, 2005 and for the years ended March 31, 2005, 2004 and 2003, respectively. At December 31, 2005, we had an accumulated deficit of approximately $45.8 million, consolidated assets of approximately $8.3 million, stockholders' equity of approximately $3.0 million, and working capital of approximately $2.0 million. Our products are in the development and early deployment stage and have not generated any significant revenue to date. Our independent auditors have issued a "going concern" audit report for our financial statements for each of the fiscal years ended March 31, 2005, March 31, 2004 and March 31, 2003.

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 enter new markets. 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 $4,648,549, $5,906,890, $6,514,217, $4,061,422, and $1,774,527 for the nine months ended December 31, 2005 and for the years ended March 31, 2005, 2004, 2003 and 2002, respectively. We expect to realize significant losses for the current year of operation. We expect to continue to incur losses until we

are able to generate sufficient revenues to support our operations and offset operating costs.

OUR FOUNDER AND FORMER PRESIDENT AND CHIEF EXECUTIVE OFFICER RESIGNED IN JUNE 2003 ALL OF HIS POSITIONS WITH ELITE, WHICH MAY HAVE A MATERIAL ADVERSE EFFECT ON US.

On June 3, 2003, Dr. Atul M. Mehta, our founder and former President and Chief Executive Officer resigned from all of his positions with Elite. In the past, we relied on Dr. Mehta's scientific expertise in developing our products. There can be no assurance that we will successfully replace Dr. Mehta's expertise. In addition, the loss of Dr. Mehta's services may adversely affect our relationships with our contract partners.

Pursuant to an agreement in April 2004 and a related agreement in October 2004, to settle a litigation initiated by Dr. Mehta in July 2003 for alleged breach of his employment agreement, the Company extended the expiration dates to November 30, 2007 of options to purchase 670,000 shares of Common Stock held by Dr. Mehta and reduced the exercise price of certain of the options and he relinquished any rights to the Company's intellectual property and agreed to certain non-disclosure and non-competition covenants. The Company also provided him with certain "piggyback" registration rights with respect to the shares issuable upon exercise of the



foregoing options granted by the Company. Dr. Mehta and members of his family sold in October 2004 an aggregate of 1,362,200 shares of Common Stock representing all of his and his affiliates holdings of securities of the Company except for the foregoing options.

OUR RESEARCH ACTIVITIES ARE CHARACTERIZED BY INHERENT RISK AND WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP PRODUCTS FOR COMMERCIAL USE THAT ARE IN OUR PIPELINE.

Our research activities are characterized by the inherent risk that the research will not yield results that will receive FDA approval or otherwise be suitable for commercial exploitation.

As of December 31, 2005, we have entered into agreements with respect to the marketing upon development of four drugs. Each agreement provides that we are to commercially develop or co-develop with the partner the product and upon securing by a partner or partners having FDA approval or other regulatory approval, and if required, we are to manufacture the product and sell it to a partner or marketing partner for distribution. The commercial development of one of the four drugs has been completed and the three other drugs are under development. No assurance can be given that sales, if any, by any marketing partner will result in profit for Elite from the product.

We have also entered into two additional co-development agreements. These products are currently in development. No assurance can be given that we will be successful in developing these products, and, if successful, that an agreement can be reached with a marketing partner for the sale of the products or that any sales of the products will result in profit for Elite.

We are also developing three additional products on our own. Two are in pilot Phase I studies and one is in the pilot bioequivalence stage. Additional studies including either pivotal bioequivalence or efficacy studies will be required for these products before commercialization.

In order for any of these products to be commercialized, the FDA requires successful completion of pivotal biostudies to file an ANDA and successful completion of pivotal clinical trials before filing a NDA. The FDA next requires successful completion of comparative studies for drug listed products. ANDAs are filed with respect to generic versions of existing FDA approved products while NDAs are filed with respect to new products.

WE COULD EXPERIENCE DIFFICULTY IN DEVELOPING AND INTEGRATING STRATEGIC ALLIANCES, CO-DEVELOPMENT OPPORTUNITIES AND OTHER RELATIONSHIPS.

With respect to products that are being developed and are available for partnering, we intend to pursue product-specific licensing, marketing agreements, co-development opportunities and other partnering arrangements in connection with the products. We have entered into partnership arrangements as to six products but no assurance can be given that we will be able to locate partners for our other products or that any arrangement is or will be suitable. In addition, assuming we identify suitable partners, the process of effectively entering into these arrangements involves risks such that our management's attention may be diverted from other business concerns and that we may have difficulty integrating the new arrangements into our existing business.



