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ELITE PHARMACEUTICALS INC /DE/  
Form S-1  
April 27, 2005

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON APRIL 27, 2005

REGISTRATION NO. 333-

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SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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

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

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

With copies to:

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

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

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

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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. |\_|

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CALCULATION OF REGISTRATION FEE

| TITLE OF EACH CLASS OF<br>SECURITIES TO BE REGISTERED | AMOUNT<br>TO BE<br>REGISTERED | PROPOSED<br>MAXIMUM<br>OFFERING<br>PRICE PER<br>SHARE | PROPOSED<br>MAXIMUM<br>AGGREGATE<br>OFFERING<br>PRICE | AMOUNT OF<br>REGISTRATION<br>FEE |
|---|-------------------------------|---|---|----------------------------------|
| Common Stock, \$.01 par value                         | 2,402,181                     | \$5.00  | \$12,010,905  | \$1,413.68                       |

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

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ELITE PHARMACEUTICALS, INC.

CROSS REFERENCE PAGE

| Registration Statement Item<br>Number and Heading<br>-----                                   | Location in Prospectus<br>-----                           |
|--|---|
| 1. Forepart of the Registration Statement and Outside Front<br>Cover Page of Prospectus..... | Cover Page  |
| 2. Inside Front and Outside Back Cover Pages of<br>Prospectus.....                           | Inside Front and Outside Cover                            |
| 3. Summary Information, Risk Factors and Ratio of Earnings to<br>Charges.....                | Prospectus Summary; Risk Factors; Selected Financial Data |
| 4. Use of Proceeds.....  | Use of Proceeds   |

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5. Determination of Offering Price.....Cover Page; Risk Factors

6. Dilution.....Dilution

7. Selling Security Holders..... N/A

8. Plan of Distribution.....Risk Factors; Offer to Class B and Class C Warrant holders

9. Description of Securities to be Registered.....Description of Capital Stock

10. Interests of Named Experts and Counsel .....Experts and Counsel

11. Information with Respect to the Registrant.....Prospectus Summary; Risk Factors; Our Business

12. Disclosure of Commission Position on Indemnification for Securities Act Liabilities.....Part II

PRELIMINARY PROSPECTUS DATED APRIL 27, 2005

PROSPECTUS  
ELITE PHARMACEUTICALS, INC.

2,402,181 SHARES  
COMMON STOCK

This Prospectus covers an aggregate of 2,402,181 shares of the common stock of ("Common Stock"), \$.01 par value, of Elite Pharmaceuticals, Inc. ("Elite" or the "Company"), a Delaware corporation, of which 1,721,179 shares are issuable upon exercise of the Company's outstanding Class C Warrants and 681,002 shares are issuable upon exercise of the Company outstanding Class B Warrants (collectively the "Warrants"). The Warrants are exercisable on or prior to November 30, 2005 at a price of \$5.00 per share.

The Common Stock is listed on the American Stock Exchange under the symbol "ELI." On April \_\_, 2005, the closing sales price of our Common Stock on the American Stock Exchange was [\_\_\_\_] per share.

AN INVESTMENT IN THE SECURITIES OFFERED HEREBY INVOLVES A HIGH DEGREE OF RISK. INVESTORS SHOULD NOT INVEST ANY FUNDS IN THIS OFFERING UNLESS THEY CAN AFFORD TO LOSE THEIR ENTIRE INVESTMENT. SEE "RISK FACTORS" BEGINNING ON PAGE 6.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION, NOR HAS THE COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The securities are being offered for cash as follows:

|                           | Price to<br>public (1) | Underwriting discounts<br>and commissions | Proceeds to<br>issuer (1) |
|---------------------------|------------------------|---|---------------------------|
| Per Share of Common Stock | \$5.00                 | None                                      | \$12,010,905              |

(1) The exercise price of each Warrant.

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Elite intends to furnish its stockholders and holders of Warrants with annual reports containing audited financial statements, examined by an independent accounting firm, and such interim reports as it may determine to furnish or as may be required by law.

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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 about the Company. Our SEC filings are also available to the public from commercial document retrieval services, from the American Stock Exchange and at the web site maintained by the SEC at <http://www.sec.gov>.

Elite has not authorized anyone to give any information or make any representation about the offering that differs from, or adds to, the information

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in this prospectus or in its documents that are publicly filed with the SEC. 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.

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 this prospectus includes forward-looking statements (as defined in Section 27A of the Securities Act and Section 21E of the Securities Exchange Act) that reflect Elite's current views with respect to future events and financial performance. Certain factors, such as unanticipated technological difficulties, the volatile and competitive environment for drug delivery products, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the degree of success, if any, in concluding business partnerships or licenses with viable pharmaceutical companies, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors" in this prospectus could cause actual results to differ materially from those in the forward-looking statements. We assume no obligation to update the matters discussed in this prospectus.

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### PROSPECTUS SUMMARY

THE FOLLOWING SUMMARY HIGHLIGHTS SELECTED INFORMATION FROM THIS PROSPECTUS 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 INCLUDED HEREIN. REFERENCES IN THIS PROSPECTUS TO THE "COMPANY," "ELITE," "WE," "OUR," AND "US" REFER TO ELITE PHARMACEUTICALS, INC., A DELAWARE CORPORATION, TOGETHER WITH OUR SUBSIDIARIES.

### THE COMPANY

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. We believe that controlled release drug delivery of a pharmaceutical compound offers a safer and more effective means of administering drugs through releasing a drug into the bloodstream or delivering it to a certain site in the body at predetermined rates or predetermined times. The goal is to provide more effective drug therapy while reducing or eliminating many of the side effects associated with conventional drug therapy and/or to reduce the frequency of administration.

We have concentrated on developing orally administered controlled release products. These products include drugs that cover therapeutic areas for pain,

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angina, hypertension, allergy and infection.

In June 2001, we entered into agreements with a pharmaceutical company, for the pharmaceutical company to market two drug products in the field of allergy treatment. The pharmaceutical company agreed that upon our development of each product it would secure the required regulatory approval, if any. We are to receive royalties based on sales of the product and revenues based on our manufacturing costs. We completed the commercial development of Lodrane 24(R), and marketing by the partner commenced in November 2004. We are currently engaged in the commercial development of the second product.

On March 30, 2005, we entered into an agreement with a marketing company and a formulation development company for us to develop a designated controlled release product, which is to be manufactured by us upon receipt of FDA approval to be secured by the formulation development company and sold to the marketing company for distribution.

