

ELITE PHARMACEUTICALS INC /DE/
Form S-3/A
July 02, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JULY 2, 2004

REGISTRATION NO. 333 - 116356

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

AMENDMENT NO.1
TO
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)

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(I.R.
Identif

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

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

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

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

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 | PROPOSED MAXIMUM AGGREGATE OFFERING PRICE |
|--|-------------------------|---|---|
| Common Stock, \$.01 par value | 1,580,000 (1) | \$3.00 (3) | \$4,740,000 |
| Common Stock, \$.01 par value | 100,000 (2) | \$3.00 (3) | \$300,000 |
| Total | | | |

(1) 1,530,000 shares acquired in a private placement and 50,000 shares to be offered upon exercise of warrants issued to the Placement Agent and its associates.

(2) Shares to be offered upon exercise of stock options held by a former Chief Executive Officer at the exercise price of \$1.00 per share.

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- (3) 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 June 7, 2004.

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

1,680,000 SHARES

ELITE PHARMACEUTICALS

COMMON STOCK

This is an offering of shares of Common Stock, \$.01 par value, of Elite Pharmaceuticals, Inc. (the "Company" or "Elite"), by the selling stockholders named in this prospectus of 1,530,000 shares acquired from the Company in a private placement; 50,000 shares by the Placement Agent and its associates upon exercise of warrants received in the private placement, and 100,000 shares upon exercise of options expiring June 13, 2005 by a former Chief Executive Officer of the Company.

The Common Stock is listed on the American Stock Exchange under the symbol "ELI." On June 28, 2004, the closing sale price of our Common Stock on the American Stock Exchange was \$2.34 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.

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.

The date of this prospectus is July 2, 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>.

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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 outcome of our negotiations to effect a major acquisition, 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.

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PROSPECTUS SUMMARY

THE FOLLOWING SUMMARY HIGHLIGHTS SELECTED INFORMATION FROM, OR INCORPORATED BY REFERENCE INTO, THIS PROSPECTUS AND MAY NOT CONTAIN ALL THE INFORMATION THAT IS IMPORTANT TO YOU. TO UNDERSTAND OUR BUSINESS AND THIS OFFERING FULLY, YOU SHOULD READ THIS ENTIRE PROSPECTUS CAREFULLY, INCLUDING THE CONSOLIDATED FINANCIAL STATEMENTS AND THE RELATED NOTES AND THE DOCUMENTS INCORPORATED BY REFERENCE INTO THIS PROSPECTUS. REFERENCES IN THIS PROSPECTUS TO THE "COMPANY," "ELITE," "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

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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 by license and the collection of royalties 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 continued to limit the number of products that we are actively developing to six (a reduction from fifteen). 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 ("NDA")) and generic drug products (which require abbreviated new drug applications ("ANDA")).

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.

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

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

PROPOSED ACQUISITION

Our Board of Directors authorized in August 2003 the negotiation of an agreement to acquire Nostrum Pharmaceuticals Inc., a privately held corporation engaged in the development of drug delivery products and systems ("Nostrum"), by

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means of a merger with our wholly-owned subsidiary.

If the merger is effected on the terms as initially proposed, the outstanding shares of Nostrum will be converted into (i) shares of our Common Stock which will represent in the aggregate 75% of the shares of our Common Stock to be outstanding immediately after such merger and (ii) options to purchase a substantial number of additional shares of our Common Stock exercisable upon satisfaction of certain conditions. No assurance can be given that the acquisition will be consummated or if consummated will be effected on materially the same terms. If an agreement is executed, it is to contain several conditions to the consummation of the merger, including approval by our stockholders and that the Company will have immediately prior to effectiveness of the merger liquid assets of at least \$8,000,000. No assurance can be given that the agreement will be executed or if executed that the foregoing terms will not be materially changed adversely to the Company or that it will be approved by the Company's stockholders.

Nostrum is a specialty pharmaceutical company engaged in the formulation and commercialization of controlled-release orally-administered generic drugs utilizing Nostrum's proprietary drug delivery technologies.

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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 \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the fiscal years ended March 31, 2004, 2003, 2002 and 2001, respectively. At March 31, 2004, we had an accumulated deficit of approximately \$35.1 million, consolidated assets of approximately \$7.9 million, stockholders' equity of approximately \$4.0 million, and working capital of approximately \$1.3 million. Our products are in the development and early deployment stage and have not generated any significant revenue to date. Our independent auditors have issued a "going concern" audit reports for our financial statements for the fiscal years ended March 31, 2004 and 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;

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- 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.

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.

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To date, we have not been profitable, and since our inception in 1990, we have not generated any significant revenues. We may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. We incurred net losses of \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the years ended March 31, 2004, 2003, 2002 and 2001, respectively. We expect to realize significant losses for the current year of operation. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

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

On June 3, 2003, Dr. Atul M. Mehta, our founder and former President and Chief Executive Officer resigned from all of his positions with Elite. In the past, we have been reliant 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.