OUR LIMITED EXPERIENCE IN CONDUCTING CLINICAL TRIALS AND SUBMITTING NDAS AND THE UNCERTAINTIES INHERENT IN CLINICAL TRIALS COULD RESULT IN DELAYS IN PRODUCT DEVELOPMENT AND COMMERCIALIZATION.

Prior to seeking FDA approval for the commercial sale of any drug we develop, which does not qualify for the FDA's abbreviated application procedures, we or our partner must demonstrate through clinical trials that these products are safe and effective for use. We have limited experience in conducting and supervising clinical trials. The process of completing clinical trials and preparing an NDA may take several years and requires substantial resources. Our studies and filings may not result in FDA approval to market our new drug products and, if the FDA grants approval, we cannot predict the timing of any approval.

IF OUR CLINICAL TRIALS ARE NOT SUCCESSFUL OR TAKE LONGER TO COMPLETE THAN WE EXPECT, WE MAY NOT BE ABLE TO DEVELOP AND COMMERCIALIZE OUR PRODUCTS.

In order to obtain regulatory approvals for the commercial sale of our potential products, we will be required to complete clinical trials in humans to demonstrate the safety and efficacy of the products. We may not be able to obtain authority from the FDA or other regulatory agencies to commence or complete these clinical trials.

The results from preclinical testing of a product that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale advanced stage clinical trials. Furthermore, we or the FDA may suspend clinical trials at any time if the subjects participating in such trials are being exposed to unacceptable health risks, or for other reasons.

The rate of completion of clinical trials is dependent in part upon the rate of enrollment of subjects. A favorable clinical trial result is a function of many factors including the size of the subject population, the proximity of subjects to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. Delays in planned subject enrollment may result in increased costs and program delays.

We may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show any potential product to be safe or efficacious. Thus, the FDA and other regulatory authorities may not approve any of our potential products for any indication.

Our business, financial condition, or results of operations could be materially adversely affected if:

- we are unable to complete a clinical trial of one of our potential products;
- the results of any clinical trial are unfavorable; or
- the time or cost of completing the trial exceeds our expectations.



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.

IF THE COMPANY IS UNABLE TO OBTAIN ADDITIONAL FINANCING NEEDED FOR THE EXPENDITURES FOR THE DEVELOPMENT AND COMMERCIALIZATION OF THE COMPANY'S DRUG PRODUCTS, IT WOULD IMPAIR THE COMPANY'S ABILITY TO CONTINUE TO MEET ITS BUSINESS OBJECTIVES.

On March 15, 2006, the Company completed a private placement, for aggregate gross proceeds of $10,000,000, of 10,000 shares of its Series B Preferred Stock convertible into 4,444,444 shares of Common Stock and warrants to purchase an aggregate of 2,222,222 shares of Common Stock, 50% of such warrants having an exercise price of $2.75 and the remaining 50% having an exercise price of $3.25. Additionally, the placement agent received warrants to purchase 355,555 shares of Common Stock with an exercise price of $2.25. As of March 31, 2006, the Company had aggregate cash and cash equivalents of approximately $10,500,000, which the Company anticipates is adequate to finance its operations for the next 12 to 18 months. Thereafter, the Company will require additional financing to insure that the Company will be able to meet the expenditures to develop and commercialize its products for which the Company has no current arrangements. Other possible sources of the required financing are the cash exercise of the Long Term Warrants issued in the October 2004 private placement, the Replacement Warrants issued in the December 2005 private placement and other warrants and



options that are currently outstanding. No representation can be made that the Company will be able to obtain 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. The Company's inability to obtain additional financing when needed would impair its ability to continue its business.

If any future financing involves the further sale of the Company's securities, the Company's then-existing stockholders' equity could be substantially diluted. On the other hand, if the Company incurred debt, the Company 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.

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, competitive position and amount of royalty income, if any, will depend in part on our ability to obtain patent protection in various jurisdictions related to our technologies, processes and products. We intend to file patent applications seeking such protection, but 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 patents may not prevent third parties from developing similar or competing products. In addition, although we are not aware of any threatened or pending actions by third parties asserting that we have infringed on their patents, and are not aware of any actions we have taken that would lead to such a claim, it is possible that we might be sued for infringement. The cost involved in bringing suits against others for infringement of our patents, or in defending any suits brought against us, can be substantial. We may not possess sufficient funds to prosecute or defend such suits. If our products were found to infringe upon patents issued to others, we would be prohibited from manufacturing or selling such products and we could be required to pay substantial damages.