Four of our other products are at different stages of development and will require FDA approval.

We are focusing our efforts on the following areas: (i) the manufacture of Lodrane 24(R) and the development and manufacturing of the second allergy product; (ii) commercial exploitation of products either by license and the collection of royalties, or through the manufacture of tablets and capsules using our developed formulations, and (iii) development of new products and the expansion of our licensing agreements with other pharmaceutical companies, including contract research and development projects, joint ventures and other collaborations.

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In an effort to reduce costs and improve focus and efficiency, we have reduced the number of products that we are actively developing from fifteen to seven, one of which has been developed and is currently being marketed. The 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 various types of drug products including branded drug products (which require new drug applications ("NDAs")) and generic drug products (which require abbreviated new drug applications ("ANDAs")).

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

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

- o having a product portfolio that includes 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.

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

### SUMMARY OF FINANCIAL DATA

| STATEMENT OPERATIONS DATA:           | YEAR ENDED MARCH 31, |                      | NINE MONTHS ENDED DE |    |
|--------------------------------------|----------------------|----------------------|----------------------|----|
|                                      | 2003                 | 2004                 | 2003                 |    |
| Net Revenues .....                   | \$ 630,310           | \$ 258,250           | \$ 30,000            | \$ |
| Loss from Operations .....           | (3,552,214)          | (4,699,506)          | (3,263,544)          |    |
| Other Income (Expenses) .....        | (508,808)            | (1,813,711)          | (1,698,937)          |    |
| Loss per share basic and diluted ... | (0.40)               | (0.58)               | (.46)                |    |
| Weighted average of shares .....     | 10,069,991           | 11,168,618           | 10,829,626           |    |
|                                      | MARCH 31,<br>2004    | DECEMBER 31,<br>2004 |                      |    |
| <b>BALANCE SHEET DATA:</b>           |                      |                      |                      |    |
| Cash and cash equivalents .....      | \$2,104,869          | \$4,564,948          |                      |    |
| Working capital .....                | 1,289,764            | 3,846,412            |                      |    |
| Total Assets .....                   | 7,853,434            | 9,562,630            |                      |    |
| Long-Term obligations .....          | 2,495,000            | 2,385,051            |                      |    |
| Shareholders' equity .....           | 4,048,192            | 6,287,565            |                      |    |

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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 "GOING CONCERN" AUDIT REPORTS.

We reported net losses of \$4,649,827, \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the nine months ended December 31, 2004 and fiscal years ended March 31, 2004, 2003, 2002 and 2001, respectively. At December 31, 2004, we had an accumulated deficit of approximately \$39.83 million, consolidated assets of approximately \$9.56 million, stockholders' equity of approximately \$6.29 million, and a working capital of approximately \$3.85 million. Our products are in the development and early deployment stage and have not generated any significant revenue to date. Our independent auditors have issued a "going concern" audit report for our financial statements for the fiscal years ended March 31, 2004 and March 31, 2003.

WE HAVE A RELATIVELY LIMITED OPERATING HISTORY, WHICH MAKES IT DIFFICULT TO EVALUATE OUR FUTURE PROSPECTS.

Although we have been in operation since 1990, we have a relatively short operating history and limited financial data upon which you may evaluate our business and prospects. In addition, our business model is likely to continue to evolve as we attempt to expand our product offerings and enter new markets. As a

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result, our potential for future profitability must be considered in light of the risks, uncertainties, expenses and difficulties frequently encountered by companies that are attempting to move into new markets and continuing to innovate with new and unproven technologies. Some of these risks relate to our potential inability to:

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

If we do not effectively address the risks we face, our business model may become unworkable and we may not achieve or sustain profitability or successfully develop any products.

WE HAVE NOT BEEN PROFITABLE AND EXPECT FUTURE LOSSES.

To date, we have not been profitable, and since our inception in 1990, we have not generated any significant revenues. We may never be profitable or, if we become profitable, we may be unable to sustain profitability. We have sustained losses in each year since our incorporation in 1990. We incurred net losses of \$4,649,827, \$6,514,217, \$4,061,422, \$1,774,527 and \$13,964,981 for the nine months ended December 31, 2004 and the years ended

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March 31, 2004, 2003, 2002 and 2001, respectively. We expect to continue to incur losses until we are able to generate sufficient revenues to support our operations and offset operating costs.

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

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

Pursuant to an agreement in April 2004 and a related agreement in October 2004, to settle a litigation initiated by Dr. Mehta in July 2003 for alleged breach of his employment agreement, the Company extended the expiration dates to November 30, 2007 of options to purchase 670,000 shares of Common Stock held by Dr. Mehta and he relinquished any rights to the Company's intellectual property and agreed to certain non-disclosure and non-competition covenants. The Company also provided him with certain "piggyback" registration rights with respect to the shares issuable upon exercise of the foregoing options granted by the Company. Dr. Mehta and members of his family sold in October 2004 an aggregate of 1,362,200 shares of Common Stock representing all of his and his affiliates holdings of securities of the Company except for the foregoing options.

OUR RESEARCH ACTIVITIES ARE CHARACTERIZED BY INHERENT RISK AND WE MAY NOT BE



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ABLE TO SUCCESSFULLY DEVELOP PRODUCTS FOR COMMERCIAL USE THAT ARE IN OUR PIPELINE.

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

We have entered into agreements with respect to the marketing upon development of three drugs. Each agreement provides that we are to commercially develop the product and upon securing by a partner or the partners of FDA approval or other regulatory approval, if required, we will manufacture the product and sell it to a partner or marketing partner for distribution. The commercial development of one drug has been completed, a second drug is under development and a third is to be developed. No assurance can be given that the marketing partner will not experience difficulty in selling the product, which would result in little revenue or profit for Elite from the product.

Of the four other products currently under development and on which we are devoting substantial attention, two products are in pilot Phase I studies and two products are in the pilot bioequivalence stage. Additional studies including either pivotal bioequivalence or efficacy studies will be required for these products before commercialization.

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

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

With respect to products that are developed and are available for commercial sale, we intend to pursue product-specific licensing, marketing agreements, co-development opportunities and other partnering arrangements in connection with the distribution of the product. We have entered into partnership arrangements as to three products but cannot be sure that we will be able to locate other partners or that the arrangement will be suitable. In addition, assuming we identify suitable partners, the process of effectively entering into these arrangements involves risks such that our management's attention may be diverted from other business concerns and that we may have difficulty integrating the new arrangements into our existing business.

