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ELITE PHARMACEUTICALS INC /DE/

Form S-3

November 16, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON NOVEMBER 16, 2004

REGISTRATION NO. 333-

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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

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

DELAWARE  
(State or other  
jurisdiction of  
incorporation or  
organization)

2834  
(Primary Standard Industrial  
Classification Code Number)

22-3542636  
(I.R.S. Employer  
Identification Number)

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

With copies to:

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

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

65878

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

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

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective Registration Statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

### CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED	PROPOSED MAXIMUM OFFERING PRICE PER SHARE (6)	PROPO MAXI AGGRE OFFER PRICE
Common Stock, \$.01 par value	6,024,119 (1)	\$1.69	\$10,180
Common Stock, \$.01 par value	2,582,790 (2)	\$1.84	\$4,752
Common Stock, \$.01 par value	3,077,721 (3)	\$1.84	\$5,663
Common Stock, \$.01 par value	1,362,200 (4)	\$1.69	\$2,302
Common Stock, \$.01 par value	696,500 (5)	\$3.00	\$2,089
TOTAL	----- 13,743,330		

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- (1) Shares to be offered upon conversion of 516,558 shares of Series A Preferred Stock issued in a private placement and up to 858,539 shares which the Series A Preferred Stockholders may receive in payment of dividends on the Series A Preferred Stock during the two year period from issuance of the Series A Preferred Stock based on an estimated fair market value of \$1.23 per share.
- (2) Shares to be offered upon exercise of Common Stock Purchase Warrants expiring December 31, 2005 issued in the private placement.

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- (3) Shares to be offered upon exercise of Common Stock Purchase Warrants issued in the private placement expiring on or prior to a date five years from the effective date of this Registration Statement.
- (4) Shares acquired from the former Chief Executive Officer of the Registrant.
- (5) Shares to be offered by other security holders included herein pursuant to registration obligations of Registrant other than those with respect to shares described in notes (1) through (4) above.
- (6) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, and based on the average of the high and low sale price per share of shares of the Common Stock on the American Stock Exchange on November 5, 2004 or with respect to the shares described in footnotes 2, 3 and 5, the higher of the foregoing price or the highest exercise price of the warrants or options which the holders of the shares to be offered is required to pay to exercise such options or warrants.

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The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

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PROSPECTUS

ELITE PHARMACEUTICALS

COMMON STOCK

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This is an offering (the "Offering") of the following shares of Common Stock, \$.01 par value, of Elite Pharmaceuticals, Inc. (the "Company" or "Elite"), by the selling stockholders named in this prospectus (the "Selling Stockholders"):

- (i) shares upon conversion of outstanding shares of Series A Preferred Stock, par value \$.01 per share acquired from the Company in a private placement and shares of Common Stock issued as a dividend on the Series A Preferred Shares;
- (ii) shares upon exercise of Common Stock Purchase Warrants expiring on or prior to December 31, 2005 (the "Short Term Warrants"), issued by the Company in the private placement;
- (iii) shares upon exercise of Common Stock Purchase Warrants expiring on or prior to a date five years from the date of this Prospectus (the "Long Term Warrants") issued by the Company in the private placement;
- (iv) shares acquired from a former Chief Executive Officer of the Company;

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- and  
(v) other shares previously acquired from the Company or to be acquired upon exercise of warrants or options acquired from the Company.

The Common Stock is listed on the American Stock Exchange under the symbol "ELI." On November [ ], 2004, the closing sales price of our Common Stock on the American Stock Exchange was \$\_\_\_ per share.

SEE "RISK FACTORS" BEGINNING ON PAGE 4 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 \_\_\_\_\_, 2004.

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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 450 Fifth Street, N.W., 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.

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. We assume no obligation to update the matters discussed in this prospectus.

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

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CONSOLIDATED FINANCIAL STATEMENTS AND THE RELATED NOTES AND THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS. REFERENCES IN THIS PROSPECTUS TO THE "COMPANY," "ELITE," "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.

### OUR BUSINESS

Elite engages primarily in researching, developing and licensing proprietary controlled release drug delivery systems and products. We are also equipped to manufacture controlled release products on a contract basis for third parties and for ourselves if, and when, our products are approved. Controlled release drug delivery of a pharmaceutical compound offers a safer and more effective means of administering drugs through releasing a drug into the bloodstream or delivering it to a certain site in the body at predetermined rates or predetermined times. The goal is to provide more effective drug therapy while reducing or eliminating many of the side effects associated with conventional drug therapy and/or to reduce the frequency of administration.

We have concentrated on developing orally administered controlled release products. These products include drugs that cover therapeutic areas for pain, angina, hypertension, allergy and infection. The Food and Drug Administration ("FDA") has not yet approved any of our products and, therefore, currently we do not market any products. Our products are at various stages of development.

We are focusing our efforts on the following areas: (i) obtaining FDA approval for one or more of six oral controlled release pharmaceutical products already in development, either directly or through other companies; (ii) commercial exploitation of these products either by license and the collection of royalties, or through the manufacture of tablets and capsules using our developed formulations, and (iii) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including contract research and development projects, joint ventures and other collaborations.

In an effort to reduce costs and improve focus and efficiency, we have reduced the number of products that we are actively developing from fifteen to six. The six products that continue in development were deemed by us to be the most suitable for continued development given our limited resources.

We are also focusing on the development of both branded drug products (which require new drug applications ("NDAs")) and generic drug products (which require abbreviated new drug applications ("ANDAs")).

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

We believe that our business strategy enables us to reduce our risk by:

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- o having a product portfolio that includes both branded and generic products in various therapeutic categories; and
- o building collaborations and establishing licensing agreements

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with companies with greater resources thereby allowing us to share costs of development and to improve cash-flow.

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 price 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.

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### RISK FACTORS

In addition to the other information contained in this prospectus, 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 A "GOING CONCERN" ANNUAL AUDIT REPORT.

We reported net losses of \$3,364,411, \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the six months ended September 30, 2004 and fiscal years ended March 31, 2004, 2003, 2002 and 2001, respectively. At September 30, 2004, we had an accumulated deficit of approximately \$38.5 million, consolidated assets of approximately \$5.3 million, stockholders' equity of approximately \$1.7 million, and a negative working capital of approximately (\$0.75) million (without giving retroactive effect to the consummation of the private placement of Series A Preferred Shares for gross proceeds of \$6,600,000). 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 the fiscal years ended 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:

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

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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

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incorporation in 1990. We incurred net losses of \$3,364,411, \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the six months ended September 30, 2004 and the years ended March 31, 2004, 2003, 2002 and 2001, respectively. 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.

As part of a settlement of a litigation initiated by Dr. Mehta in July 2003 for alleged breach of his employment agreement, the Company extended the expiration date of options to purchase 770,000 shares of Common Stock (reduced by a subsequent agreement to 670,000 shares) held by Dr. Mehta 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 holdings of securities of the Company except for the foregoing options. The purchasers are offering the shares acquired by means of this prospectus (see "Selling Stockholders").

WE HAVE NOT YET SUCCESSFULLY DEVELOPED A PRODUCT FOR COMMERCIAL USE, AND IF WE ARE UNABLE TO DO SO OUR BUSINESS MAY NOT CONTINUE.

We have not yet developed a product to the stage of generating commercial sales. 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. Of the products currently under development and on which we are devoting substantial attention, we have had three products in pilot Phase I studies, two products in bioequivalence stage and an additional product in preclinical testing. Additional studies including either pivotal bioequivalence or efficacy studies will be required before commercialization.