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 also rely upon trade secrets and proprietary know-how. We seek to protect this know-how in part by confidentiality agreements. We consistently require our employees and potential business partners to execute confidentiality agreements prior to doing business with us. However, it is possible that an employee would disclose confidential information in violation of his or her agreement, or that our trade secrets would otherwise become known or be independently developed in such a manner that we will have no practical recourse.



We are not engaged in any litigation, nor contemplating any, with regard to a claim that someone has infringed one of our patents, revealed any of our trade secrets, or otherwise misused our confidential information.

THE PHARMACEUTICAL INDUSTRY IS SUBJECT TO EXTENSIVE FDA REGULATION AND FOREIGN REGULATION, WHICH PRESENTS NUMEROUS RISKS TO US.

The manufacturing and marketing of pharmaceutical products in the United States and abroad are subject to stringent governmental regulation. The sale of any of our products for use in humans in the United States will require the approval of the FDA. Similar approvals by comparable agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacture and marketing of pharmaceutical products. Obtaining FDA approval for a new therapeutic product may take several years and involve substantial expenditures. The eight products currently under development have not yet been approved for sale or use in humans in the United States or elsewhere.

If we or our licensees fail to obtain or maintain requisite governmental approvals or fail to obtain or maintain approvals of the scope requested, it will delay or preclude us or our licensees or marketing partners from marketing our products. It could also limit the commercial use of our products.

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.

IF KEY PERSONNEL WERE TO LEAVE ELITE 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 controlled release drug delivery systems and 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 having a maximum limit of $5,000,000; 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, 2006.

OUR STOCK PRICE HAS BEEN VOLATILE AND MAY FLUCTUATE IN THE FUTURE.

There has been significant volatility in the market prices for publicly traded shares of pharmaceutical companies, including ours. For the twelve months ended March 31, 2006, the closing sale price on the American Stock Exchange of our Common Stock fluctuated from a high of $4.42 per share to a low of $1.68 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.

As of this date sales of substantial amounts of the Common Stock in the public market are eligible for sale by these holders pursuant to exemption or registration under the Securities Act. Perceptions that substantial sales may take place in the future may lower the Common Stock's market price.

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

On January 4, 2006, the Company received a letter from the American Stock Exchange ("AMEX") notifying it that, based on the Company's unaudited financial statements as of September 30, 2005, the Company is not in compliance with the continued listing standards set forth in the AMEX Company Guide in that under one listing standard its shareholders' equity is less than $4,000,000 and it had losses from continuing operations and/or net losses in three of its four most recent fiscal years and under another listing standard its shareholders' equity is less than $6,000,000 and it had losses from continuing operations and/or net losses in its five most recent fiscal years. The Company, at the request of AMEX, submitted a plan on February 3, 2006 advising AMEX of action, it has taken, and will take, to bring it in compliance with the continued listing standards within a maximum of 18 months from January 4, 2006. On March 15, 2006, the Company completed a private placement of its Series B Preferred Stock and warrants to purchase Common Stock. The Company received $10,000,000 in gross proceeds from the private placement. On March 21, 2006, the Company submitted an update to the plan it had previously submitted on February 6, 2006. Upon notice of the recent private placement and the acceptance of the updated plan, AMEX provided the Company with an extension until July 3, 2007 to regain compliance with the continued listing standards. AMEX will allow the Company to maintain its AMEX listing through the plan period, subject to periodic review of the Company's progress by the AMEX staff. If the Company is not in compliance with the continued listing standards or does not make progress consistent with such plan during the plan period, AMEX may then initiate delisting proceedings. The failure to maintain listing of the Common Stock on AMEX will have an adverse effect on the market and the market price for the 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 the Company's Common Stock or the issuance of shares of an additional series of Preferred Stock could be used to make a change of control of the Company 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 the Company. 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 its 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 the Company's Common Stock to acquire control of the Company with a view to consummating a merger, sale of all or part of the



Company's 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 the Company, 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

The Company will not receive any proceeds from the sale of shares of Common Stock by the Selling Stockholders by this prospectus. The proceeds (a maximum of approximately $738,525) of the prior sale by the Company to the Selling Stockholders of up to 246,175 shares of Common Stock upon exercise of the Replacement Warrants will be used for working capital.

## DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 65,000,000 shares of Common Stock, par value $.01 per share, and 5,000,000 shares of Preferred Stock, par value $.01 per share (the "PREFERRED STOCK"), including shares of Series A Preferred Stock consisting of 143,442 shares, none of which are outstanding, and including shares of Series B 8% Convertible Preferred Stock (the "SERIES B PREFERRED STOCK"), consisting of 10,000 shares, all of which are outstanding. As of March 31, 2006, there were outstanding 19,190,159 shares of Common Stock, 10,000 shares of Series B Preferred Stock, options to purchase 2,971,250 shares of our Common Stock and warrants to purchase 5,572,019 shares of Common Stock.