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

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

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of any approval.

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

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

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

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

We may not be able to successfully complete any clinical trial of a potential product within any specified time period. In some cases, we may not be able to complete the trial at all. Moreover, clinical trials may not show any potential product to be safe or efficacious. Thus, the

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FDA and other regulatory authorities may not approve any of our potential products for any indication.

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

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

WE ARE DEPENDENT ON A SMALL NUMBER OF SUPPLIERS FOR OUR RAW MATERIALS, AND ANY DELAY OR UNAVAILABILITY OF RAW MATERIALS CAN MATERIALLY ADVERSELY AFFECT OUR ABILITY TO PRODUCE PRODUCTS.

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved. In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers. Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

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- o greater possibility for disruption due to transportation or communication problems;
- o the relative instability of some foreign governments and economies;
- o interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and
- o uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

In addition, recent changes in patent laws in certain foreign jurisdictions (primarily in Europe) may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable United States or foreign patents. Any inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, could have a material adverse effect on us.

The delay or unavailability of raw materials can materially adversely affect our ability to produce products. This can materially adversely affect our business and operations.

IF WE NEED ADDITIONAL FINANCING IN ORDER TO SATISFY OUR SIGNIFICANT CAPITAL REQUIREMENTS AND ARE UNABLE TO OBTAIN ADDITIONAL FINANCING, IT WOULD IMPAIR OUR ABILITY TO CONTINUE TO DO BUSINESS.

We completed a \$6,600,000 private placement in October 2004 of (i) 516,558 shares of our Series A Preferred Stock convertible into shares of Common Stock, (ii) warrants ("Short Term Warrants") expiring December 31, 2005 and warrants ("Long Term Warrants") expiring December 27, 2009 to purchase at a price ranging from \$1.54 to \$1.84 per share 5,165,580 shares of Common Stock, and (iii) Long Term Warrants issued to the Placement Agent to purchase 494,931 shares of Common Stock at prices ranging from \$1.23 to \$1.47 per share. As of March 7, 2005, all of the shares of the Series A Preferred Stock have been converted into 5,200,120 shares of Common Stock. We anticipate, based on our currently proposed plans and

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assumptions relating to our operations, that we have sufficient capital to satisfy our contemplated cash requirements through March 31, 2006. After that time, we may require additional financing. In particular, we expect to make substantial expenditures as we further develop and seek to commercialize our products. As of December 31, 2004 we were depleting our cash which amounted to approximately \$4.56 million on that date at the rate of \$300,000 per month. We expect that our rate of spending will accelerate as the result of increased costs and expenses associated with seeking regulatory approval and commercialization of products now in development. We have no current arrangements with respect to additional financings other than the potential exercise of the Short Term and Long Term Warrants issued in the October 2004 private placement and the warrants issued to the Placement Agent, the Class B and Class C Warrants and other warrants and options that are currently outstanding. We have no way of knowing whether any of the options or warrants will be exercised and if so the extent by which their exercise will be pursuant to cashless exercise provisions. We do not currently have commitments for their exercise or other financing, 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.

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If any future financing involves the sale of our securities, our then-existing stockholders' equity could be substantially diluted. On the other hand, if we incurred debt, we would be subject to risks associated with indebtedness, including the risk that interest rates might fluctuate and cash flow would be insufficient to pay principal and interest on such indebtedness. If our plans change, or our assumptions change or prove to be inaccurate, or our cash flow proves to be insufficient to fund our operations due to unanticipated expenses or problems, we would be required to seek additional financing sooner than anticipated.

IF WE ARE UNABLE TO PROTECT OUR INTELLECTUAL PROPERTY RIGHTS AND AVOID CLAIMS THAT WE INFRINGED ON THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, OUR ABILITY TO CONDUCT BUSINESS MAY BE IMPAIRED.

Our success, competitive position and amount of royalty income, if any, will depend in part on our ability to obtain patent protection in various jurisdictions related to our technologies, processes and products. We intend to file patent applications seeking such protection, but we cannot be certain that these applications will result in the issuance of patents. If patents are issued, third parties may sue us to challenge such patent protection, and although we know of no reason why they should prevail, it is possible that they could. It is likewise possible that our patents may not prevent third parties from developing similar or competing products. In addition, although we are not aware of any threatened or pending actions by third parties asserting that we have infringed on their patents, and are not aware of any actions we have taken that would lead to such a claim, it is possible that we might be sued for infringement. The cost involved in bringing suits against others for infringement of our patents, or in defending any suits brought against us, can be substantial. We may not possess sufficient funds to prosecute or defend such suits. If our products were found to infringe upon patents issued to others, we would be prohibited from manufacturing or selling such products and we could be required to pay substantial damages.

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

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terms. The failure to obtain the necessary licenses or other rights could preclude the sale, manufacture or distribution of our products.

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

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

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

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The manufacturing and marketing of pharmaceutical products in the United States and abroad are subject to stringent governmental regulation. The sale of any of our products for use in humans in the United States will require the approval of the FDA. Similar approvals by comparable agencies are required in most foreign countries. The FDA has established mandatory procedures and safety standards that apply to the clinical testing, manufacture and marketing of pharmaceutical products. Obtaining FDA approval for a new therapeutic product may take several years and involve substantial expenditures. None of our products has been approved for sale or use in humans in the United States or elsewhere.

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

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

The pharmaceutical industry is highly competitive, and we may be unable to compete effectively. In addition, it is undergoing rapid and significant technological change, and we expect competition to intensify as technical advances in each field are made and become more widely known. An increasing number of pharmaceutical companies have been or are becoming interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that competition in the field of drug delivery will increase in the future as other specialized research and development companies begin to concentrate on this aspect of the business. Some of the major pharmaceutical companies have invested and are continuing to invest significant resources in the development of their own drug delivery systems and technologies and some have invested funds in such specialized drug delivery companies. Many 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.

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IF KEY PERSONNEL WERE TO LEAVE ELITE OR IF WE ARE UNSUCCESSFUL IN ATTRACTING QUALIFIED PERSONNEL, OUR ABILITY TO DEVELOP PRODUCTS COULD BE MATERIALLY HARMED.

Our success depends in large part on our ability to attract and retain highly qualified scientific, technical and business personnel experienced in the development, manufacture and marketing of controlled release drug delivery systems and products. Our business and financial results could be materially harmed by the inability to attract or retain qualified personnel.