Successful completion of pivotal biostudies is required for us to file an ANDA with the FDA, and successful completion of pivotal clinical trials is



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required for us to file a NDA with the FDA. ANDAs are filed with respect to generic versions of existing FDA approved products while NDAs are filed with respect to new products. In order for any of our products to be commercialized, FDA approval is required.

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

If we develop a product that is available for commercial sale, we intend to pursue product-specific licensing, marketing agreements, co-development opportunities and other partnering arrangements in connection with the distribution of the product. We cannot be sure that we will be able to locate suitable partners for these transactions. In addition, assuming we

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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 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

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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:

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

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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:

- o greater possibility for disruption due to transportation or communication problems;
- o the relative instability of some foreign governments and economies;
- o 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
- o 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 WE NEED ADDITIONAL FINANCING IN ORDER TO SATISFY OUR SIGNIFICANT CAPITAL REQUIREMENTS, AND ARE UNABLE TO OBTAIN ADDITIONAL FINANCING, IT WOULD IMPAIR OUR ABILITY TO CONTINUE TO DO BUSINESS.

We completed a private placement in October 2004 of (i) 516,558 shares of our Series A Preferred Stock convertible into 5,165,580 of shares of Common Stock, (ii) Short Term and Long Term Warrants to purchase at a price ranging

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from \$1.54 to \$1.84 per share a like number of shares of Common Stock, and (iii) Long Term Warrants issued to the Placement Agent to purchase 494,931 shares of Common Stock at prices ranging from \$1.23 to \$1.47 per share. The private placement resulted in gross proceeds of \$6,600,000. We anticipate, based on our currently proposed plans and assumptions relating to our operations, that we have sufficient capital to satisfy our contemplated cash requirements through March 31, 2006. After that time, we may require additional financing. In particular, we expect to make substantial expenditures as we further develop and seek to commercialize our products. As of October 31, 2004 we are currently depleting our cash at the rate of \$225,000 per month. We expect that our rate of spending will accelerate as the result of increased costs and expenses associated with seeking regulatory approval and commercialization of products now in development. We have no current arrangements with respect to additional financing other than the potential exercise of the Short Term and Long Term Warrants issued in the October 2004 private placement and the warrants issued to the Placement Agent and other warrants and options that are currently outstanding. We have no way of knowing whether any of the options or warrants will be exercised. We do not currently have commitments for other financing, and so do not know

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whether additional financing would be available to us on favorable terms, or at all. Our inability to obtain additional financing when needed would impair our ability to continue our business.

If any future financing involves the 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. If our plans change, or our assumptions change or prove to be inaccurate, or our cash flow proves to be insufficient to fund our operations due to unanticipated expenses or problems, we would be required to seek additional financing sooner than anticipated.

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.

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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.

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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 prior 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. None of our products has 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

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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.

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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 \$1,000,000; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. Our insurance coverage 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 September 30, 2004.

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 eighteen months ended September 30, 2004, the closing sale price on the American Stock Exchange of our Common Stock fluctuated from a high of \$4.31 per share to a low of \$1.05 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:

- o Results of our clinical trials;
- o Approval or disapproval of abbreviated new drug applications or new drug applications;
- o Announcements of innovations, new products or new patents by us or by our competitors;
- o Governmental regulation;
- o Patent or proprietary rights developments;
- o Proxy contests or litigation;
- o News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- o Economic and market conditions, generally and related to the

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pharmaceutical industry;

- o Healthcare legislation;
- o Changes in third-party reimbursement policies for drugs; and
- o Fluctuations in our operating results.

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THE OFFERING FOR SALE OF A SIGNIFICANT NUMBER OF RESTRICTED SHARES OF COMMON STOCK ELIGIBLE FOR RESALE IN ADDITION TO THE SHARES OF COMMON STOCK WHICH MAY BE OFFERED UPON CONVERSION OF SERIES A PREFERRED SHARES AND EXERCISE OF THE SHORT TERM AND LONG TERM WARRANTS CAN HAVE A MATERIAL ADVERSE EFFECT ON THE MARKET PRICE OF THE COMMON STOCK.

As of November 9, 2004, there were 12,130,926 shares of our Common Stock issued. This prospectus relates to the offering by Selling Stockholders of up to 1,362,200 shares acquired from the former Chief Executive Officer and up to an additional 10,826,091 shares which are registered for resale upon conversion of the shares of Series A Preferred Stock outstanding (exclusive of shares of Common Stock which may be issued as a dividend on outstanding shares of Series A Preferred Stock) and exercise of the Short Term and Long Term Warrants. Sales of substantial amounts of the Common Stock in the public market by these holders or perceptions that such sales may take place may lower the Common Stock's market price.

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

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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.

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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:

- o Control of the market for the security by one or a few broker-dealers;
- o "Boiler room" practices involving high-pressure sales tactics;
- o Manipulation of prices through prearranged matching of purchases and sales;
- o The release of misleading information;
- o Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- o 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 of the sale by the Company to the Selling Stockholders of up to 6,330,511 shares of Common Stock upon exercise of the Short Term and Long Term Warrants and options and other warrants (a maximum of approximately \$10,291,144) 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, including 660,000 shares of Series A Preferred Stock. As of November 9, 2004, there were outstanding 12,130,926 shares of Common Stock, 516,558 shares of Series A Preferred Stock (the "Series A Preferred Shares") convertible into 5,165,580 shares of Common Stock and options and warrants to purchase a total of 10,891,800 shares of our Common Stock including the 6,330,511 shares issuable upon exercise of the Short Term Warrants, Long Term Warrants and options held by the Selling Stockholders.

COMMON STOCK

SUBJECT TO THE RIGHTS OF THE HOLDERS OF THE SERIES A PREFERRED SHARES AND OF ANY OTHER 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.

On October 6, 2004, pursuant to the authority of its Board of Directors, Elite 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 (the Series A Preferred Shares). THE FOLLOWING SUMMARY OF CERTAIN OF THE RIGHTS AND LIMITATIONS OF THE SERIES A PREFERRED SHARES IS QUALIFIED BY THE FULL DESCRIPTION OF THE RIGHTS AND LIMITATIONS SET FORTH IN THE SERIES A PREFERRED CERTIFICATE.



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The Series A Preferred Shares are to accrue dividends at the annual rate of \$0.984 per share (a rate of 8% per annum on the \$12.30 per share paid for the first tranche of the Series A Preferred Shares sold) payable at the Company's option, in cash or shares of Common Stock with each share of Common Stock so issued to be valued at its Current Market Price which is defined as the average weighted (based on sale volume) closing price for the 30 consecutive trading day period ending on the last trading day before the date of valuation. To the extent not paid in cash within 10 days following the dividend payment date of June 1 or December 1, the Company will be required to make the payment in shares of Common Stock. Dividends may not be payable on Common Stock or any other capital stock ranked junior to the Series A Preferred Shares prior to the satisfaction of the dividend obligation on the Series A Preferred Shares.