### COMMON STOCK

SUBJECT TO THE RIGHTS OF THE HOLDERS OF ANY SERIES OF PREFERRED STOCK, WHICH MAY BE ISSUED:

The holders of outstanding shares of Common Stock are entitled to receive dividends out of assets legally available therefore at such times and in such amounts as our Board of Directors may from time to time determine.

Each stockholder is entitled to one vote for each share of Common Stock held on all matters submitted to a vote of stockholders.

The Common Stock is not entitled to preemptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of Elite, the remaining assets legally available for distribution to stockholders, after payment of claims or creditors, are distributable



ratably among the holders of the Common Stock outstanding at that time. Each outstanding share of Common Stock is fully paid and nonassessable.

See "PREFERRED STOCK" for senior rights of outstanding shares of Series A Preferred Stock with respect to dividends and liquidation and their rights to participate on as a converted basis with the Common Stock in liquidation payments to Common Stock and voting.

### PREFERRED STOCK

The Company's Board of Directors has authority to issue up to 5,000,000 shares of Preferred Stock in one or more series and to fix the powers, designations, rights, preferences and restrictions thereof, including dividend rights, conversion rights, voting rights, redemption terms, liquidation preferences and the number of shares constituting each such series, without any further vote or action by the Company's stockholders.

SERIES A PREFERRED STOCK. On October 6, 2004, pursuant to the authority of its Board of Directors, the Company filed with the Secretary of State of Delaware the Certificate of Designations, Preferences and Rights of Series A Preferred Stock (the "SERIES A PREFERRED CERTIFICATE") providing for 660,000 authorized shares. On March 10, 2006 the Company filed a Certificate of Retirement with the Secretary of State of Delaware to retire 516,558 shares of Series A Preferred Stock. No shares of Series A Preferred Stock are outstanding.

SERIES B PREFERRED STOCK. On March 15, 2006, pursuant to the authority of its Board of Directors, the Company filed with the Secretary of State of Delaware the Certificate of Designations, Preferences and Rights of Series B Preferred Stock (the "SERIES B PREFERRED CERTIFICATE") providing for 10,000 authorized shares.

In March 2006, the Company in a private placement issued an aggregate of 10,000 shares of Series B Preferred Stock and warrants, expiring March 15, 2011, to purchase 2,222,222 shares of Common Stock.

The Series B Preferred Stock accrue dividends at the rate of 8% per annum on their purchase price of $1,000 per share (increasing to 15% per annum after March 15, 2008) payable quarterly on January 1, April 1, July 1 and October 1, in cash or shares of Common Stock (95% of the average of the volume weighted average price ("VWAP") for the 20 consecutive trading days ending on the trading day that is immediately prior to the dividend payment date) in accordance with the terms of the Series B Preferred Certificate. Any dividends, whether paid in cash or shares of Common Stock, that are not paid within 5 trading days, following a dividend payment date, shall continue to accrue and shall entail a late fee, which must be paid in cash, at the rate of 18% per annum or the lesser rate permitted by applicable law (such fees to accrue daily, from the dividend payment date through and including the date of payment). The first payment to be made on April 1, 2006. No payment or dividends may be payable on Common Stock or any other capital stock ranked junior to the Series B Preferred Stock prior to the satisfaction of the dividend obligation on the Series B Preferred Stock.

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Upon the liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary ("LIQUIDATION"), each share of Series B Preferred Stock is to be entitled to a preference equal to the Stated Value (the per share purchase price ($1,000 subject to adjustment)), plus any accrued but unpaid dividends thereon and any other fees or liquidated damages owing thereon which preference is prior to any other capital stock ranked junior to the Series B Preferred Stock.

The holders of Series B Preferred Stock do not have any voting rights except as specifically provided in the Series B Preferred Certificate or as required by law. The Company may not without the prior affirmative vote of holders of at least 70% of the then outstanding shares of Series B Preferred Stock: (i) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Series B Preferred Certificate, (ii) authorize or create any class of stock ranking as to dividends, redemption or distribution of assets upon a Liquidation senior to or otherwise pari passu with the Series B Preferred Stock, (iii) amend its certificate of incorporation, bylaws or other charter documents in any manner that adversely affects any rights of the holders of the Series B Preferred Stock, (iv) increase the authorized number of shares of Series B Preferred Stock, (v) enter into any agreement with respect to any of the foregoing, (vi) other than Permitted Indebtedness (as defined in the Preferred Certificate) prior to March 16, 2009 incur any indebtedness for borrowed money of any kind,