IF WE WERE SUED ON A PRODUCT LIABILITY CLAIM, AN AWARD COULD EXCEED OUR INSURANCE COVERAGE AND COST US SIGNIFICANTLY.

The design, development and manufacture of our products involve an inherent risk of product liability claims. We have procured product liability insurance having a maximum limit of \$5,000,000; however, a successful claim against us in excess of the policy limits could be very expensive to us, damaging our financial position. The amount of our insurance coverage, which had been limited due to our limited financial resources, may be materially below the

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coverage maintained by many of the other companies engaged in similar activities. To the best of our knowledge, no product liability claim has been made against us as of March 15, 2005.

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 February 28, 2005, the closing sale price on the American Stock Exchange of our Common Stock fluctuated from a high of \$4.79 per share to a low of \$1.05 per share. The per share price of our Common Stock may not remain at or exceed current levels. The market price for our Common Stock, and for the stock of pharmaceutical companies generally, has been highly volatile. The market price of our Common Stock may be affected by:

- o Results of our clinical trials;
- o Approval or disapproval of abbreviated new drug applications or new drug applications;
- o Announcements of innovations, new products or new patents by us or by our competitors;
- o Governmental regulation;
- o Patent or proprietary rights developments;
- o Proxy contests or litigation;
- o News regarding the efficacy of, safety of or demand for drugs or drug technologies;
- o Economic and market conditions, generally and related to the 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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As of March 7, 2005, all of the issued 516,558 shares of Series A Preferred Stock have been converted into an aggregate of 5,200,120 shares of Common Stock. All of the shares issued upon conversion have been registered under the Securities Act of 1933 for resale. In addition, we have registered under the Securities Act of 1933, as amended for reoffering the shares of Common Stock which may be acquired upon exercise of the Short Term Warrants, Long Term Warrants and the Placement Agent Warrants as well as 670,000 shares which may be acquired upon exercise of options at prices ranging from \$1.00 to \$3.00 per share granted to Dr. Atul Mehta. As of this date sales of substantial amounts of the Common Stock in the public market are eligible for sale by these holders. Perceptions that substantial sales may take place in the future may lower the Common Stock's market price.

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

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One of the requirements for the continued listing of Common Stock on the American Stock Exchange for a company that has net losses for its five most recent fiscal years is that it have a stockholders' equity of at least \$6,000,000. The Company is expected to sustain a net loss for the year ending March 31, 2005, and as a result will have sustained net losses in its five most recent fiscal years. As of December 31, 2004, based on unaudited information, the Company had stockholders equity of approximately \$6.29 million. The related provision of the American Stock Exchange guide provides that the Exchange will not normally consider removing a stock from listing if the total value of the Company's market capitalization is at least \$50,000,000 as well as satisfying other conditions which the Company meets and expects to meet. As of March 31, 2005 the Company's stockholder's equity exceeded \$6,000,000. The failure to maintain listing of the Common Stock on the Exchange will have an adverse effect on the market and the market price for the Common Stock.

THE ISSUANCE OF ADDITIONAL SHARES OF OUR COMMON STOCK OR OUR PREFERRED STOCK COULD MAKE A CHANGE OF CONTROL MORE DIFFICULT TO ACHIEVE.

The issuance of additional shares of the Company's Common Stock or the issuance of shares of an additional series of Preferred Stock could be used to make a change of control of the Company more difficult and expensive. Under certain circumstances, such shares could be used to create impediments to or frustrate persons seeking to cause a takeover or to gain control of the Company. Such shares could be sold to purchasers who might side with the Board in opposing a takeover bid that the Board determines not to be in the best interests of its stockholders. It might also have the effect of discouraging an attempt by another person or entity through the acquisition of a substantial number of shares of the Company's Common Stock to acquire control of the Company with a view to consummating a merger, sale of all or part of the Company's assets, or a similar transaction, since the issuance of new shares could be used to dilute the stock ownership of such person or entity.

IF PENNY STOCK REGULATIONS BECOME APPLICABLE TO OUR COMMON STOCK THEY WILL IMPOSE RESTRICTIONS ON THE MARKETABILITY OF OUR COMMON STOCK AND THE ABILITY OF OUR STOCKHOLDERS TO SELL SHARES OF OUR STOCK COULD BE IMPAIRED.

The SEC has adopted regulations that generally define a "penny stock" to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than

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\$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:

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- 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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### OUR BUSINESS

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

We have concentrated on developing orally administered controlled release products. These products include drugs that cover therapeutic areas for pain, angina, hypertension, allergy and infection. The Food and Drug Administration (FDA) has not yet approved any of our products, each of which is at a different stage of development. One of our products has been commercially developed and is being marketed by a pharmaceutical company partner. One is under development for marketing by the same company. A third product is to be developed pursuant to a recent agreement with another pharmaceutical company.



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We are focusing our efforts on the following areas: (i) manufacturing of Lodrane 24(R) and the development and manufacture of the two other products referred to above; (ii) commercial exploitation of our products either by license and the collection of royalties, or through the manufacture of tablets and capsules using our formulations, and (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 enhance efficiency, we reduced the number of products that we are actively developing from fifteen to seven. The seven products, one of which have been commercially developed, five that are in development and one to be developed, were deemed by us to be the most suitable for development given our limited resources.

We are focusing on the development of various types of drug products, including 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.

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

- o having a diverse 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.

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### RESEARCH AND DEVELOPMENT

During the nine months ended December 31, 2004 and each of the last three fiscal years, we have focused on research and development activities. We spent \$1,937,794 in the nine months ended December 31, 2004, \$2,075,074 in the fiscal year ended March 31, 2004, \$2,013,579 in the fiscal year ended March 31, 2003 and \$1,609,108 in the fiscal year ended March 31, 2002 on research and development activities.

Of our seven controlled release products, two are for pain (the Oxycodone CR and a related abuse resistant product), one (diltiazem) is for cardiovascular indications, two are for allergy indications, one is for an anti-infective indication and one is for an undisclosed indication. One of the allergy products has been developed and is being marketed by a pharmaceutical company which has the responsibility for regulatory matters and is to market the second drug for allergy indications upon completion of its commercial development. The drug for the undisclosed indication is to be developed by us pursuant to a March 30, 2005 agreement. See "Manufacturing and Development Contracts".