Each Series A Preferred Share is entitled to a preference equal to \$12.30 per share subject to adjustment plus accrued but unpaid dividends upon the liquidation, dissolution or winding-up of the Company, or a "Change of Control Event", which preference is senior to the Common Stock. In addition, each Series A Preferred Share participates on an as converted basis with the Common Stock with respect to any remaining assets after the distribution on the Series A Preferred Shares as described in the preceding sentence. A "Change in Control Event", is defined to mean the first to occur of (i) a sale of all or substantially all of the assets of the Company, (ii) an acquisition, reorganization, merger, consolidation of the Company or a similar transaction (except for a consolidation or merger where the holders of capital stock prior to the merger or consolidation possess more than 50% of the voting power immediately after the merger or consolidation), or (iii) a transaction or series of transactions in which a person or group of persons as a group acquire 50% or more of the Common Stock on a fully diluted basis or of the voting power of the Company, unless the consideration paid for the Series A Preferred Shares (on an as converted basis) in any such transactions is more than \$3.69 per share (subject to adjustment) or the event is approved by the holders of a majority of the outstanding Series A Preferred Shares.

The Series A Preferred Shares as a class have the right to elect one Director with the Placement Agent of the private placement in which the Series A Preferred Shares were sold to make the first designation. The holders of Series A Preferred Shares vote with the holders of shares of Common Stock as one class with each Series A Preferred Share entitled to such number of votes equal to the number of shares of Common Stock into which the share is then convertible.

So long as at least 20% of the Series A Preferred Shares issued by the Company are outstanding certain actions may not be effected by the Company without the prior consent of the holders of a majority of the then outstanding Series A Preferred Shares, including a change in the terms of the Series A Preferred Shares, issuance of equity security having a preference senior or pari passu with the Series A Preferred Shares, certain changes to the Company's Certificate of Incorporation or By-laws, incurrence of indebtedness for borrowed money with certain exceptions, redemption of shares of Common Stock with certain exceptions, loans other than in the ordinary course of business with certain exceptions, certain insider transactions, and declaration or payment of dividends other than (i) upon the Series A Preferred Shares, or (ii) in connection with a split of the Common Stock.

Each Series A Preferred Shares is convertible into ten shares of Common Stock. The conversion rate is 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 \$1.23 (subject to adjustment). The Series A Preferred Shares are to be automatically converted into shares of Common Stock in the event of (i) notice from holders of a majority of the Series A Preferred Shares, or (ii) the Company provides written notice to the holders that the Current Market Price of Common Stock for the immediate prior 30 consecutive trading days at an average daily trading volume of at least 50,000 shares per day on each such trading day exceeded \$3.69 (subject to adjustment), or (iii) the occurrence of a transaction which values Series A Preferred Shares (on an as converted basis) at \$3.69 per share (subject to adjustment) or greater and the consideration to be paid to the Series A Preferred Shareholders is cash or shares which are traded on a national securities exchange or NASDAQ and are registered under the Securities Act of 1933 for resale or (iv) concurrently with a closing of a public offering of shares of Common Stock at a price equal to at least \$3.69 per share (subject to adjustment) with proceeds to the Company of at least \$20,000,000.

#### 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:

- o 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,
- o 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
- o 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 corporation's 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.

## PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY

Our Common Stock is quoted on the American Stock Exchange under the symbol "ELI." The following table shows, for the periods indicated, the high and low sales prices per share of our Common Stock as reported by the American Stock Exchange.

## COMMON STOCK

QUARTER ENDED:	HIGH	LOW
FISCAL YEAR		
ENDING MARCH 31, 2005:		
September 30, 2004.....	\$2.35	\$1.05
June 30, 2004.....	\$4.31	\$2.15
FISCAL YEAR		
ENDING MARCH 31, 2004:		
March 31, 2004.....	\$3.80	\$2.40
December 31, 2003.....	\$3.30	\$2.70
September 30, 2003.....	\$3.49	\$2.05
June 30, 2003 .....	\$3.45	\$1.34
FISCAL YEAR		
ENDING MARCH 31, 2003:		
March 31, 2003.....	\$2.20	\$1.45
December 31, 2002.....	\$3.15	\$1.80
September 30, 2002.....	\$5.25	\$2.41
June 30, 2002.....	\$7.75	\$4.50
FISCAL YEAR		
ENDING MARCH 31, 2002:		
March 31, 2002.....	\$8.30	\$5.65
December 31, 2001.....	\$7.75	\$5.90
September 30, 2001.....	\$11.50	\$5.10
June 30, 2001.....	\$11.45	\$4.85

On November 9 2004, the last sale price of our Common Stock, as reported by the American Stock Exchange, was \$1.69 per share.

We have never paid cash dividends on our capital stock. No dividend may be paid on our Common Stock without the approval of holders of a majority of the outstanding shares of Series A Preferred Stock. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business, and do not anticipate paying any cash dividends in the foreseeable future.

See "Description of Capital Stock - Preferred" for the senior dividend rights of the Series A Preferred Shares at the annual rate of \$0.984 per share and our option to pay such dividends in shares of Common Stock valued at "fair market value" as defined.

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## MANAGEMENT

### Board of Directors

The table below sets forth the names and ages, as of November 9, 2004, of each of the Directors and the period during which each such person has served on the Board of Directors of the Company.

NAME AND BUSINESS ADDRESS	AGE	DIRECTOR SINCE
Bernard Berk (1)	55	2004
John A. Moore(1)	38	2002
Harmon Aronson 26 Monterey Drive Wayne, NJ 07470	61	1999
Eric L. Sichel 411 Highview Road Engelwood, NJ 07631	44	2001

(1) His address is c/o Elite Pharmaceuticals Inc., 165 Ludlow Avenue, Northvale, NJ 07647

The principal occupation and employment of each such person during the past five years is set forth below. In each instance in which dates are not provided in connection with a nominee's business experience, such nominee has held the position indicated for at least the past five years.

Bernard Berk was appointed the Chief Executive Officer of the Company in June 2003, a Director in February 2004 and Chairman of the Board on May 12, 2004. Mr. Berk has been the President and Chief Executive Officer of Michael Andrews Corporation, a pharmaceutical management consultant firm, since 1996. Mr. Berk devotes and is to devote during his employment under his employment agreement substantially all of his time to the operations of the Company. From 1994 until 1996, Mr. Berk was President and Chief Executive Officer of Nale Pharmaceutical Corporation. From 1989 until 1994, Mr. Berk was Senior Vice President of Sales, Marketing and Business Development of Par Pharmaceuticals, Inc. Mr. Berk holds a B.S. from New York University.

John A. Moore served as Chairman of the Board from June 2003 to May 12, 2004. He has been Chief Executive Officer and President of Edson Moore Healthcare Ventures Inc., an investment entity, since July 2002. Mr. Moore had been from 1994 through June 2002 Chief Executive Officer and President and since 1994 a director of Optimer, Inc., a research based polymer development company. He is also a director and Chairman of ImaRx Therapeutics, Inc., a privately-held company engaged in medical technology development and a director of Medi-Hut Co., Inc., a publicly traded medical products company. Mr. Moore holds a B.A. in history from Rutgers University.

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Harmon Aronson, Ph.D. has been employed since 1997 as President of Aronson Kaufman Associates, Inc., a New Jersey-based consulting firm that provides manufacturing, FDA regulatory and compliance services to pharmaceutical and biotechnology companies. Its clients include United States and international firms manufacturing bulk drugs and finished pharmaceutical dosage products who are seeking FDA approval for their products for the U.S. market. Prior to 1997,

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Dr. Aronson was employed by Biocraft Laboratories, a leading generic drug manufacturer, rising to the position of Vice President of Quality Management; prior to that he held the position of Vice President of Non-Antibiotic Operations, where he was responsible for the manufacturing of all the firm's non-antibiotic products. Dr. Aronson holds a Ph.D. in Physics from the University of Chicago.