(vii) other than Permitted Liens (as defined in the Series B Preferred Certificate) prior to March 16, 2009, incur any liens of any kind, (viii) other than as permitted by the Series B Preferred Certificate, repay or repurchase other than more than a de minimis number of shares of Common Stock or securities convertible or exchangeable into Common Stock, (ix) pay cash dividends or distributions on any of our securities junior to the Series B Preferred Stock or (x) enter into any agreement or understanding with respect to clauses (iii), (vi), (vii), or (viii). Notwithstanding the above, the Company may issue any security issued in connection with a Strategic Transaction (as defined in the Series B Preferred Certificate) that ranks as to dividends, redemption or distribution of assets upon a Liquidation pari passu with or junior to the Series B Preferred Stock without the prior affirmative vote of holders of the then outstanding shares of Series B Preferred Stock.

Each share of Series B Preferred Stock is initially convertible into 444.4444 shares of Common Stock at $2.25 initial conversion price, subject to adjustment for certain events, including dividends, stock splits, combinations and the sale of Common Stock or securities convertible into or exercisable for Common Stock at a price less than the then applicable conversion price. If the Company does not meet its share delivery requirements set forth in the Series B Preferred Certificate, the holders of Preferred Stock shall be entitled to (i) liquidated damages, payable in cash, and (ii) cash equal to the amount by which such holder's total purchase price for the shares of Common Stock exceeds the product of (1) the aggregate number of shares of Common Stock that such holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed.

The Company may force conversion of the Series B Preferred Stock in the event the Company provides written notice to the holders of the Series B Preferred Stock that the VWAP (as defined in the Series B Preferred Certificate) for each 20 consecutive trading day period



during a Threshold Period (as defined in the Series B Preferred Certificate) of Common Stock exceeded $5.38 (subject to adjustment) and the volume for each trading day during such Threshold Period exceed 50,000 shares (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like).

Upon the occurrence of certain Triggering Events (as defined in the Preferred Certificate), each share of Series B Preferred Stock is to be redeemed for cash in an amount equal to (i) 130% of the Stated Value, (ii) all accrued but unpaid dividends thereon and (iii) all liquidated damages and other costs, expenses or amounts due in respect of the Series B Preferred Stock (the "TRIGGERING REDEMPTION AMOUNT"). If at any time the SEC, the Company's auditors, American Stock Exchange (or similar trading exchange) or any other governmental or regulatory authority having jurisdiction over the Company determines that a Triggering Event for which a holder shall be entitled to a cash redemption constitutes a condition for redemption which is not solely within the control of the Company (as set forth in Item 28 of Rule 5-02 of Regulation S-X of the Securities Exchange Act of 1934, as amended), or that as a result of any such Triggering Event, the Series B Preferred Stock shall not be included in the Company's balance sheet under the heading "stockholder equity", then the holders of Series B Preferred Stock shall not be entitled to receive a cash payment, but instead shall be entitled to receive shares of Common Stock in the manner described in the next sentence. Upon the occurrence of certain other Triggering Events, each share of Series B Preferred Stock is to be redeemed for shares of Common Stock equal to the number of shares of Common Stock equal to the

Triggering Redemption Amount divided by 85% of the average of the VWAP for the 10 consecutive trading days immediately prior to the date of the redemption.

The Company may redeem all of the Series B Preferred Stock outstanding, at any time after March 15, 2008 for a redemption price, payable in cash, for each share of Series B Preferred Stock equal to (i) 150% of the Stated Value, (ii) accrued but unpaid dividends thereon and (iii) all liquidated damages and other amounts due in respect of the Series B Preferred Stock.

ANTI-TAKEOVER PROVISIONS

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. Section 203 of the Delaware Law provides, subject to a number of exceptions, that a Delaware corporation may not engage in any of a broad range of business combinations with a person or an affiliate, or an associate of an affiliate, who is an "interested stockholder" for a period of three years from the date that person became an interested stockholder unless:

- the transaction resulting in a person becoming an interested stockholder, or the business combination, is approved by the board of directors of the corporation before the person becomes an interested stockholder,

- the interested stockholder acquired 85% or more of the outstanding voting stock of the corporation in the same transaction that makes this person an interested stockholder, excluding shares owned by persons who are both officers and directors of the corporation, and the shares held by certain employee stock ownership plans, or



- on or after the date the person becomes an interested stockholder, the business combination is approved by the corporation's board of directors and by the holders of at least 66-2/3% of the corporations outstanding voting stock at an annual or special meeting, excluding the shares owned by the interested stockholder.