Under the settlement of a litigation initiated by Dr. Mehta in July 2003 for alleged breach of his employment agreement we paid Dr. Mehta \$400,000 and certain expense reimbursements, and the Company received a short term option for it or its designees to acquire all of the shares of Common Stock owned by Dr. Mehta and his affiliate at \$2.00 per share. As part of the settlement the Company also extended the expiration date of options to purchase 770,000 shares of Common Stock 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 770,000 shares issuable upon exercise of the foregoing options granted by the Company including the 100,000 shares which have been registered by the Registration Statement of which this prospectus is a part.

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

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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 one product in a prelaunch stage, one product in a pilot Phase I study, two products in a bioequivalence stage and two additional products 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 required for us to file a NDA with the FDA. ANDAs are filed with respect to generic versions of existing FDA approved products

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while NDAs are filed with respect to new products. In order for any of our products to be commercialized, FDA approval is required.

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 December, 2003 of shares of our Common Stock yielding gross proceeds of \$3,290,000 before commissions and expenses. (See "Selling Stockholders") We anticipate, based on our currently proposed plans and assumptions relating to our operations, and assuming the successful consummation of at least one of the proposed financings referred to below, that we have sufficient capital to satisfy our contemplated cash requirements through March 31, 2005. In particular, we expect to make substantial expenditures as we further develop and seek to commercialize our products. We also 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. One of the conditions to consummation of a proposed acquisition (see "Our Business - Proposed Acquisition") as currently proposed is that we have liquid assets of approximately \$8,000,000. We have no current arrangements for financings; however, (i) we are currently negotiating an equipment purchase financing agreement, which we anticipate closing in the reasonably foreseeable future; (ii) we have entered into a non-binding agreement in principle with a broker-dealer to effect a private placement of shares of our Common Stock and (iii) there is the potential exercise of options and warrants 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 financings, and so do not know 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 and to consummate the proposed acquisition on the terms proposed. 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

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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 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,

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although we are not aware of any threatened or pending actions by third parties asserting that we have infringed on their patents, and are not aware of any actions we have taken that would lead to such a claim, it is possible that we might be sued for infringement. The cost involved in bringing suits against others for infringement of our patents, or in defending any suits brought against us, can be substantial. We may not possess sufficient funds to prosecute or defend such suits. If our products were found to infringe upon patents issued to others, we would be prohibited from manufacturing or selling such products and we could be required to pay substantial damages.

In addition, we may be required to obtain licenses to patents, or other proprietary rights of third parties, in connection with the development and use of our products and technologies as they relate to other persons' technologies. At such time as we discover a need to obtain any such license, we will need to establish whether we will be able to obtain such a license on favorable terms. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

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

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

See also the risk under the heading "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".

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

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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

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licensees or marketing partners from marketing our products. It could also limit the commercial use of our products.

THE PHARMACEUTICAL INDUSTRY IS HIGHLY COMPETITIVE AND SUBJECT TO RAPID AND SIGNIFICANT TECHNOLOGICAL CHANGE, WHICH COULD IMPAIR OUR ABILITY TO IMPLEMENT OUR BUSINESS MODEL.

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, it is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. Such companies may develop new formulations and products, or may improve existing ones, more efficiently than we can. Our success, if any, will depend in part on our ability to keep pace with the changing technology in the fields in which we operate.

IF OTHER 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.

WE HAVE BEEN DEPENDENT ON CONTRACTS WITH A FEW MAJOR CUSTOMERS FOR SUBSTANTIALLY ALL OF OUR REVENUES, AND IF THOSE CONTRACTS TERMINATE OR EXPIRE, WE WILL BE WITHOUT THE STREAMS OF REVENUE THAT THEY HAVE REPRESENTED, UNLESS WE ARE ABLE TO NEGOTIATE OTHER CONTRACTS WITH OTHER CUSTOMERS THAT GENERATE SIMILAR REVENUES.

Each year we have had some customers that accounted for a large percentage of our sales. If our contracts with these customers terminate or expire, we will lose substantially all of our revenues. As a result of inadequate funds to conduct research and development we were unable to generate material revenues under existing contracts - for the year ended March 31, 2004 we had only \$258,250 of revenue, of which \$108,250 were research and development fees earned in conjunction with our distinct development, license and manufacture agreements. There can be no assurance that at the time that any of

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our current contracts expire, other contracts will be in place generating material revenue.

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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 May 31, 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 twelve months ended March 31, 2004, the closing sale price on the American Stock Exchange of our Common Stock fluctuated from a high of \$3.80 per share to a low of \$1.34 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 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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IF ADDITIONAL AUTHORIZED SHARES OF OUR COMMON STOCK ARE AVAILABLE FOR ISSUANCE OR SHARES ELIGIBLE FOR FUTURE SALE WERE INTRODUCED INTO THE MARKET, IT COULD HURT OUR STOCK PRICE AND MAKE A CHANGE OF CONTROL MORE DIFFICULT TO ACHIEVE.