Eric L. Sichel, M.D. has been since 1997, owner and President of Sichel Medical Ventures, Inc., a company that provides biotechnology company assessments and investment banking services. From 1995 through 1996, Dr. Sichel was a senior analyst in the biotechnology field for Alex Brown & Sons, Inc. Prior to that, Dr. Sichel was affiliated with Sandoz Pharmaceuticals Corp. in various capacities, including associate director of transplantation/immunology. Dr. Sichel holds an M.B.A. from Columbia University and an M.D. from UMDNJ--New Jersey Medical School, and is licensed to practice medicine by the State of New York.

The holders of the Series A Preferred Stockholders are entitled to elect a director, but have not made their selection as of November 9, 2004

Each director holds office (subject to our By-Laws) until the next annual meeting of stockholders and until such director's successor has been elected and qualified.

### COMMITTEES

The Board of Directors has an Audit Committee and, since March 2004, a Nominating Committee. The Board has no other standing committees. The Audit Committee members are John A. Moore, Harmon Aronson and Eric L. Sichel. The Company's Board of Directors has adopted a written charter for the Audit Committee, a copy of which was included as an appendix to the Company's proxy statement sent to stockholders in connection with the annual meeting of stockholders held October 11, 2001.

The Company deems the members of its Audit Committee to be independent as independence is defined in Section 121(A) of the American Stock Exchange Listing Standards, as amended effective December 1, 2003. The Board determined that Mr. Sichel, an independent director, qualifies as the audit committee financial expert within the meaning of that term under the applicable regulations under the Securities Exchange Act of 1934.

The Nominating Committee is authorized to select the nominees of the Board of Directors for election as directors. The members are John A. Moore, Harmon Aronson and Bernard Berk.

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### COMPENSATION OF DIRECTORS

Each non-affiliated director receives \$2,000 as compensation for each meeting of the Board of Directors attended.

Pursuant to an authorization by the Board of Directors, Mr. Moore received \$46,875 as compensation for the period from January 1, 2004 through May 12, 2004, the date of his resignation as Chairman of the Board, for his services as Chairman in assisting the Chief Executive Officer in the management of the Company's operations.

### EXECUTIVE OFFICERS

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Our executive officers of the Company are Bernard Berk and Mark I. Gittelman. Our executive officers, except for Mr. Berk who has a long term employment agreement, will serve until the next annual meeting of directors and until their successors have been duly elected and qualified. There are no family relationships between any of our directors and executive officers.

Bernard Berk, age 55, was appointed Chief Executive Officer in June 2003 and a director in February 2004 and Chairman of the Board on May 12, 2004. See "Management - Board of Directors" for his business background.

Mark I. Gittelman, age 44, CPA, the Chief Financial Officer, Secretary and Treasurer of the Company, is the President of Gittelman & Co., P.C., an accounting firm in Clifton, NJ. Prior to forming Gittelman & Co., P.C. in 1984, he worked as a certified public accountant with the international accounting firm of KPMG Peat Marwick, LLP. Mr. Gittelman holds a B.S. in accounting from New York University and a Masters of Science in Taxation from Farleigh Dickinson University. He is a Certified Public Accountant licensed in New Jersey and New York, and is a member of the American Institute of Certified Public Accountants ("AICPA"), and the New Jersey State and New York States Societies of CPAs. Other than Elite Labs, no company with which Mr. Gittelman was affiliated in the past was a parent, subsidiary or other affiliate of the Company.

The Company entered into a three-year employment agreement effective July 23, 2003 with Mr. Berk providing for (i) his fulltime employment as Chief Executive Officer at an annual base salary of \$200,000, (ii) the grant to him of options which vest immediately to purchase 300,000 shares of Common Stock at a price of \$2.01 per share, the closing share price on the American Stock Exchange on the date of grant and (iii) the grant of options to purchase an additional 300,000 shares at the \$2.01 per share to vest on consummation of a "strategic transaction" while he is employed as Chief Executive Officer. The consummation of such transaction will result in the increase of his base annual salary to \$310,140 effective with the consummation. A strategic transaction is defined as any one of the following transactions provided that the net value of the consideration to the Company or its stockholders determined in good faith by the Board of Directors is at least \$10,000,000: (i) the sale of all or substantially all of the assets of the Company, (ii) a merger or consolidation or business combination, or (iii) the sale by the Company of debt or equity securities.

Either party upon notice may terminate Mr. Berk's employment except that a termination by the Company without cause or because of his permanent disability or a termination by him for cause will result in severance pay in the form of the continuation of his base salary for the

balance of the term or two years, whichever is longer, less in the event of termination for permanent disability the amount of payments under a disability insurance policy maintained by the Company. The Company is also to continue to pay during the foregoing period the premiums for life and disability insurance policies. Furthermore, in the event that Mr. Berk terminates his employment following a "change of control" event he is to receive, payable in 24 monthly installments, an amount which will depend on the fair value of the consideration determined in good faith by the Board of Directors received by the Company or stockholders from the "change of control" event less related expenses ("Net Fair Value") -- \$500,000 if the Net Fair Value is \$10 million or less; the greater of \$500,000 or twice his then base annual salary, if the Net Fair Value is greater than \$10,000,000 but not more than \$20 million, or \$1,000,000 if the Net Fair Value is greater than \$20,000,000. A "change of control" event is (i) a merger

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or consolidation in which securities possessing more than 50% of the voting power is issued to persons other than the holders of voting securities of the Company immediately prior to the event, (ii) the sale, transfer or disposition of all or substantially all the assets of the Company, or (iii) the sale by the Company of securities to a third party.

The agreement contains Mr. Berk's non-competition covenant for a period of one year from termination.

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### EXECUTIVE OFFICER COMPENSATION

The following table sets forth the annual and Long Term compensation for services in all capacities to the Company for the three years ended March 31, 2004, awarded or paid to, or earned by Bernard Berk, the Company's President and Chief Executive Officer since June 2003 and Dr. Atul M. Mehta, our former President and Chief Executive Officer. No other executive officer of the Company received compensation exceeding \$100,000 during those periods. See "Certain Relationships and Related Transactions" for fees paid to an affiliate of Mark I. Gittelman, the Company's Chief Financial Officer, Treasurer and Secretary.

#### SUMMARY COMPENSATION TABLE

ANNUAL COMPENSATION						LONG TERM INCENTIVE COMPENSATION	
(a) Name and Principal Position	(b) Fiscal Year(1)	(c) Salary	(d) Bonus	(e) Other Annual Compensation(5)	(f) Restricted Stock Awards	(g) Securities Underlying Options	
Bernard Berk, President and Chief Executive Officer	2003-04	\$166,667	--	--	--	300,000	
Atul M. Mehta, Ph.D. former President and Chief executive Officer(2)	2003-04	\$ 53,684	--	\$ 3,040	--	--(3)	
	2002-03	\$330,140	--	\$ 3,040	--	--	
	2001-02	\$272,855	--	\$ 83,856	--	50,000	

(1) The Company's fiscal year begins on April 1 and ends on March 31. The information is provided for each fiscal year beginning April 1.

(2) Dr. Mehta resigned as an employee and as a director of Elite as of June 3, 2003.

(3) As part of a settlement of a litigation between Dr. Mehta and the Company the expiration dates of options granted to him prior to April 1, 2001 to purchase 770,000 shares were extended in April 2004 to June 30, 2005 (subsequently by agreement reduced to 670,000 options with the expiration date

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extended to December 31, 2007).

(4) By action on February 21, 2002, our Board of Directors corrected a clerical error in options for 425,000 shares of our Common Stock granted to Dr. Mehta. This correction did not result in any additional shares being subject to options held by Dr. Mehta, any change in the exercise price or a change in any other material terms.