The table below presents information with respect to the development of the five products under development. For some of the products, we intend to make NDA filings under Sections 505(b)(1) or 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Drug Price Act"). Accordingly, we anticipate, as to which there is no assurance, that the development timetable for the products for which such NDA filings are made would be shorter and less

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expensive. Completion of development of products by us depends on a number of factors, however, and there can be no assurance that specific time frames will be met during the development process or that the development of any particular products will be continued.

In the table, Pilot Phase I studies for the NDA products are generally preliminary studies done in healthy human subjects to assess the tolerance/safety and pharmacokinetics of the product. Additional larger studies in humans will be required prior to submission of the product to the FDA for review. Pilot bioequivalence studies are initial studies done in humans for generic products and are used to assess the likelihood of achieving bioequivalence for generic products. Larger pivotal bioequivalence studies will be required prior to submission of the product to the FDA for review.

| DEVELOPMENT STAGE          | NUMBER OF PRODUCTS | NDA/ANDA |
|----------------------------|--------------------|----------|
| Preclinical                | 1                  | ANDA     |
| Pilot Phase I study        | 2                  | NDA      |
| Pilot bioequivalence study | 2                  | ANDA     |

### MANUFACTURING AND DEVELOPMENT CONTRACTS

In September 1999 Elite entered into an agreement with an undisclosed partner to co-develop a chrono diltiazem product. A pilot pharmacokinetic study has been conducted, but until we have additional resources to devote to this product and locate a partner, we will not perform further clinical studies.

In June 2001, we entered into two development contracts pursuant to which we agreed to commercially develop two products in exchange for development fees, certain payments,

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royalties and manufacturing rights. The product, Lodrane 24(R), was first commercially offered in November 2004, and we are to receive revenues for manufacturing the product and a royalty on sales. Development of the second product continues.

The payments under the foregoing agreements for the year ended March 31, 2004 and the nine months ended December 31, 2004 were not material.

On March 30, 2005, we entered into an agreement with a dermatological marketing company and a formulation development company pursuant to which we are to commercially develop a drug with the marketing company to share in the development costs. Upon its development and the securing of the required FDA approval by the formulation development company, we are to manufacture and sell the commercially developed drug to the marketing company for distribution. In addition to the sales price to the marketing company, we are to share the profits, if any, realized upon sales.

### JOINT VENTURE WITH ELAN

In October 2000, we entered into a joint venture, ERL, with Elan to develop products using drug delivery technologies and expertise of both companies. ERL was initially owned 80.1% by us and 19.9% by Elan. ERL funded its research through capital contributions from its partners based on the partners'

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respective ownership percentage.

On September 30, 2002, we entered into an agreement with Elan to terminate the joint venture (the "Termination Agreement"). Pursuant to the Termination Agreement, we terminated the joint venture and acquired from Elan its entire interest in ERL. As a result of the Termination Agreement, we owned 100 percent of ERL's capital stock. On December 31, 2002, ERL was merged into a new Delaware corporation, Elite Research, our wholly-owned subsidiary.

Under the Termination Agreement, we acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by the joint venture. In exchange for this assignment, we agreed to pay Elan a royalty on certain revenues that may be realized in the future from the once-a-day Oxycodone product that was in development by the joint venture, if and when FDA approval is obtained. In the future, we will be solely responsible for funding product development. The joint venture had completed the initial Phase I study for its first product, the once-a-day Oxycodone formulation.

The joint venture had also performed work on a second, related product in the central nervous system therapeutic area. Initial formulation work on a third product combining Oxycodone with a narcotic antagonist has been performed. We have the exclusive rights to the proprietary, development and commercial exploitation for the worldwide markets for these two products developed by ERL. We will not have to pay Elan royalties on revenues that may be realized from these products.

Under the joint venture, Elan had received 409,165 shares of our common stock, warrants exercisable at \$18.00 per share for 100,000 shares of our common stock, and Series A and Series B preferred stock of Elite Labs, which were convertible into 764,221 shares and 52,089 shares, respectively, of our common stock. Under the Termination Agreement, Elan and its transferees retained the securities, and the shares of Series A and Series B preferred stock were converted

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into our common stock under the preexisting terms for conversion. We did not pay, nor did Elan receive, any cash consideration under the Termination Agreement.

### PATENTS

We have secured five United States patents of which two have been assigned for a fee. In addition one patent has been allowed, but not yet issued and we have pending applications for three United States patents and five foreign patents.

The pending patent applications relate to three different control release pharmaceutical products on which we are working. Included among these patent applications is an application for a U.S. patent for a narcotic agonist and antagonist product that we are developing to be used with oxycodone and other narcotics to minimize the abuse potential for the narcotics was filed. We intend to apply for patents for other products in the future; however, there can be no assurance that any of the pending applications or other applications which we may file will be granted.

Prior to the enactment in the United States of new laws adopting certain changes mandated by the General Agreement on Tariffs and Trade (GATT), the exclusive rights afforded by a U.S. Patent were for a period of 17 years measured from the date of grant. Under these new laws, the term of any U.S.

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Patent granted on an application filed subsequent to June 8, 1995, terminates 20 years from the date on which the patent application was filed in the United States or the first priority date, whichever occurs first. Future patents granted on an application filed before June 8, 1995, will have a term that terminates 20 years from such date, or 17 years from the date of grant, whichever date is later.

Under the Drug Price Act, a U.S. Product patent or use patent may be extended for up to five years under certain circumstances to compensate the patent holder for the time required for FDA regulatory review of the product. The benefits of this Act are available only to the first approved use of the active ingredient in the drug product and may be applied only to one patent per drug product. There can be no assurance that we will be able to take advantage of this law.

Also, different countries have different procedures for obtaining patents, and patents issued by different countries provide different degrees of protection against the use of a patented invention by others. There can be no assurance, therefore, that the issuance to us in one country of a patent covering an invention will be followed by the issuance in other countries of patents covering the same invention, or that any judicial interpretation of the validity, enforceability, or scope of the claims in a patent issued in one country will be similar to the judicial interpretation given to a corresponding patent issued in another country. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology.

We also rely upon unpatented proprietary and trade secret technology that we seek to protect, in part, by confidentiality agreements with our collaborative partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we will have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and technological advances will not otherwise become known to others.

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In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology.

### TRADEMARKS

We have received Notices of Allowance from the U.S. Patent and Trademark Office granting trademark protection for the following trademarks: Albulite CR, Nifelite CR, Diltilite CD, Ketolite CR, Verelite CR and Glucolite CR. However, since we currently plan to license our products to marketing partners and not to sell under our brand name, we do not currently intend to register or maintain any trademarks.