As of June 21, 2004, there were 25,000,000 shares of our Common Stock authorized, of which 12,104,423 shares were outstanding. In addition, as of that date there were 5,071,289 shares eligible for issuance upon exercise of currently outstanding options and warrants, although options for 790,000 of those shares of stock had not yet vested. If every warrant and option holder exercised his or her rights, once all the currently unvested options vested, there would be 17,175,712 shares of Common Stock outstanding. The stockholders are being asked at the adjourned Annual Meeting of Stockholders scheduled to be held on July 21, 2004 to approve a proposed amendment to the Company's Certificate of Incorporation to increase the authorized shares of capital stock from 25,000,000 shares of Common Stock to 65,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock. No assurance can be given that the amendment will be approved.

Currently, more than 9,500,000 outstanding shares are eligible for resale in addition to the 1,530,000 shares which are to be offered by the selling stockholders and the 150,000 shares which are registered for resale upon exercise of outstanding warrants and options. We are unable to estimate the amount, timing or nature of future sales of outstanding Common Stock. 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.

If the proposed amendment of the Certificate of Incorporation to increase the authorized capital stock is approved by our shareholders, our Board of Directors will be authorized to issue additional shares on such terms as it may determine.

The additional authorized but unissued shares of the Company's Common Stock or the issuance of one or more series of Preferred Shares that would become available for issuance if the amendment is approved 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. The amendment 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

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

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

- 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.

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NO REPRESENTATION CAN BE MADE THAT A PROPOSAL TO ACQUIRE NOSTRUM WILL BE APPROVED BY OUR BOARD AND IF SO APPROVED, WILL BE APPROVED BY OUR STOCKHOLDERS, OR THAT IF EFFECTED IT WILL BE CONSUMMATED ON NO LESS FAVORABLE TERMS THAN INITIALLY PROPOSED.

The business of Nostrum is subject to most of the risks set forth above with respect to our business. (Note that a claim of patent infringement was filed against Nostrum in September 2003.) If the proposed transaction is effected, the Company and our stockholders will also be subject to additional risk factors including:

A. We would depend on the efforts of Dr. Nirmal Mulye, Ph.D., its president and holder of approximately 90% of its outstanding shares. A loss or diminution of his services would have a material adverse effect on the operating results and financial condition of the Company.

B. We would have to expand our staff. No assurance can be given that we would be successful in hiring additional key personnel or that the additional staff would prove beneficial.

C. Nostrum's principal operations to date derive from development and distribution agreements with three pharmaceutical companies. In the event of a termination of the agreements by a pharmaceutical company or Nostrum, payments under the related agreement by the pharmaceutical company to Nostrum are recoverable by the pharmaceutical company, primarily as credits or setoffs against royalty obligations,.

D. The proposed acquisition of Nostrum by means of a merger of a wholly owned subsidiary of Elite with Nostrum would, if effected on the terms initially proposed, result in the issuance of three times the number of all shares then outstanding and options to purchase a substantial number of additional shares. In such event the holders of our Common Stock will suffer material dilution in their equity and voting rights and Dr. Mulye will have the power to elect all of our directors, except that it is currently proposed that the agreement will provide for the current management of the Company to designate initially three of the seven directors which are to constitute the Board of Directors;

USE OF PROCEEDS

The Company will not receive any proceeds from the sale of shares by this prospectus.

DESCRIPTION OF CAPITAL STOCK

As of June 21, 2004, there were outstanding 12,104,423 shares of Common Stock and options and warrants to purchase a total of 5,071,289 shares of our Common Stock including the 50,000 shares to be offered upon exercise of warrants held by the Placement Agent and its associates and 100,000 shares to be offered upon exercise of options held by the former Chief Executive Officer of Elite, but exclusive of options to purchase up to 1,500,000 shares which

may be granted under the 2004 Elite Option Plan approved by our stockholders at the June 22, 2004 Annual Meeting.

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Our stockholders at the adjourned Annual Meeting scheduled to be held on July 21, 2004 are being asked to approved an amendment of our Certificate of Incorporation which would increase our authorized capital stock from 25,000,000 shares of Common Stock to 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. No representation can be made that the proposed amendment, approval of which will require the affirmative vote of a majority of the outstanding shares, will be approved.

COMMON STOCK

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, subject if the proposed amendment is approved to the rights of the holders of any shares of Preferred Stock which may be outstanding, 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.

PREFERRED STOCK

If the proposed amendment to the Company's Certificate of Incorporation is approved, the Company's Board of Directors will have the authority to issue 5,000,00 shares of Preferred Stock in one or more series and to fix the powers, designations, rights, preferences and restrictions thererof, 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. The Company currently has no plans to issue any shares of Preferred Stock.

ANTI-TAKEOVER PROVISIONS

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

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- 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,

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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 corporations outstanding voting stock at an annual or special meeting, excluding the shares owned by the interested stockholder.