(5) Other Annual Compensation represents use of a Company car, premiums paid by the Company for life insurance on Dr. Mehta's life for the benefit of his wife and the purchase price

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of \$80,856 for options acquired from Dr. Mehta.

(6) Does not include 300,000 options which are exercisable only upon occurrence of a "strategic event".

### OPTION GRANTS TO AND EXERCISED BY EXECUTIVE OFFICERS IN LAST FISCAL YEAR

Options granted to executive officers of the Company named in the Summary Compensation Table during the fiscal year ended March 31, 2004 were as follows:

NAME	NUMBER OF SHARES UNDERLYING OPTIONS GRANTED	% OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN FISCAL YEAR	EXERCISE PRICE	EXPIRATION DATE	POTENTIAL ASSUMED STOCK 5%
Bernard Berk	300,000 (1)	41.4%	\$2.01	6/2/13	\$982,
Atul M. Mehta(2)	--	--	--	--	--

(1) Does not include grant of options to purchase 300,000 shares at \$2.01 per share which are exercisable only upon occurrence of a "strategic event". See "Executive Officers".

(2) Pursuant to a settlement which closed in April 2004 of a litigation with the Company and a subsequent agreement, the expiration dates of options to purchase 670,000 shares granted prior to year ended March 31, 2002 while he was an executive officer were extended to December 31, 2007.

No options were exercised by executive officers during the fiscal year ended March 31, 2004.

NAME	NUMBER OF SHARES UNDERLYING UNEXERCISED OPTIONS AT YEAR-END*	VALUE OF UNEXERCISED IN-THE-MONEY OPTIONS AT YEAR-END (1)
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	EXERCISABLE	UNEXERCISABLE	EXERCISABLE	UNEXERCISABLE
Atul M. Mehta (2)	270,000*	-0-	\$0	--
	100,000	-0-	\$0	--
	100,000	-0-	\$48,000	--
	100,000	-0-	\$98,000	--
	100,000	-0-	\$148,000	--
	100,000	-0-	\$198,000	--
Bernard Berk (3)	300,000	300,000	\$291,000	\$291,000

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\*Giving retroactive effect to a litigation settlement which became effective in April 2004. An October 21, 2004 agreement reduced by 100,000 the 270,000 options and reduced their exercise price from \$10.00 to \$2.34 per share.

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(1) The dollar values are calculated by determining the difference between \$2.98 per share, the closing sale share price of the Common Stock on March 31, 2004 on the American Stock Exchange and the exercise price of the respective options.

(2) Dr. Mehta resigned as an officer/employee and director as of June 3, 2003.

(3) Mr. Berk entered the employ of the Company in June 2003

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Company is a party to an agreement dated February 26, 1998 whereby fees are paid to Gittelman & Co., P.C., a firm wholly owned by Mark I. Gittelman, the Company's Chief Financial Officer, Secretary and Treasurer, in consideration for services rendered by the firm as internal accountant and financial and management consultant. The firm's services include the services rendered by Mr. Gittelman in his capacity as Chief Financial Officer, Treasurer and Secretary. For the fiscal years ended March 31, 2004, 2003 and 2002, the fees paid by the Company under the agreement were \$168,750, \$167,544 and \$91,260, respectively. The services rendered by the firm to the Company averaged 128, 127 and 69 hours per month, respectively, of which an average of 30 hours per month were services rendered by him in his capacity as an officer of the Company.

We also had a contractual relationship with Donald Pearson, then a Director of the Company, which expired on November 30, 2003, providing for Mr. Pearson to: (i) refer potential customers who will license or collaborate in the development or purchase of the technology of the Company and (ii) render financial consulting services to the Company. Under the arrangement, Mr. Pearson received consulting fees aggregating \$25,600, \$38,400 and \$12,800 for fiscal years ended March 31, 2004, 2003 and 2002, respectively. The referral fees were to be a percentage ranging from 5% to 1% of the first \$5,000,000 of revenues generated by his referrals after deducting expenses and a credit for the consulting fees. No revenues were generated under the arrangement. The Company also has a similar customer referral arrangement with Mr. Harmon Aronson, a Director, to pay him a percentage of net revenues generated by customers referred by him. No fees have been earned under his arrangement.

See "Executive Officers" for information as to an employment agreement with Bernard Berk.

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SECURITY OWNERSHIP OF OUR DIRECTORS,  
EXECUTIVE OFFICERS AND PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding beneficial ownership of our Common Stock and our Series A Preferred Stock as of November 9, 2004 by (i) each director and named executive officer, (ii) each beneficial holder of at least 5% of the outstanding shares of Common Stock or of Series A Preferred Stock, and (iii) all executive officers and directors as a group. The Series A Preferred Stockholders are entitled to elect one Director and on matters submitted to Common Stockholders they are entitled to vote on an as converted basis with the Common Stock as one class. On November 9, 2004 there were outstanding 12,130,926 shares of Common Stock and 516,558 shares of Series A Preferred Stock convertible into 5,165,580 shares of Common Stock.

Shares not outstanding but deemed beneficially owned by virtue of the right of any individual to acquire shares within 60 days are treated as outstanding only when determining the amount and percentage of the class owned by such individual. Each person has sole voting and investment power with respect to the shares shown, except as noted. Unless otherwise indicated, the address of the person named is c/o Elite Pharmaceuticals, Inc., 165 Ludlow Avenue, Northvale, New Jersey 07647.

NAME AND ADDRESS	NUMBER OF SHARES	PERCENTAGE OF CLASS
DIRECTORS AND NAMED EXECUTIVE OFFICERS		
Harmon Aronson, Director*	70,000 Common (1)	**
Eric L. Sichel, Director*	60,000 Common (2)	**
John A. Moore, Director*	905,109 Common (3)	7.2%
Mark I. Gittelman, CFO, Treasurer and Secretary 300 Colfax Avenue Clifton, New Jersey 07013	10,000 Common (4)	**
Bernard Berk, Chairman of the Board and Chief Executive Officer*	465,300 Common (5)	3.7%
5% BENEFICIAL OWNERS		
Dr. Atul Mehta c/o Andrew Giles Freda, Esq. Edwards & Caldwell LLC 1600 Route 208 North Hawthorne, NJ 07647	670,000 Common (6)	5.2%
Jerome Belson 495 Broadway New York, New York 10012	969,000 Common (7)	7.8%
Marlin Fund, LP ***	30,894 Preferred 617,880 Common (8)	6.0% 4.8%
Marlin Fund Offshore, LTD ***	40,651 Preferred 813,020 Common (8)	7.9% 6.3%

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Valor Capital Management LP ***	60,976 Preferred	12.4%
	1,219,520 Common (8)	9.1%
S.A.C. Capital Associates LLC ***	81,301 Preferred	16.3%
	1,626,020 Common (8)	11.8%
Little Wing LP ***	33,600 Preferred	6.7%
	672,000 Common (8)	5.2%
Jess S. Morgan & Co. Inc ***	80,143 Preferred	16.1%
	1,602,860 Common (8)	11.7%
All Directors and Officers as a group	1,510,709 Common (9)	11.6%

\* See "Management - Board of Directors" for his address

\*\* Less than 1% of outstanding shares

\*\*\* See "Selling Stockholders" for address

(1) Comprised of options to purchase 70,000 shares.

(2) Represents options to purchase 40,000 shares and 20,000 shares owned as co-tenant with Dana Cernea.