### GOVERNMENT REGULATION AND APPROVAL

The design, development and marketing of pharmaceutical compounds, on which our success depends, are intensely regulated by governmental regulatory agencies, including the FDA. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecution based on products or manufacturing practices that violate statutory requirements. In addition, administrative remedies can involve voluntary withdrawal of products, as well as

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the refusal of the FDA to approve ANDAs and NDAs. The FDA also has the authority to withdraw approval of drugs in accordance with statutory due process procedures.

Before a drug may be marketed, it must be approved by the FDA. The FDA approval procedure for an ANDA relies on bioequivalency tests which compare the applicant's drug with an already approved reference drug, rather than with clinical studies. Because we concentrated, during our first few years of business operations, on developing products which are intended to be bioequivalent to existing controlled-release formulations, we expect that such drug products will require ANDA filings and not clinical efficacy and safety studies, which are generally more expensive and time-consuming.

The FDA approval procedure for an NDA is generally a two-step process. During the Initial Product Development stage, an investigational new drug application ("IND") for each product is filed with the FDA. A 30-day waiting period after the filing of each IND is required by the FDA prior to the commencement of initial clinical testing. If the FDA does not comment on or question the IND within such 30-day period, initial clinical studies may begin. If, however, the FDA has comments or questions, they must be answered to the satisfaction of the FDA before initial clinical testing can begin. In some instances this process could result in substantial delay and expense. These initial clinical studies generally constitute Phase I of the NDA process and are conducted to demonstrate the product tolerance/safety and pharmacokinetic in healthy subjects.

After Phase I testing, extensive efficacy and safety studies in patients must be conducted. After completion of the required clinical testing, an NDA is filed, and its approval, which is required for marketing in the United States, involves an extensive review process by the FDA. The NDA itself is a complicated and detailed application and must include the results of extensive clinical and other testing, the cost of which is substantial. However, the NDA filings contemplated by us on already marketed drugs would be made under Sections 505 (b) (1) or 505 (b) (2) of the Drug Price Act, which do not require certain studies that would otherwise be necessary; accordingly, the development timetable should be shorter. While the FDA is required to review applications within a certain timeframe in the review process, the FDA frequently

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requests that additional information be submitted. The effect of such request and subsequent submission can significantly extend the time for the NDA review process. Until an NDA is actually approved, there can be no assurance that the information requested and submitted will be considered adequate by the FDA to justify approval. The packaging and labeling of our developed products are also subject to FDA regulation. It is impossible to anticipate the amount of time that will be needed to obtain FDA approval to market any product.

Whether or not FDA approval has been obtained, approval of the product by comparable regulatory authorities in any foreign country must be obtained prior to the commencement of marketing of the product in that country. The Company intends to conduct all marketing in territories other than the United States through other pharmaceutical companies based in those countries. The approval procedure varies from country to country, can involve additional testing, and the time required may differ from that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general each country has its own procedures and requirements, many of which are time consuming and expensive. Thus, there can be substantial delays in obtaining required approvals from both the FDA and foreign regulatory authorities after the relevant applications are filed. After such approvals are obtained, further

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delays may be encountered before the products become commercially available.

All facilities and manufacturing techniques used for the manufacture of products for clinical use or for sale must be operated in conformity with Good Manufacturing Practice ("GMP") regulations issued by the FDA. In the event the Company engages in manufacturing on a commercial basis for distribution of products, it will be required to operate its facilities in accordance with GMP regulations. If we hire another company to perform contract manufacturing for us, we must ensure that our contractor's facilities conform to GMP regulations.

Under the Generic Drug Enforcement Act, ANDA applicants (including officers, directors and employees) who are convicted of a crime involving dishonest or fraudulent activity (even outside the FDA regulatory context) are subject to debarment. Debarment is disqualification from submitting or participating in the submission of future ANDAs for a period of years or permanently. The Generic Drug Enforcement Act also authorizes the FDA to refuse to accept ANDAs from any company which employs or uses the services of a debarred individual. We do not believe that we receive any services from any debarred person.

We are also subject to federal, state, and local laws of general applicability, such as laws relating to working conditions. We are also licensed by, registered with, and subject to periodic inspection and regulation by the DEA and New Jersey state agencies, pursuant to federal and state legislation relating to drugs and narcotics. Certain drugs that we may develop in the future may be subject to regulations under the Controlled Substances Act and related statutes. At such time as we are able to manufacture products, we may become subject to the Prescription Drug Marketing Act, which regulates wholesale distributors of prescription drugs.

### COMPLIANCE WITH ENVIRONMENTAL LAWS

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices of corporations as to which we are the successor. We do not expect that compliance with such environmental laws

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will have a material effect on our capital expenditures, earnings or competitive position in the foreseeable future. There can be no assurance, however, that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on our capital expenditures, earnings or competitive position.

### COMPETITION

We compete in two related but distinct areas: we seek to perform contract research and development work regarding controlled-release drug technology for other pharmaceutical companies, and to develop and market (either on our own or by license to other companies) proprietary controlled-release pharmaceutical products. In both areas, our competition consists of those companies which develop controlled-release drugs and alternative drug delivery systems.

In recent years, an increasing number of pharmaceutical companies have become interested in the development and commercialization of products incorporating advanced or novel drug delivery systems. We expect that

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competition in the field of drug delivery will significantly increase in the future since smaller specialized research and development companies are beginning 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 these companies have greater financial and other resources as well as more experience than we do in commercializing pharmaceutical products. Certain companies have a track record of success in developing controlled-release drugs. Significant among these are Alpharma, Inc., Andrx Corporation, Elan Corporation Plc, Biovail Corporation, Ethypharm S.A., Eurand, Impax Laboratories, Inc., K-V Pharmaceutical Company, Penwest Pharmaceuticals Company and Skyepharma Plc. Each of these companies has developed expertise in certain types of drug delivery systems, although such expertise does not carry over to developing a controlled-release version of all drugs. Such companies may develop new drug formulations and products or may improve existing drug formulations and products more efficiently than we can. In addition, almost all of our competitors have vastly greater resources than we do. While our product development capabilities and, if obtained, patent protection may help us to maintain our market position in the field of advanced drug delivery, there can be no assurance that others will not be able to develop such capabilities or alternative technologies outside the scope of our patents, if any, or that even if patent protection is obtained, such patents will not be successfully challenged in the future.