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

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

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 | | HIGH |
|-------------------------|--|--------|
| QUARTER ENDED | | |
| FISCAL YEAR | | |
| ENDING MARCH 31, 2004: | | |
| March 31, 2004..... | | \$3.80 |
| December 31, 2003..... | | \$3.30 |
| September 30, 2003..... | | \$3.49 |
| June 30, 2003 | | \$3.45 |

| | | |
|-------------------------|--|--------|
| FISCAL YEAR | | |
| ENDING MARCH 31, 2003: | | |
| March 31, 2003..... | | \$2.20 |
| December 31, 2002..... | | \$3.15 |
| September 30, 2002..... | | \$5.25 |

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| | |
|-------------------------|---------|
| June 30, 2002..... | \$7.75 |
| FISCAL YEAR | |
| ENDING MARCH 31, 2002: | |
| March 31, 2002..... | \$8.30 |
| December 31, 2001..... | \$7.75 |
| September 30, 2001..... | \$11.50 |
| June 30, 2001..... | \$11.45 |

On June 28, 2004, the last reported sale price of our Common Stock, as reported by the American Stock Exchange, was \$2.34 per share.

We have never paid cash dividends on our capital 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.

MANAGEMENT

Board of Directors

The Board of Directors in May 2004 by Board resolution set the number of Directors constituting the Board of Directors commencing with the Annual Meeting of Stockholders held on June 22, 2004 at four, a reduction from seven.

The table below sets forth the names and ages, as of June 25, 2004, of each of the Directors (Mr. Bernard Berk is Chairman of the Board and Chief Executive Officer of the Company), 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) | 39 | 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 occupations 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,

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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.

Harmon Aronson, Ph.D. has been employed since 1997 as the 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, 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. He is also a director of Elite Research, Ltd. Other than Elite Research Ltd., no company with which Dr. Aronson was affiliated in the past was a parent, subsidiary or other affiliate of the Company.

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.

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from UMDNJ--New Jersey Medical School, and is licensed to practice medicine by the State of New York.

There is no family relationship between the persons nominated or chosen by the Company to become directors.

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. All of our executive officers, except for Mr. Berk who has a long term employment agreement, are serving 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.

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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, except for Mr. Moore, 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.

Audit Committee Report: The following is the Audit Committee Report made by all its members with respect to our financial statements as of and for the year ended March 31, 2004.

The Audit Committee reviewed and discussed the audited financial statements with management. The Audit Committee discussed with the independent auditors of the Company the matters required to be discussed by SAS 61 (Codification of Statements on Auditing Standards, AU 380), as modified or supplemented. The Audit Committee received the written disclosures and the letter from the independent accountants required by Independence Standards Board Standard No. 1 (Independence Standards Board Standard No. 1, Independence Discussions with Audit Committees), as modified or supplemented. The Audit Committee discussed with the independent accountant the independent accountant's independence. Based upon the foregoing review and discussions, the Audit Committee recommended to the Board of Directors of the Company that the audited financial statements of the Company be included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2004 as filed with the Commission.

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

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

Our executive officers of the Company are Bernard Berk and Mark I.

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Gittelman.

Bernard Berk, age 55, was appointed Chief Executive Officer in June 2003, 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 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 full time 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 \$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.

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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 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.

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

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 Co | |
|---|--------------------------|---------------|--------------|--|-----------------------------------|--|
| (a) Name and Principal Position | (b) Fiscal Year(1) | (c) Salary | (d) Bonus | (e) Other Annual Compen- sation(3) | (f) Restricted Stock Awards | (g) Securities Underlying Options |
| Bernard Berk, President and Chief Executive Officer | 2003-04 | \$166,667 | -- | -- | -- | 300,000 (4) |
| Atul M. Mehta, Ph.D. former President and Chief executive Officer(2) | 2003-04 | \$ 53,684 | -- | \$ 3,040 | -- | -- (5) |
| | 2002-03 | \$330,140 | -- | \$ 3,040 | -- | -- |
| | 2001-02 | \$272,855 | -- | \$83,856 | -- | 50,000 (6) |

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(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

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June 3, 2003.

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

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

(5) 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 13, 2005.

(6) 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.

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 FUTURE 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 transaction". See "Executive Officers".

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(2) Pursuant to a settlement which closed in April 2004 of a litigation with the Company the expiration dates of options to purchase 770,000 shares granted prior to year ended March 31, 2002 while he was an executive officer were extended.

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

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| NAME | SHARES EXERCISED | VALUE REALIZED | NUMBER OF SHARES UNDERLYING | | VALUE OF UNEXERCISED I | |
|------------------|------------------|----------------|--|---------------|------------------------|-----------|
| | | | UNEXERCISED OPTIONS AT YEAR-END* EXERCISABLE | UNEXERCISABLE | OPTIONS AT YEAR-E | UNEXER |
| Atul M. Mehta | -0- | -0- | 270,000 | -0- | | \$0 |
| (2) | -0- | -0- | 100,000 | -0- | | \$0 |
| | -0- | -0- | 100,000 | -0- | | \$48,000 |
| | -0- | -0- | 100,000 | -0- | | \$98,000 |
| | -0- | -0- | 100,000 | -0- | | \$148,000 |
| | -0- | -0- | 100,000 | -0- | | \$198,000 |
| Bernard Berk (3) | -0- | -0- | 300,000 | 300,000 | | \$291,000 |

*Giving retroactive effect to a litigation settlement which became effective in April 2004.

(1) The dollar values are calculated by determining the difference between \$2.98 per share, the closing 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, a Director until June 22, 2004, 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 \$28,800, \$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.