(3) Includes (i) options held by Mr. Moore to purchase 360,000 shares and (ii) 110,000 shares of Common Stock beneficially owned by Edson Moore Healthcare Ventures, Inc. ("Edson Moore"), of which he is president and a 50% stockholder, including 100,000 shares issuable upon exercise of a warrant with an exercise price of \$18.00 per share.

(4) Comprised of options to purchase 10,000 shares.

(5) Includes options to purchase 330,000 shares.

(6) Comprised of options to purchase 670,000 shares..

(7) Includes (i) warrants to purchase 281,000 shares of Common Stock, (ii) 53,900 shares held by Maxine Belson, wife of Jerome Belson, (iii) 63,300 held by other members of his family, and (iv) 50,000 shares held by the Jerome Belson Foundation.

(8) 50% of the shares are shares issuable upon conversion of the Series A Preferred and 50% of the shares are shares issuable upon exercise of the Short Term and Long Term Warrants. The Short Term and Long Term Warrants provide that they are not exercisable if the exercise would result in the holder and the holder's affiliates beneficially owning (as determined in accordance with Section 13(d) of the Securities Exchange Act) in aggregate more than 9.99% of the outstanding shares of Common Stock. The percentages shown do not give effect to such limitation.

(9) Includes options and warrants to purchase an aggregate of 910,000 shares.

Except as otherwise set forth, information as to the stock ownership of each person was provided to the Company by such person.

Other than the Stock Option Plan, the Company does not have any compensation plans or arrangements benefiting employees or non-employees under

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which equity securities of the Company are authorized for issuance in exchange for consideration in the form of goods or services.

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### SELLING STOCKHOLDERS

The Selling Stockholders are offering (A) shares of our Common Stock which may be acquired upon conversion of the Series A Preferred Shares including shares of Common Stock which may be received as dividends on the Series A Preferred Shares and shares of Common Stock which may be acquired upon exercise of Short Term and Long Term Warrants; (B) shares of Common Stock acquired from Dr. Atul Mehta, the former Chief Executive Officer of the Company and members of his family (the "Mehta Sale"); and (C) other shares of Common Stock which we have agreed to register at our expense including shares which may be acquired upon exercise of outstanding options held by Dr. Mehta. The Series A Preferred Shares and the Short Term and Long Term Warrants were acquired in a private placement effected in three tranches, the first involving the sale of 379,122 Series A Preferred Shares at a price of \$12.30 per share convertible into 3,791,220 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 3,791,220 shares at a price of \$1.54 per share, the second tranche involving the sale of 119,286 Series A Preferred Shares at a price of \$14.00 per share convertible into 1,192,860 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 1,192,860 shares of Common Stock at a price of \$1.75 per share, and the third involving the sale of 18,150 Series A Preferred Shares at a price of \$14.70 per share convertible into 181,500 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 181,500 shares of Common Stock at a price of \$1.84 per share. We paid Indigo Securities Inc., the Placement Agent, and selected dealers cash commissions aggregating \$633,510.70 and issued to them Long Term Warrants to purchase 357,495 shares of Common Stock at a price of \$1.23 per share, 119,286 shares of Common Stock at a price of \$1.40 per share and 18,150 shares of Common Stock at a price of \$1.47 per share.

We have granted the purchasers in the private placement certain demand and piggy-back registration rights under the Securities Act of 1933, as amended, at our expense with respect to the offering of shares of Common Stock acquired upon conversion of the Series A Preferred Shares and exercise of the Long Term Warrants and Short Term Warrants.

We have agreed also to file the Registration Statement of which this prospectus is a part to register for reoffering the (A) shares of Common Stock acquired upon conversion of the Series A Preferred Shares and exercise of the Short Term and Long Term Warrants and (B) the shares of Common Stock acquired in the Mehta Sale.

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

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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

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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. In addition to the shares shown below being offered by the Private Placement Selling Stockholders, the Registration Statement also covers shares of Common Stock which may be issued as a dividend on the Series A Preferred Shares acquired in the private placement.

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, none of the Selling Stockholders has had a significant relationship with us within the past three years, other than as a result of the ownership of our shares or other securities. 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 12,130,926 shares of our Common Stock outstanding as of November 9, 2004 and assumes that, except for the shares issuable to a Selling Stockholders upon conversion or exercise, none of the Series A Preferred Shares will be converted and none of the Short Term Warrants or Long Term Warrants or outstanding warrants or options will have been exercised after the offering.

Name and Address	Shares Beneficially Owned Prior to Offering*	Number of Shares Which May Be Sold (* )	Shares Own Offer Number P
-----			
PRIVATE PLACEMENT SELLING STOCKHOLDERS:			
Chris Dick and Hedy E. Rogers 2067 Leedom Drive, Newton, PA 18940	62,520 (1)	32,520	30,000
-----			
Shirley Rae Sullivan 42 Liberty Common, Rye, NH 03870	40,660	40,660	0
-----			
Periscope Partners LP 1600 Flat Rock Rd. Penn Valley, PA 19072	243,900	243,900	0
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Little Wing LP 153 East 53rd Street, Ste. 2600, New York, NY 10022	672,000	672,000	0
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Tradewinds Fund Ltd.	141,000	141,000	0

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153 East 53rd Street, Ste. 2600,  
New York, NY 10022

S.A.C. Capital Associates, LLC PO. Box 58, Victoria House, The Valley, Anguilla, BVI	1,626,020	1,626,020	0
Marlin Fund II, LP PO Box 224229, Christiansted, VI 00822	113,820	113,820	0
Marlin Fund Offshore, LDC PO Box 224229, Christiansted, VI 00822	81,300	81,300	0

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Name and Address	Shares Beneficially Owned Prior to Offering*	Number of Shares Which May Be Sold (* )	Shares Own Offer Number P
Marlin Fund Offshore, Ltd. PO Box 224229, Christiansted, VI 00822	813,020	813,020	0
Marlin Fund, LP PO Box 224229, Christiansted, VI 00822	617,880	617,880	0
Jerry Teppel 13 Lucille Court, Edson, NJ 08820	406,500	406,500	0
Wheaten HealthCare Partners LP 212 Durham Avenue, Building 1, Suite 201, Metuchen, NJ 08840	406,500	406,500	0
Charan R. Behl, Ph.D. 658 Veterans Memorial HWY, Apt. 1A, Hanppange, NY 11788	400,000	400,000	0
Eric Brachfeld 890 West End Ave., Apt. 16D, New York, NY 10025	20,000	20,000	0
Gregory Osborn 202 Mountain Ave., Ridgewood, NJ 07450	20,000	20,000	0
William A. Lewis IV 201 East 87th Street, Apt. 9J, New York, NY 10128	200,000	200,000	0

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Myron Neugeboren 199 Wells Hill Road, Lakeville, CT 06039	81,300	81,300	0
Bushido Capital Master Fund, LP. Bushido Capital Partners, Ltd., 275 Seventh Avenue, Suite 2000, New York, NY 10001	406,500	406,500	0
Valor Capital Management 137 Rowagton Ave. Rowagton, CT 06853	1,219,520	1,219,520	0
Keith Barksdale 95 Wildwood Rd. Ridgewood, NJ 07450	40,000	40,000	0
Indigo Securities, LLC 780 Third Avenue New York, NY 10017	494,931 (2)	494,931	0