Under Section 203 of the Delaware Law, an "interested stockholder" is defined as any person who is either the owner of 15% or more of the outstanding voting stock of the corporation or an affiliate or associate of the corporation and who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within the three-year period immediately prior to the date on which it is sought to be determined whether such person is an interested stockholder.

A corporation may, at its option, exclude itself from coverage of Section 203 of the Delaware Law by amending its certificate of incorporation or by-laws, by action of its stockholders, to exempt itself from coverage, provided that the amendment to the certificate of incorporation or by-laws does not become effective until 12 months after the date it is adopted.



SELLING STOCKHOLDERS

The Selling Stockholders are offering shares of our Common Stock acquired upon exercise of Replacement Warrants. The Replacement Warrants were issued in a private placement, to those holders of our Short Term Warrants and Long Term

Warrants who exercised for cash a five year replacement warrant exercisable at a price of $3.00 per share for the number of shares of our Common Stock as is equal to 30% of the aggregate number of shares of Common Stock acquired upon exercise of such Long Term and/or Short Term Warrant for cash. We paid Indigo Securities, LLC, the Placement Agent, and its selected dealers cash commissions aggregating $76,418.37 and issued to them warrants to purchase an aggregate of 25,473 shares of Common Stock. at a price of $3.00 per share.

We have agreed to file, at our expense, the Registration Statement of which this prospectus is a part to register for reoffering the shares of Common Stock acquired upon exercise of the Replacement Warrants.

The following table details the name of each Selling Stockholder, the number of shares of our Common Stock owned by each Selling Stockholder and the number of shares of our Common Stock that may be offered for resale under this prospectus. To the extent permitted by law, the Selling Stockholders which are not natural persons may distribute shares from time to time, to one or more of their respective affiliates, which may sell shares pursuant to this prospectus. We have registered the shares to permit the Selling Stockholders and their respective permitted transferees or other successors in interest that receive their shares from Selling Stockholders after the date of this prospectus to resell the shares. Because each Selling Stockholder may offer all, some or none of the shares it holds, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, no definitive estimate as to the number of shares that will be held by each Selling Stockholder after the offering can be provided. The Selling Stockholders may from time to time offer all or some of the shares pursuant to this offering. Pursuant to Rule 416 under the Securities Act of 1933, the Registration Statement of which this prospectus is a part also covers 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.

The following 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 by footnote, the Selling Stockholders have sole voting and investment power with their respective shares. Percentages in the table below are based on 19,190,159 shares of our Common Stock outstanding as of March 31, 2006 and assumes that all of the Replacement Warrants will have been exercised.

No selling stockholders are broker-dealers or affiliates or employees of broker-dealers other than Indigo Securities, LLC, Eric Brachfeld and Edward Neugeboren.

Except as described below, none of the selling stockholders within the past three years has had any material relationship with us or any of our affiliates:

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- Mr. Chris Dick, is the Executive Vice President of Corporate Development of the Company;
- Dr. Charan Behl is the Executive Vice President and Chief Scientific Officer of the Company;
- Indigo Securities, LLC has acted as a placement agent and as a financial advisor to the Company;

- Mr. Edward Neugeboren is a current director of the Company and an employee of Indigo Securities, LLC;
- Mr. Myron Neugeboren is the father of Mr. Edward Neugeboren; and
- Mr. Eric Brachfeld is the managing member of Indigo Securities, LLC.

| Name and Address | Shares Beneficially Owned Prior to Offering* | Number of Shares Which May Be Sold* | Shares Owned After Offering Number | S |
|---|---|---|---|---|
| Chris Dick and Hedy E. Rogers<br>3043 Comfort Road<br>New Hope, PA 18938 | 135,377(1) | 2,439 | 132,938 | |
| Wheaten HealthCare Partners LP<br>212 Durham Avenue, Building 1, Suite 201<br>Metuchen, NJ 08840 | 383,738(2) | 30,488 | 353,250 | |
| Charan R. Behl, Ph.D.<br>658 Veterans Memorial HWY,<br>Apt. 1A Hanppange, NY 11788 | 546,000(3) | 30,000 | 516,000 | |
| Eric Brachfeld<br>890 West End Ave., Apt. 16D,<br>New York, NY 10025 | 85,534(4) | 1,500 | 84,034 | |
| Myron Neugeboren<br>199 Wells Hill Road<br>Lakeville, CT 06039 | 44,340(5) | 3,049 | 41,291 | |
| Edward Neugeboren<br>282 New Norwalk Road<br>New Canaan, CT 06840 | 221,063(6) | 3,049 | 218,014 | |
| Valor Capital Management<br>137 Rowagton Ave.<br>Rowagton, CT 06853 | 998,736(7) | 91,464 | 907,272 | |
| Neil V. Moody Revocable Trust<br>c/o Neil V. Moody<br>100 Sands Point Road, #305<br>Longboat Key, Fl 34228 | 127,949(8) | 14,144 | 113,805 | |
| Fineman Revocable Trust<br>c/o David Fineman<br>40 Lincoln Avenue<br>Piedmont, CA 94611 | 155,370(9) | 10,715 | 144,655 | |