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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 as of April 30, 2004 by (i) each director and named executive officer, (ii) each beneficial holder of at least 5% of the outstanding shares and (iii) all executive officers and directors as a group. On such date, we had 12,104,423 shares of Common Stock outstanding. 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 Common Stock 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 ----- | Pe --- |
|---|---------------------------|-----------|
| Harmon Aronson, Director* | 70,000 (1) | |
| Eric L. Sichel, Director* | 60,000 (2) | |
| John A. Moore, Director* | 1,224,218 (3) | |
| Bernard Berk, Chairman of the Board and Chief Executive Officer* | 300,000 (4) | |
| Mark I. Gittelman, CFO, Treasurer and Secretary 300 Colfax Avenue Clifton, New Jersey 07013 | 10,000 (5) | |
| Dr. Atul Mehta c/o Andrew Giles Freda, Esq. Edwards & Caldwell LLC 1600 Route 208 North Hawthorne, NJ 07647 | 2,257,700 (6) | |
| Edson Moore Healthcare Ventures, Inc. 403 Marsh Lane Wilmington, Delaware 19804 | 914,218 (7) | |
| Jerome Belson 495 Broadway New York, New York 10012 | 905,100 (8) | |
| ALL DIRECTORS AND OFFICERS AS A GROUP | 1,664,218 (9) | |

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

** Less than 1% of outstanding shares

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(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) Represents (i) options personally held by Mr. Moore to purchase 310,000 shares and (ii) 914,218 shares of Common Stock beneficially owned by Edson Moore Healthcare Ventures, Inc. ("Edson Moore"), of which he is president and principal stockholder. The 914,218 shares of Common Stock are comprised of: (i) 764,218 shares of Common Stock issued to Edson Moore upon the exchange of 12,915 shares of Series A Preferred Stock, per value \$1.00 per share, of Elite Laboratories, Inc., (ii) a warrant to purchase 100,000 shares of Common Stock (exercisable through October 17, 2005) at an exercise price of \$18.00 per share and (iii) 50,000 shares acquired in a recent private placement.

(4) Comprised of options to purchase 300,000 shares.

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

(6) Based on his Schedule 13D filed on April 28, 2004 with the Securities and Exchange Commission and includes options to purchase 770,000 shares, and 312,600 shares owned by his wife, members of his family or an affiliate.

(7) See clause (ii) of note 3 above.

(8) Based on information contained in a Schedule 13D, as amended, filed by Jerome Belson on November 15, 2002. Includes (i) 535,200 shares held by Jerome Belson, (ii) 53,900 shares held by Maxine Belson, wife of Jerome Belson, (iii) 7,000 shares held by Brianne Goldstein, daughter of Jerome Belson, (iv) 28,000 shares held by Majorie Belson, daughter-in-law of Jerome Belson, (v) 25,000 shares owned by the grandchildren of Jerome Belson and (vi) warrants to purchase 256,000 shares of common stock.

(9) Includes options and warrants to purchase an aggregate of 730,000 shares.

Except as otherwise set forth, information on 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 which equity securities of the Company are authorized for issuance in exchange for consideration in the form of goods or services.

The Company is informed and believes that as of April 20, 2004, Cede & Co. held 7,069,228 shares of the Company's Common Stock as nominee for Depository Trust Company, 55 Water Street, New York, New York 10004. It is our understanding that both Cede & Co. and Depository Trust Company disclaim any beneficial ownership therein and claim that such shares are held for the account of numerous other persons, no one of whom is believed to beneficially own five

percent or more of the Common Stock of the Company.

SELLING STOCKHOLDERS

1,530,000 shares of Common Stock offered by the selling stockholders were acquired by them at a price of \$2.00 per share in a private placement by the Company completed in December, 2003, including 70,000 shares acquired by certain of our officers and directors or their affiliates. An additional 50,000 shares of Common Stock may be offered by Montauk Financial Group, Inc., the Placement Agent in the private placement and its associates upon exercise of warrants at \$2.00 per share issued to them along with a cash commission to the Placement Agent of \$72,500 as consideration for the Agent's services. The expiration date of the warrants is December 2, 2008.

The following table details the name of each selling stockholder, the Placement Agent and each associate (collectively, the "selling stockholders"), the number of shares of our Common Stock beneficially owned by each selling stockholder and the number of shares of our Common Stock that may be offered for resale under this prospectus. To the extent permitted by law, the selling stockholders which are not natural persons may distribute shares from time to time, to one or more of their respective affiliates, which may sell shares pursuant to this prospectus. We have registered the shares to permit the selling stockholders and their respective permitted transferees or other successors in interest that receive their shares from selling stockholders after the date of this prospectus to resell the shares. Because each selling stockholder may offer all, some or none of the shares it holds, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares, no definitive estimate as to the number of shares that will be held by each selling stockholder after the offering can be provided. The selling stockholders may from time to time offer all or some of the shares pursuant to this offering. Pursuant to Rule 416 under the Securities Act of 1933, the Registration Statement of which this prospectus is a part also covers any additional shares of our Common Stock which become issuable in connection with such shares because of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of outstanding shares of our Common Stock. The following table has been prepared on the assumption that all shares offered under this prospectus will be sold to parties unaffiliated with the selling stockholders. Except as indicated by footnote, 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 12,104,423 shares of our Common Stock outstanding as of April 30, 2004 and assumes that none of the outstanding warrants or options (including the options held by Dr. Atul Mehta) will have been exercised after the offering.