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Name and Address	Shares Beneficially Owned Prior to Offering*	Number of Shares Which May Be Sold (* )	Shares Own Offer Number P
Neil V. Moody Revocable Trust c/o Neil V. Moody 100 Sands Point Road, #305 Longboat Key, Fl 34228	188,580	188,580	0
Jess S. Morgan & Co. Inc. 5750 Wilshire Blvd. Suite 590 Los Angeles, CA 90036	1,602,860	1,602,860	0
Fineman Revocable Trust c/o David Fineman 40 Lincoln Avenue Piedmont, CA 94611	142,860	142,860	0
RC II Ltd. The Metropole Roseville Street St. Helier Jersey Channel Islands, UK JEI 4HE	214,280	214,280	0
Amy Daly PO Box 882890 Steamboat Springs, CO 80488	142,860	142,860	0
Peter J. O'Gorman	94,280	94,280	0

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Rosemary A. O'Gorman  
31 Old Chimney Road  
Upper Saddle River, NJ 07458

Sunrise Equity Partners, LP 641 Lexington Avenue, 25th Floor New York, NY 10022	363,000	363,000	0
TOTAL	10,856,091*	10,856,091	30,000
MEHTA SALE SELLING STOCKHOLDERS:			
David Altschuler/ David Kamlet T/C 20 Crossways Park Dr., North Suite 406 Woodbury, NY 11797	62,000	20,000	42,000
Jerome Belson 495 Broadway New York, NY 10012	969,000 (3)	200,000	769,000
Bernard Berk c/o Elite Pharmaceuticals, Inc 165 Ludlow Avenue Northvale, NJ 07647	465,300 (4)	70,800	394,500
Harvey Blitz 72-19 137th Street Flushing, NY 11367	80,000	50,000	30,000

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Name and Address	Shares Beneficially Owned Prior to Offering*	Number of Shares Which May Be Sold (* )	Shares Own Offer Number P
The Gerald Brauser Irrevocable Trust 820 SW 10th Avenue Bay 8R Pompano Beach, Fl 33069	594,000	400,000	194,000
Susan Brauser 200 West 79th Street, Apt 15R New York, NY 10024	119,584 (5)	25,000	94,584
Robert Cantor 215 E 68th St., Apt. 15P New York, NY 10001	25,000	25,000	0
Leonard Cohen 750 Broad Street	37,000	20,000	17,000



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Shrewsbury, NJ 07702

Dennis Connors 461 Stonehenge Cr. Rockledge, Fl 33014	15,050	8,000	7,050
Stephen Dachs Revocable Trust, Steve Dachs Trustee 16035 W. Prestwick Place Miami Lakes, FL 33014	31,300	10,000	21,300
Lindsay Dart 11661 San Vincent Blvd., Rm 701 Los Angeles, CA 90049	45,000	25,000	20,000
David and Roberta Friedman 2574 Eagle Run Lane Weston, FL 33327	63,500	25,000	38,500
F&M 18 Investment Partnership c/o John Moroney P.O. Box 699 Spring Lake, NJ 07762	40,000	20,000	20,000
Joseph Giamanco 4 White Rock Terrace Holmdel, NJ 07733	350,000	200,000	150,000
Howard Gordon 6000 SW 21st St. Plantation, FL 33317	73,000	30,000	43,000
Robert Karsten 121 East 60th, 9A New York, NY 10022	193,840	30,000	163,840
Frank Lagano 147 Buckingham Rd. Tenafly, NJ 07670	107,500	70,000	37,500
Dorand Nichols 2440 SW 102nd Dr. Davie, FL 33324	24,700	10,000	14,700

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Name and Address	Shares Beneficially Owned Prior to Offering*	Number of Shares Which May Be Sold (* )	Shares Own Offer Number P
Linda and Stephen Posner, Trustees for the Stephen J. Posner Trust 18 Ursula Dr.	170,600 (6)	30,000	140,600 (

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Roslyn, NY 11576

RB Holdings II, LLC (7) 800 Third Avenue, 21st Floor New York, NY 10002	3,400	3,400	0
Richard Rimer 17 Chemin De La Sapinere 1253 Vanooevres Geneva Switzerland	50,000	50,000	0
Joe Roselle 56 Gillespie Ave. Fair Haven, NJ 07704	20,000	20,000	0
Philip C. Wiener 511 Pearl Street Oceanside, NY 11572	5,000	5,000	0
Stanley Zaslow 12331 Rockledge Circle Boca Raton, FL 33428	5,000	5,000	0
Bruce and Eva Zwigard 8935 Arvida Dr. Coral Gables, FL 33156	11,500	10,000	1,500
TOTAL FOR MEHTA SALE SELLING STOCKHOLDERS	3,561,274	1,362,200	2,199,074
OTHER SELLING STOCKHOLDERS:			
Atul Mehta, Ph.D 76 Walsh Drive Mahwah, NJ 07430	670,000 (8)	670,000	0
CEOcast, Inc. 55 John Street, 11th Floor New York, NY 10038	26,500	26,500	0
TOTAL FOR OTHER SELLING STOCKHOLDERS	696,500	696,500	0

\* The shares offered by the Private Placement Selling Stockholders are the shares which may be acquired by them upon conversion of Series A Preferred Shares and upon exercise of Short Term and Long Term Warrants. Such shares are included in the beneficial ownership of the Selling Stockholder prior to offering. The beneficial ownership of the Private Placement Selling Stockholders prior to the offering and the shares of Common Stock which may be sold will be increased to the extent (i) the Selling Stockholder has not converted his Series A Preferred Shares on or prior to a dividend payment date and (ii) we elect to pay the dividend at the rate of \$0.984 per annum per share in whole or in part by the issuance of shares of our Common Stock at their "fair market" value (see "Description of Capital Stock - Preferred Stock" for the determination of "fair market value"). If the Private Placement Selling Stockholder does not convert the Series A Preferred Shares owned prior to a dividend payment date the number of shares of Common Stock beneficially owned and which may be sold by Selling Stockholder will be increased by an amount on each semiannual payment date which is 2% of the amount set forth in

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the first column divided by the "fair market value" of a share of Common Stock for such payment date except for Mr. Dick's as to which the 2% factor will be applied to all but 30,000 shares.

\*\* Less than 1%

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- (1) Includes 30,000 shares issuable upon exercise of options held by Mr. Dick.
- (2) Shares which may be acquired upon exercise of Warrants received for services of the Placement Agent.
- (3) Includes (i) warrants to purchase 281,000 shares of Common Stock, (ii) 53,900 shares held by Maxine Belson, wife of Jerome Belson, (iii) 63,300 held by other members of his family, and (iv) 50,000 shares held by the Jerome Belson Foundation.
- (4) Chief Executive Officer and Director of the Company and includes 330,000 shares issuable upon exercise of options.
- (5) Includes 60,000 shares held by a trust in which she is a beneficiary, but does not include the 594,000 shares held by the Gerald Brauser Irrevocable Trust
- (6) Includes 135,600 issuable upon exercise of warrants
- (7) Counsel to the Company.
- (8) Shares which may be acquired upon exercise of options.

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### 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:

- o 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;
- o at fixed prices, which may be changed; or
- o 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:

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- o 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;
- o a broker-dealer may purchase as principal and resell shares for its own account pursuant to this prospectus;
- o an exchange distribution in accordance with the rules of the Amex or a quotation system;
- o upon the exercise of options written relating to the shares;
- o ordinary brokerage transactions or transactions in which the broker solicits purchasers;
- o a privately-negotiated transaction; and
- o 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 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 be a Selling Stockholder under this prospectus.

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

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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

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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.

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### 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 legally issued. RB Holdings II LLC, an affiliate of Reitler Brown & Rosenblatt LLC is a Selling Stockholder.