### SOURCES AND AVAILABILITY OF RAW MATERIALS; MANUFACTURING

We manufacture for commercial sale by our partner, ECR Pharmaceuticals, one product, Lodrane 24(R) and for which to date we have obtained sufficient amounts of the raw materials for its production. We are not currently in the manufacturing phase for any other products and do not expect that significant amounts of raw materials will be required for their production. We currently obtain the raw materials that we need from over twenty suppliers.

We have acquired pharmaceutical manufacturing equipment with the intention of manufacturing products that we develop and, on a contract basis, products developed by other pharmaceutical companies. In anticipation of this manufacturing and for the manufacture of the Lodrane 24(R), we have registered our facilities with the FDA and the DEA.

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### DEPENDENCE ON ONE OR A FEW MAJOR CUSTOMERS

Each year we have had some customers that have accounted for a large percentage of our limited sales. If our contracts with any of these customers terminate or expire, we will lose substantially all of our revenues. We are constantly working to develop new relationships with existing or new customers, but despite these efforts we may not, at the time that any of our current contracts expire, have other contracts in place generating similar revenue.

### EMPLOYEES

As of February 28, 2005, we had 15 full-time employees and 2 part-time employees. Both full-time and part-time employees are engaged in administration, research and development. None of our employees is represented by a labor union and we have never experienced a work stoppage. We believe our relationship with our employees to be good. However, our ability to achieve our financial and operational objectives depends in large part upon our continuing ability to attract, integrate, retain and motivate highly qualified personnel, and upon the continued service of our senior management and key personnel.

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### PROPERTIES

Our facility, which we own, is located at 165 Ludlow Avenue, Northvale, New Jersey, and contains approximately 20,000 square feet of floor space. This real property and the improvements thereon are encumbered by a mortgage in favor of the New Jersey Economic Development Authority (NJEDA) as security for a loan through tax-exempt bonds from the NJEDA to Elite. The mortgage document contains certain customary provisions including, without limitation, the right of NJEDA to foreclose upon a default by Elite.

We are currently using our facilities as a laboratory and office space and intend to use it in the future also for manufacturing. Properties used in our operations are considered suitable for the purposes for which they are used and are believed to be adequate to meet our needs for the reasonably foreseeable future.

### USE OF PROCEEDS

If all the Company's B Warrants and C Warrants are exercised, the proceeds will be \$12,010,905, before deducting expenses of this offering estimated at approximately \$ [\_\_\_\_\_]; such proceeds will be used for working capital.

### CAPITALIZATION

The following table sets forth the outstanding indebtedness and capital stock as of December 31, 2004 giving retroactive affect to the subsequent conversion of the balance of Series A Preferred Shares outstanding on December 31, 2004 and to be outstanding assuming the exercise of the outstanding 2,402,181 Class B and Class C Warrants without giving effect to the expenses of this offering

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|  | OUTSTANDING  | TO BE OUTSTANDING |
|--|--------------|-------------------|
| <b>LONG TERM INDEBTEDNESS</b>  |              |                   |
| 7% Mortgage Bonds, net of current portion of \$165,000   | \$2,180,000  | \$2,180,000       |
| Notes Payable, net of current portion of \$130,000   | \$205,000    | \$205,000         |
| <b>CAPITAL STOCK</b>   |              |                   |
| Preferred Stock, authorized 5,000,000 shares, par value \$.01 - none outstanding   | --           | --                |
| Common Stock, authorized 65,000,000 shares, par value \$.01 - 17,443,467 Shares outstanding, and 19,848,648 shares to be outstanding (1) | \$174,435    | \$198,456         |
| Additional paid in capital   | \$46,289,033 | \$58,275,916      |

(1) In addition to the shares to be outstanding, 5,660,511 shares are reserved for issuance upon exercise of the Short Term Warrants, Long Term Warrants and Placement Agent Warrants and 2,377,050 shares are reserved for issuance upon exercise of outstanding options granted to officers, directors, employees and consultants.



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## DILUTION

As of December 31, 2004 the net tangible book value per share of Common Stock based on the Company's unaudited balance sheet as of December 31, 2004 was \$0.47. Assuming exercise of all the outstanding Class B and Class C Warrants the pro forma net tangible book value as of December 31, 2004 would be \$1.175. As indicated in the following table purchasers of shares of Common Stock pursuant to the exercise of a Class B Warrant or a Class C Warrant, based on the unaudited December 31, 2004 Balance Sheet, will suffer an immediate dilution of \$3.825 per share.

|   |         |
|---|---------|
| Per share exercise price.....                     | \$5.00  |
| Tangible book value per share as of 12/31/04..... | \$0.47  |
| Pro forma tangible book value as of 12/31/04      | \$1.175 |
|   | -----   |
| Dilution per share.....                           | \$3.825 |
|   | =====   |

## SELECTED FINANCIAL DATA

The selected statement of operations data set forth below with respect to the years ended, March 31, 2002, 2003 and 2004 and the balance sheet data at March 31, 2003 and 2004, are derived from, and are qualified by reference to, the financial statements of the Company included elsewhere in this Prospectus, which financial statements have been audited by Miller, Ellin & Co. LLP, independent accountants, as indicated in their report included elsewhere and which contains an explanatory paragraph which indicates that there is substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are described in Note 2 to the financial statements. The selected statement of operations data for the years ended March 31, 2000 and 2001 and the balance sheet data as of March 2000, 2001, and 2002 have been derived from the financial statements of the Company not included in this

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Prospectus. The selected balance sheet data as of December 31, 2004 and the statement of operations data for the nine months ended December 31, 2003 and 2004 are derived from the Company's unaudited financial statements included in this Prospectus and include, in the opinion of management, all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such data. Results of operations for the nine month period ended December 31, 2004 are not necessarily an indication of the results to be expected for the entire year ending March 31, 2005.