| Name and Address | Shares Owned Prior to Offering | Number of Shares Which May Be Sold | Shares Owned Offer Number P |
|------------------|--------------------------------|------------------------------------|-----------------------------|
| ----- | ----- | ----- | ----- |

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| | | | |
|--|---------|--------|---------|
| Edson Moore Healthcare Ventures, Inc. (1) 403 Marsh Lane Wilmington, DE 19804 | 914,218 | 50,000 | 864,218 |
|--|---------|--------|---------|

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| Name and Address | Shares Owned Prior to Offering | Number of Shares Which May Be Sold | Shares Own Offer Number P |
|--|-----------------------------------|---------------------------------------|---------------------------------|
| Eric I. Sichel/Dana Cernea, as co-tenants (2) 411 Highview Road Englewood, NJ 02631 | 60,000 (2) | 20,000 | 40,000 |
| Daniel Brandwein 916 Gulfstream Ct. Weston, FL 33327 | 12,500 | 12,500 | 0 |
| William J. Kurinsky 4 Cotswold Circle Ocean Township, NJ 07712 | 12,500 | 12,500 | 0 |
| Sharon Will 3014 SW 41st Lane Ocala, FL 34474 | 425,900 (3) | 25,000 | 400,900 |
| Dianne Will 9 Prospect Hill Road, Ext. Pine Plains, NY 12567 | 17,000 | 12,500 | 4,500 |
| Dennis Levine 4101 N. Ocean Blvd. 1805D Boca Raton, FL 33431 | 50,000 | 50,000 | 0 |
| Steve T. Kelley 8982 Becker Allen Park, MI 48101 | 12,500 | 12,500 | 0 |
| Paul Becker 222 Wellington Road Mineola, NY 11501 | 25,000 | 25,000 | 0 |
| Robert Karsten 121 East 60th Street New York, NY 10022 | 163,840 | 100,000 | 63,840 |
| Lawrence Gorelick DDS PC Retirement Trust | 12,500 | 12,500 | 0 |

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530 Route Six
Mahopac, NY 10541

| | | | |
|--|--------|--------|-------|
| Helen DeSantis 8 Rolling Drive Brookville, NY 11545 | 12,500 | 12,500 | 0 |
| E. Gerald Kay 201 Rte 22 Hillside, NJ 07205 | 57,500 | 50,000 | 7,500 |
| Kenneth Wilk 678 Princeton Ave. Brick, NJ 08724 | 25,000 | 25,000 | 0 |
| Robert and Susan Moran 39 Soundview Drive Fort Salonga, NY 11768 | 12,500 | 12,500 | 0 |

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| Name and Address | Shares Owned Prior to Offering | Number of Shares Which May Be Sold | Shares Owned Offered Number P |
|---|--------------------------------|------------------------------------|-------------------------------|
| Ronald Robinson 134 Mineola Blvd. Mineola, NY 11501 | 12,500 | 12,500 | 0 |
| Stanley Ast 7 Clay Street New City, NY 10956 | 14,500 (4) | 12,500 | 2,000 (4) |
| Delores Bowman 21-07 Greenwood Drive Fairlawn, NJ 07410 | 50,000 | 50,000 | 0 |
| Michael Sokol 40 East 84th Street New York, NY 10028 | 20,000 | 20,000 | 0 |
| Murray Alon 64-40 Ellwell Crescent Rego Park, NY 11374 | 25,000 | 25,000 | 0 |
| Israel Cohen 13852 Via DaVinci Del Ray Beach, FL 33446 | 45,000 (5) | 40,000 | 5,000 (5) |
| Frank B. Carr 2005 Chestnut Hills Drive | 313,400 (6) | 50,000 | 263,400 (6) |

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Cleveland Heights, OH 44106-460

| | | | |
|--|-------------|---------|-------------|
| David Garceau 14 Birdsall Farm Drive Armonk, NY 10504 | 534,460 (7) | 75,000 | 459,460 (7) |
| Lee Johnson Trust 14750 El Camino Real Del Mar, CA 92014 | 25,000 | 25,000 | 0 |
| Robert Rosenblum 74 Magnolia Lane Jericho, NY 11753 | 15,000 | 15,000 | 0 |
| Daniel Orenstein 1385 York Avenue, Apt. 31B New York, NY 10021 | 26,500 (8) | 20,000 | 6,500 (8) |
| Ronald Schaffer 1016 Fifth Avenue New York NY 10028 | 25,000 | 25,000 | 0 |
| Ronald Menello 22 Calt Drive Hazlet, NJ 07730 | 35,000 | 35,000 | 0 |
| Joseph Giamanco 4 White Rock Terrace Holmdel, NJ 07733 | 374,000 (9) | 100,000 | 274,000 (9) |