| Name and Address | Shares Beneficially Owned Prior to Offering* | Number of Shares Which May Be Sold* | Shares Owned After Offering Number | S |
|---|---|---|---|---|
| RC II Ltd.<br>The Metropole<br>Roseville Street<br>St. Helier Jersey<br>Channel Islands, UK JEI 4HE | 233,044(10) | 16,071 | 216,973 | |
| Amy Daly<br>PO Box 882890<br>Steamboat Springs, CO 80488 | 82,146(11) | 10,715 | 71,431 | |
| Peter J. O'Gorman<br>Rosemary A. O'Gorman<br>31 Old Chimney Road<br>Upper Saddle River, NJ 07458 | 86,455(12) | 7,071 | 79,384 | |
| Indigo Securities, LLC<br>780 Third Avenue<br>New York, NY 10017 | 319,899 (13) | 25,473 | 294,426 | |

* The shares offered by the Private Placement Selling Stockholders are the shares which may be acquired by them upon exercise of Replacement Warrants.

** Less than 1%

(1) Includes 100,000 shares issuable upon exercise of options held by Mr. Dick, Long Term Warrants to purchase 8,130 shares of Common Stock and Replacement Warrants to purchase 2,439 shares of Common Stock held by Mr. Dick and Hedy Rogers as joint tenants.

(2) Includes Long Term Warrants to purchase 101,625 shares of Common Stock and Replacement Warrants to purchase 30,488 shares of Common Stock.

(3) Includes Long Term Warrants to purchase 100,000 shares of Common Stock and Replacement Warrants to purchase 30,000 shares of Common Stock. Dr. Behl is an executive officer of the Company.

(4) Includes Long Term Warrants to purchase 5,000 shares of Common Stock and Replacement Warrants to purchase 1,500 shares of Common Stock and other warrants to purchase 63,781 shares of Common Stock.

(5) Includes Long Term Warrants to purchase 10,163 shares of Common Stock and Replacement Warrants to purchase 3,049 shares of Common Stock.

(6) Includes 30,000 shares issuable upon exercise of options held by Mr. Neugeboren, Replacement Warrants to purchase 3,049 shares of Common Stock and Long Term Warrants to purchase 10,163 shares of Common Stock and other warrants to purchase 147,363 shares of Common Stock.

(7) Includes Long Term Warrants to purchase 304,880 shares of Common Stock and Replacement Warrants to purchase 91,464 shares of Common Stock.

(8) Includes Long Term Warrants to purchase 47,145 shares of Common Stock and Replacement Warrants to purchase 14,144 shares of Common Stock.

(9) Includes Long Term Warrants to purchase 35,715 shares of Common Stock and Replacement Warrants to purchase 10,715 shares of Common Stock.

(10) Includes Long Term Warrants to purchase 53,570 shares of Common Stock and Replacement Warrants to purchase 16,071 shares of Common Stock.

(11) Includes Long Term Warrants to purchase 35,715 shares of Common Stock and Replacement Warrants to purchase 10,715 shares of Common Stock.

(12) Includes Long Term Warrants to purchase 23,570 shares of Common Stock and Replacement Warrants to purchase 7,071 shares of Common Stock.



(13) Includes Replacement Warrants to purchase 25,473 shares of Common Stock and other warrants to purchase 294,426 shares of Common Stock.

## PLAN OF DISTRIBUTION

### OFFER AND SALE OF SHARES

A Selling Stockholder, including in such definition in this section, the Placement Agent and its associates, or a pledgee, donee, transferee or other successor-in-interest who receives shares offered by the prospectus from a Selling Stockholder as a gift, pledge, partnership distribution or other non-sale related transfer, may offer and sell shares in the following manner:

- on the American Stock Exchange ("AMEX") or otherwise at prices and at terms then prevailing or at prices related to the then current market price;
- at fixed prices, which may be changed; or
- in privately-negotiated transactions.