### EXPERTS

Our consolidated financial statements as of March 31, 2004 and March 31, 2003 and for the years ended March 31, 2004, March 31, 2003 and March 31, 2002, 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

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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, 2004, filed with the Commission on July 15, 2003;
- b. our quarterly report on Form 10-Q for the quarter ended June 30, 2004, filed with the Commission on August 13, 2004;
- c. our quarterly report on Form 10-Q for the quarter ended September 30, 2004, filed with the Commission on November 12, 2004;
- d. our current reports on Form 8-K filed with the Commission on July 29, 2004, August 5, 2004, August 9, 2004, October 12, 2004, October 18, 2004 and November 1, 2004.

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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.

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PART II

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## INFORMATION NOT REQUIRED IN PROSPECTUS

### ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following is a statement of the estimated expenses incurred by Elite Pharmaceuticals, Inc. in connection with the distribution of the securities registered under this registration statement:

	AMOUNT TO BE PAID *
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SEC Registration Fee.....	\$ 3,221.83
Legal Fees and Expenses.....	\$19,500.00
Accounting Fees and Expenses.....	\$ 1,000.00
Printing Expenses.....	\$ 2,000.00
Miscellaneous.....	\$ 2,000.00
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Total.....	\$27,721.83

\* Estimated

### ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Pursuant to authority conferred by Section 102 of the Delaware General Corporation Law (the "DGCL"), Elite's Certificate of Incorporation, as amended, contains a provision providing that the personal liability of a director is eliminated to the fullest extent provided by the DGCL. The effect of this provision is that no director of Elite is personally liable to Elite or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for (i) any breach of the director's duty of loyalty to Elite or its stockholders, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) unlawful payment of dividends as provided in Section 174 of the DGCL and (iv) any transaction from which the director derived an improper personal benefit. This provision is intended to eliminate the risk that a director might incur personal liability to Elite or its stockholders for breach of duty of care. The Certificate of Incorporation, as amended, also provides that if the Delaware Law is amended to eliminate or limit further the liability of directors, then the liability of a director of Elite shall be eliminated or limited, without further stockholder action.

Section 145 of the DGCL contains provisions permitting and, in some situations, requiring Delaware corporations, such as Elite, to provide indemnification to their officers and directors for losses and litigation expenses incurred in connection with their service to the corporation in those capacities. The by-laws of Elite contain such a provision requiring that we

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indemnify our directors and officers to the fullest extent permitted by law, as the law may be amended from time to time.

Elite in its subscription agreement with each of the purchasers in the private placement of the Series A Preferred Stock has agreed to indemnify the purchaser against damages or losses and expenses arising from any losses or expenses incurred in connection with a loss or alleged loss arising from a

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material misstatement in or a material omission from the Registration Statement except for a material misstatement or omission based on written information provided to Elite by the purchaser.

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

### ITEM 16. EXHIBITS

- 4.1 Certificate of Incorporation, together with all amendments thereto, incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-4, Registration No. 333-101686 filed with the Commission on December 6, 2002 and Exhibit 3.1 to Registrant's Current Report on Form 8-K\*.
- 4.2 By-laws of Elite, as amended. Incorporated by reference to Exhibit 3.1 to Elite's Registration Statement on Form SB-2, Registration No. 333-90633, made effective on February 28, 2000.
- 4.3 Form of Common Stock certificate. Incorporated by reference to Exhibit 4.1 to Elite's Registration Statement on Form SB-2, Registration No. 333-90633, made effective on February 28, 2000.
- 4.4 Form of Series A Preferred Stock certificate. Incorporated by reference to Exhibit 4.5 to Elite's Current Report on Form 8-K\*.
- 4.5 Form of Short Term Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.6 to Elite's Current Report on Form 8-K\*.
- 4.6 Form of Long Term Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.7 to Registrant's Current Report on Form 8-K\*.
- 4.7 Form of Common Stock Purchase Warrant issued to Indigo Securities Inc., and its associates. Incorporated by reference to Exhibit 4.8 to Elite's Current Report on Form 8-K\*.
- 4.8 Form of subscription agreement with investors with registration rights as an exhibit. Incorporated by reference to Exhibit 10.11 to Elite's Current Report on Form 8-K\*.
- 4.9 Amended and Restated Option to Purchase Shares to Dr. Atul Mehta.
- 5.1 Opinion of Reitler Brown & Rosenblatt LLC
- 23.1 Consent of Miller, Ellin & Company LLP
- 23.2 Consent of KPMG.
- 23.3 Consent of Reitler Brown & Rosenblatt LLC (included in Exhibit 5.1 above)
- 24.1 Power of Attorney (included on Signature page).

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\* Dated October 6, 2004 and filed with the Commission on October 12, 2004.



ITEM 17. UNDERTAKINGS

The undersigned Registrant hereby undertakes:

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

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

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

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

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

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

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

(4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement

relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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(B) INsofar AS INDEMNIFICATION FOR LIABILITIES ARISING UNDER THE SECURITIES ACT OF 1933 MAY BE PERMITTED TO DIRECTORS, OFFICERS AND CONTROLLING PERSONS OF THE REGISTRANT PURSUANT TO THE FOREGOING PROVISIONS, OR OTHERWISE, THE REGISTRANT HAS BEEN ADVISED THAT IN THE OPINION OF THE SECURITIES AND EXCHANGE COMMISSION SUCH INDEMNIFICATION IS AGAINST PUBLIC POLICY AS EXPRESSED IN THE SECURITIES ACT OF 1933 AND IS, THEREFORE, UNENFORCEABLE. IN THE EVENT THAT A CLAIM FOR INDEMNIFICATION AGAINST SUCH LIABILITIES (OTHER THAN THE PAYMENT BY THE REGISTRANT OF EXPENSES INCURRED OR PAID BY A DIRECTOR, OFFICER OR CONTROLLING PERSON OF THE REGISTRANT IN THE SUCCESSFUL DEFENSE OF ANY ACTION, SUIT OR PROCEEDING) IS ASSERTED AGAINST THE REGISTRANT BY SUCH DIRECTOR, OFFICER OR CONTROLLING PERSON IN CONNECTION WITH THE SECURITIES BEING REGISTERED, THE REGISTRANT WILL, UNLESS IN THE OPINION OF ITS COUNSEL THE MATTER HAS BEEN SETTLED BY CONTROLLING PRECEDENT, SUBMIT TO A COURT OF APPROPRIATE JURISDICTION THE QUESTION WHETHER SUCH INDEMNIFICATION BY IT IS AGAINST PUBLIC POLICY AS EXPRESSED IN THE SECURITIES ACT OF 1933 AND WILL BE GOVERNED BY THE FINAL ADJUDICATION OF SUCH ISSUE.

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

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

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Borough of Northvale, State of New Jersey, on November 12, 2004.

ELITE PHARMACEUTICALS, INC.

/s/ Bernard Berk

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Bernard Berk  
President and Chief Executive Officer

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

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might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue hereof.

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

Dated: November 12, 2004 /s/ Bernard Berk  
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Bernard Berk  
Chief Executive Officer and  
Chairman of the Board of Directors

Dated: November 12, 2004 /s/ Mark I. Gittelman  
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Mark I. Gittelman  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: November 12, 2004 /s/ John A. Moore  
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John A. Moore  
Director

Dated: November \_\_, 2004 -----  
Eric L. Sichel  
Director

Dated: November 12, 2004 /s/ Harmon Aronson  
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Harmon Aronson  
Director