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| Name and Address | Shares Owned Prior to Offering | Number of Shares Which May Be Sold | Shares Owned After Offering Number P |
|--|--------------------------------|------------------------------------|--------------------------------------|
| Frank Lagano 147 Buckingham Rd. Tenefly, NJ 07670 | 100,000 | 100,000 | 0 |
| Ronald Brown 4149 Old Manchester Ct. Mason, OH 45040 | 31,250 (10) | 25,000 | 6,250 (10) |
| Baji A. Palkhiwala 211 Trenor Drive New Rochelle, NY 10804 | 100,400 | 25,000 | 75,400 |
| Gerald Brauser 820 Andrews Ave. Pompano Beach, FL 33069 | 254,000 | 100,000 | 154,000 |

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| | | | |
|--|--------------|--------|--------------|
| John N. Hatsopoulos 3 Woodcock Lane Lincoln, MA 01773 | 25,000 | 25,000 | 0 |
| Scott Waldman 105 The Intervale Roslyn, NY 11576 | 12,500 | 12,500 | 0 |
| Nora Sosnowski PO Box 8944 Albany, NY 12208 | 12,500 | 12,500 | 0 |
| Henderson Orthopedic Profit Sharing Plan 451 Run Creek Road, #103 Henderson, NC 27536 | 25,000 | 25,000 | 0 |
| Michael Stahl 23325 Ladrillo Street Woodland Hills, CA 91367 | 12,500 | 12,500 | 0 |
| Lindsey Dart 520 11th Street, Apt. 1 Washington, D.C. 2003 | 20,000 | 20,000 | 0 |
| Bridge Ventures, Inc. 1241 Gulf of Mexico Drive Longboat Key, FL 34228 | 432,750 (11) | 25,000 | 407,750 (11) |
| Seymour Orenstein 5 Shelly Lane Great Neck, NY 11023 | 20,000 | 20,000 | 0 |
| Marvin Sheeber 641 Fifth Avenue, Apt. 43B New York, NY 10022 | 25,000 | 25,000 | 0 |
| Kevin and Jeanne Hurley 3 Port Ct. Manorville, NY 11949 | 15,000 | 15,000 | 0 |

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| Name and Address | Shares Owned Prior to Offering | Number of Shares Which May Be Sold | Shares Own Offer Number P |
|--|-----------------------------------|---------------------------------------|---------------------------------|
| Warren and Marianne Gilbert 1200 N. Bayshore Drive, #210 North Miami, FL 33181 | 25,000 (12) | 12,500 | 12,500 (12) |

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| | | | |
|--|-------------|-------------|-------------|
| C. Ames Byrd 513 Market Street Pacomke City, MD 21851 | 25,000 | 25,000 | 0 |
| Robert J. Moore 21 Lighthouse Way Darien, CT 06820 | 25,000 | 25,000 | 0 |
| Martin and Beata Beck 614 N. June Street Los Angeles, CA 90004 | 42,500 (12) | 25,000 | 17,500 (12) |
| Leonard Luttinger 830 Cordova Blvd. NE St. Peterson, FL 33704 | 12,500 | 12,500 | 0 |
| Robert Walker 467 Andrews Road Mineola, NY 11501 | 12,500 | 12,500 | 0 |
| Albert Saphier MD IRA 4922 Bay Way Place Tampa, FL 33629 | 42,500 (13) | 12,500 | 30,000 (13) |
| Kevin J. Martin P.O. Box 270 Mineola, NY 11501 | 44,386 (14) | 32,500 (14) | 11,886 |
| Daniel J. Walsh P.O. Box 270 Mineola, NY 11501 | 49,886 (14) | 32,500 (14) | 17,386 |
| Christine Walker 467 Andrews Avenue Mineola, NY 11501 | 2,500 (15) | 2,500 (15) | 0 |
| Montauk Financial Group, Inc. 328 Newman Springs Road Red Bank, NJ 07701 | 7,500 (16) | 7,500 (16) | 0 |

- (1) Mr. John A. Moore, a director and former Chairman of our Board of Directors, is president and principal stockholder of Edson Moore Healthcare Ventures, Inc.
- (2) Represents (i) options personally held by Mr. Sichel, a former director of the Company, to purchase 40,000 shares and (ii) 20,000 shares acquired Mr. Sichel and Dana Cernea as co-owners in our private placement. The 20,000 shares are being offered by this prospectus.
- (3) Includes warrants to purchase 175,000 shares, (including warrants to purchase 100,000 shares held by Saggi Capital Corp., a consultant to the Company with which she is affiliated).