A Selling Stockholder or a pledgee, donee, transferee or other successor-in-interest who receives shares offered by this prospectus from a Selling Stockholder, may sell the shares in one or more of the following types of transactions at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices:

- a block trade in which a broker-dealer engaged to sell shares may sell all of such shares in one or more blocks as agent;
- a broker-dealer may purchase as principal and resell shares for its own account pursuant to this prospectus;
- an exchange distribution in accordance with the rules of the Amex or a quotation system;
- upon the exercise of options written relating to the shares;
- ordinary brokerage transactions or transactions in which the broker

solicits purchasers;

- a privately-negotiated transaction; and
- any combination of the foregoing or any other available means allowable under law.

From time to time, a Selling Stockholder may transfer, pledge, donate or assign its shares or replacement warrants to lenders or others and each of those persons will be deemed to be a "Selling Stockholder" for purposes of this prospectus. The number of shares beneficially owned by a Selling Stockholder may decrease as, when and if he takes such actions. The plan of distribution for the Selling Stockholder's shares sold under this prospectus will otherwise remain unchanged, except that the transferees, pledges, donees or other successors will become Selling



Stockholders under this prospectus. The Company will prepare and file an amendment to supplement to this prospectus to identify any additional Selling Stockholders.

A Selling Stockholder may enter into hedging, derivative or short sale transactions with broker-dealers in connection with sales or distributions of the shares being offered by this prospectus or otherwise. In these transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with the Selling Stockholder. A Selling Stockholder also may sell shares short and redeliver the shares to close out short positions and engage in derivative or hedging transactions. A Selling Stockholder may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of the shares. The broker-dealer may then resell or otherwise transfer the shares under this prospectus. A Selling Stockholder also may loan or pledge the shares to a broker-dealer. The broker-dealer may sell the loaned shares or upon a default the broker-dealer may sell the pledged shares under this prospectus.

SELLING THROUGH BROKER-DEALERS

A Selling Stockholder may select broker-dealers to sell its shares. Usual and customary or specifically negotiated brokerage fees or commissions may be paid by the Selling Stockholders. Broker-dealers so engaged may arrange for other broker-dealers, commissions or discounts or concessions in amounts to be negotiated immediately before any sale. In connection with such sales, these broker-dealers, any other participating broker-dealers, and a Selling Stockholder and certain pledges, donees, transferees and other successors-in-interest, may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, as amended (the "SECURITIES ACT") in connection with the sale of the shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Because a Selling Stockholder may be deemed to be an "underwriter" within the meaning of Section 2(11) of the Securities Act, the Selling Stockholder will be subject to the prospectus delivery requirements of the Securities Act.

Any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act or other exemption from registration may be sold under Rule 144 or such other exemption from registration rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sales of the shares covered by this prospectus.

Under current applicable rules and regulations of the Securities Exchange Act of 1934, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our Common Stock for a period of two business days prior to the commencement of such distribution. In addition, each Selling Stockholder will be subject to applicable provisions of the Securities Exchange Act of 1934 and the associated rules and regulations under the Securities Exchange Act of 1934, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our Common Stock by the Selling Stockholders. We will make copies of this prospectus available to the Selling Stockholders and inform them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares being offered pursuant to this prospectus.



The Selling Stockholders are not obligated to, and there is no assurance that the Selling Stockholders will, sell any or all of the shares.

We will bear all costs, expenses and fees in connection with the registration of the resale of the shares covered by this prospectus. The Selling Stockholders will pay any applicable underwriters' commissions and expenses, brokerage fees or transfer taxes.

## LEGAL MATTERS

Reitler Brown & Rosenblatt LLC, New York, New York, as counsel to the Company 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

Our consolidated financial statements as of March 31, 2005, March 31, 2004 and March 31, 2003 and for the years ended March 31, 2005, March 31, 2004 and March 31, 2003, incorporated by reference in this prospectus, have been audited by Miller, Ellin & Company, LLP, New York, New York, independent certified public accountants, as indicated in its report with respect thereto, and is incorporated by reference in this prospectus in reliance upon its report given upon the authority of said firm as experts in accounting and auditing.

## INCORPORATION BY REFERENCE

The Securities and Exchange 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, 2005, filed with the Commission on June 29, 2005;

b. our quarterly report on Form 10-Q for the quarter ended June 30, 2005, filed with the Commission on August 15, 2005;

c. our quarterly report on Form 10-Q for the quarter ended September 30, 2005, filed with the Commission on November 14, 2005;

d. our quarterly report on Form 10-Q for the quarter ended December 31, 2005, filed with the Commission on February 14, 2005; and



e. our current reports on Form 8-K dated January 4, 2006, January 10, 2006, January 31, 2006, March 9, 2006, March 10, 2006, March 15, 2006, March 22, 2006 and March 29, 2006.

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.