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- (4) Includes 2,000 shares issuable upon exercise of warrants.
- (5) Includes 5,000 shares issuable upon exercise of warrants.
- (6) Includes 171,200 shares issuable upon exercise of warrants
- (7) Includes 201,585 shares issuable upon exercise of warrants.
- (8) Includes 2,500 shares issuable upon exercise of warrants.
- (9) Includes 65,000 shares issuable upon exercise of warrants.
- (10) Includes 6,250 shares issuable upon exercise of warrants.
- (11) Includes 103,750 shares issuable upon exercise of warrants.
Bridge Ventures Inc. is a consultant to the Company.
- (12) Includes 12,500 shares issuable upon exercise of warrants.
- (13) Includes 10,000 shares issuable upon exercise of warrants.
- (14) Includes 24,386 shares issuable upon exercise of warrants of which
20,000 shares will be offered upon exercise of warrants received
as an associate of the Placement Agent.
- (15) Represents the shares issuable upon exercise of the warrants
received as an associate of the Placement Agent.
- (16) Represents the shares issuable upon exercise of the warrants
received as an associate of the Placement Agent.

An agreement between Dr. Atul Mehta, our former Chairman of the Board and Chief Executive Officer, settling a litigation instituted against Elite alleging a breach of his employment agreement provided, among other things, for the extension to June 13, 2005 of the expiration dates of options to purchase 770,000 shares with exercise prices ranging from \$1.00 to \$10.00 per share, of which options to purchase 70,000 shares had expired, and the grant of piggyback registration rights to Dr. Mehta at our expense with respect to the shares issuable upon exercise of the options. Pursuant to Dr. Mehta's request his offering of 100,000 shares issuable upon exercise of options at a price of \$1.00 per share is covered by this prospectus.

See "Security Ownership of Our Directors, Executive Officers and Principal Stockholders" for Dr. Mehta's address and his beneficial holdings of shares of our Common Stock as of April 30, 2004. Assuming the sale by Dr. Mehta of all 100,000 shares subject to the options, the beneficial ownership of Dr. Mehta based on his holdings as of April 30, 2004 would

be reduced to 2,154,700 shares, or 16.7% of the shares to be outstanding assuming no other exercise of outstanding options or warrants.

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PLAN OF DISTRIBUTION

Offer and Sale of Shares

A selling stockholder, including in such definition in this section, Dr. Mehta and 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 their 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:

- 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, pledgees, 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

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

Selling through Broker-Dealers

A selling stockholder may select broker-dealers to sell its shares. 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 pledgees, donees, transferees and other successors-in-interest, may be deemed to be "underwriters" within the meaning of Section 2(11) of the Securities Act of 1933, as amended (the "Securities Act") in connection with the sale of the shares. Accordingly, any such commission, discount or concession received by them and any profit on the resale of the shares purchased by them may be deemed to be underwriting discounts or commissions under the Securities Act. Because a selling stockholder may be deemed to be an "underwriter" within the meaning of Section 2(11) of the Securities Act, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sales of the shares covered by this prospectus.

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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.

EXPERTS

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

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The Securities and Exchange Commission allows us to incorporate by reference the information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference into this registration statement is considered to be part of this registration statement, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings 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 June 29, 2004;
- b. our current reports on Form 8-K, dated April 2, 2004, April 16, 2004, May 5, 2004 and May 14, 2004; and
- c. our definitive proxy statement, in Schedule 14A dated May 13, 2004, filed with the Commission on May 19, 2004 with respect to our Annual Meeting of the Stockholders held on June 22, 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

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

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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 * | |
| ----- | |
| SEC Registration Fee..... | \$ 638.56 |
| Legal Fees and Expenses..... | \$20,000.00 |
| Accounting Fees and Expenses..... | \$ 1,000.00 |
| Printing Expenses..... | \$ 2,000.00 |
| Miscellaneous..... | \$ 2,000.00 |
| | ----- |
| Total..... | \$25,638.56 |

* 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

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corporation in those capacities. The by-laws of Elite contain such a provision requiring that we indemnify our directors and officers to the fullest extent permitted by law, as the law may be amended from time to time.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant 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

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- 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
- 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 certificate representing shares of Elite's Common Stock. 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 Common Stock Purchase Warrant issued to Montauk Financial Group and its associates.**
- 5.1 Opinion of Reitler Brown & Rosenblatt LLC**
- 10.1 Settlement Agreement and Mutual Release in action of Atul M. Mehta, Ph.D. v. Elite Pharmaceuticals, Inc., Elite Laboratories, Inc. and John Moore, dated as of April 21, 2004.**
- 10.2 Employment Agreement dated July 23, 2003 between Company and Bernard Berk incorporated by reference to Exhibit 10.9 to Elite's Report on Form 10-Q for the three months ended June 30, 2003.**
- 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).

* Filed with this Amendment No.1.

** Filed as an exhibit to the Form S-3 filed with the Commission on June 10, 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

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

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

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

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

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

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

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

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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 June 30, 2004.

ELITE PHARMACEUTICALS, INC.

/s/ Bernard Berk

Bernard Berk
President and Chief Executive Officer

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

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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: June 30, 2004

/s/ Bernard Berk

Bernard Berk

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Chief Executive Officer and
Chairman of the Board of Directors

Dated: June 30, 2004

/s/ Mark I. Gittleman

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

Dated: June 30, 2004

/s/ John A. Moore

John A. Moore
Director

Dated: June 30, 2004

/s/ Eric L. Sichel

Eric L. Sichel
Director

Dated: June 30, 2004

/s/ Harmon Aronson

Harmon Aronson
Director

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