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|                                   | YEAR ENDED MARCH 31, |           |              |            |              |
|-----------------------------------|----------------------|-----------|--------------|------------|--------------|
| STATEMENT OF OPERATIONS DATA: ... | 2000                 | 2001      | 2002         | 2003       | 2004         |
| Net Revenues .....                | \$ 10,315            | \$ 95,246 | \$ 1,197,507 | \$ 630,310 | \$ 2,000,000 |

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|   |                |                 |                |                |                |
|---|----------------|-----------------|----------------|----------------|----------------|
| OPERATING EXPENSES:                                     |                |                 |                |                |                |
| Research and development .....                          | 1,988,649      | 1,475,487       | 1,609,108      | 2,013,579      | 2,013,579      |
| General and administrative .....                        | 984,736        | 777,118         | 763,687        | 1,858,069      | 1,858,069      |
| Depreciation and amortization ..                        | 86,290         | 194,038         | 266,919        | 310,876        | 310,876        |
|   | -----          | -----           | -----          | -----          | -----          |
|   | 3,059,675      | 2,446,643       | 2,639,714      | 4,182,524      | 4,182,524      |
|   | -----          | -----           | -----          | -----          | -----          |
| Loss from Operations .....                              | (3,049,360)    | (2,351,397)     | (1,442,207)    | (3,552,214)    | (3,552,214)    |
| OTHER INCOME (EXPENSES):                                |                |                 |                |                |                |
| Interest Income .....                                   | 210,877        | 329,583         | 260,055        | 96,692         | 96,692         |
| Litigation settlement .....                             | --             | --              | --             | --             | --             |
| Sale of New Jersey tax losses .                         | --             | --              | 137,818        | 71,674         | 71,674         |
| Interest expense .....                                  | (137,709)      | (227,301)       | (220,123)      | (227,907)      | (227,907)      |
| Expense relating to issuance<br>of stock options .....  | --             | --              | --             | (20,550)       | (20,550)       |
| Equity in Loss of Joint Venture                         | --             | (12,079,827)    | --             | (186,379)      | (186,379)      |
| Expense relating to issuance<br>of stock warrants ..... | --             | --              | --             | --             | --             |
| Expense relating to repricing<br>of stock options ..... | --             | --              | --             | --             | --             |
| Expense relating to warrant<br>exchange offer .....     | --             | --              | --             | (242,338)      | (242,338)      |
|   | -----          | -----           | -----          | -----          | -----          |
|   | 73,168         | (11,977,545)    |                | (508,808)      | (508,808)      |
|   | -----          | -----           | -----          | -----          | -----          |
| Loss Before Provision for                               |                |                 |                |                |                |
| Income Taxes .....                                      | \$ (2,976,192) | \$ (14,328,942) | \$ (1,772,097) | \$ (4,061,022) | \$ (4,061,022) |
| Net Loss .....  | \$ (2,976,392) | \$ (13,964,981) | \$ (1,774,527) | \$ (4,061,422) | \$ (4,061,422) |
| Net Loss Attributable to                                |                |                 |                |                |                |
| Common Shareholders .....                               | \$ (2,976,392) | \$ (13,564,981) | \$ (1,774,527) | \$ (4,061,422) | \$ (4,061,422) |
| Net (loss) per common share .....                       | \$ (0.35)      | \$ (1.53)       | \$ (0.19)      | \$ (0.40)      | \$ (0.40)      |
| Basic and Diluted Loss per                              |                |                 |                |                |                |
| Common Share .....                                      | \$ (0.35)      | \$ (1.53)       | \$ (0.19)      | \$ (0.40)      | \$ (0.40)      |
| Weighted average number                                 |                |                 |                |                |                |
| shares outstanding .....                                | 8,287,648      | 9,135,369       | 9,561,299      | 10,069,991     | 11,111,111     |

YEAR ENDED MARCH 31,

|  | 2000         | 2001          | 2002         | 2003         | 2004         |
|--|--------------|---------------|--------------|--------------|--------------|
|  | -----        | -----         | -----        | -----        | -----        |
| BALANCE SHEET DATA:                                    |              |               |              |              |              |
| Cash and cash equivalents ....                         | \$ 3,937,217 | \$ 7,296,702  | \$ 6,852,434 | \$ 3,264,081 | \$ 2,111,111 |
| Working capital .....                                  | \$ 4,134,837 | \$ 7,773,673  | \$ 7,054,961 | \$ 2,950,513 | \$ 1,234,567 |
| Total assets .....                                     | \$ 9,162,383 | \$ 12,350,301 | \$12,724,498 | \$ 8,696,222 | \$ 7,890,123 |
| Long-Term obligations,<br>excluding current portion .. | \$ 2,885,000 | \$ 2,765,000  | \$ 3,788,148 | \$ 2,720,000 | \$ 2,456,789 |
| Shareholders' equity .....                             | 5,564,603    | 9,180,254     | 8,153,884    | 5,426,501    | 4,077,890    |

MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD LOOKING STATEMENT

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The Company has included in this Prospectus certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 concerning the Company's business, operations and financial condition. "Forward-looking statements" consist of all non-historical information, and the analysis of historical information, including the references to future revenue growth, collaborative agreements, future expense growth, future credit exposure, earnings before interest, taxes, depreciation and amortization, future profitability, anticipated cash resources, anticipated capital expenditures, capital requirements, and the Company's plans for future periods. In addition, the words "could", "expects", "anticipates", "objective", "plan", "may affect", "may depend", "believes", "estimates", "projects" and similar words and phrases are also intended to identify such forward-looking statements.

Actual results could differ materially from those projected in the Company's forward-looking statements due to numerous known and unknown risks and uncertainties, including, among other things, unanticipated technological difficulties, the volatile and competitive environment for drug delivery products, changes in domestic and foreign economic, market and regulatory conditions, the inherent uncertainty of financial estimates and projections, the uncertainties involved in certain legal proceedings, instabilities arising from terrorist actions and responses thereto, and other considerations described as "Risk Factors". Such factors may also cause substantial volatility in the market price of the Company's Common Stock. All such forward-looking statements are current only as of the date on which such statements were made. The Company does not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

### OVERVIEW

The Company is involved in the development of controlled drug delivery systems and products. Its products are in varying stages of development and testing. In addition, from time to time, the Company has also conducted research and development projects on behalf of other pharmaceutical companies although these activities have generated only limited revenue to date.

### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion addresses the Company's consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgment, including those related to long-lived assets, intangible assets, income taxes, equity-based compensation, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily

apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among

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others, affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

The Company's most critical accounting policies include the recognition of revenue upon completion of certain phases of projects under research and development contracts. Revenues from these contracts are recognized when management determines the Company has completed its obligation under each phase. The Company also assesses a need for an allowance to reduce its deferred tax assets to the amount that it believes are more likely than not to be realized. Management estimates its net operating losses will probably not be utilized in the near future, and has not recognized a tax benefit from this deferred tax asset. If management anticipated the Company being profitable, a deferred tax benefit would be recognized and such estimate would increase net income and earnings per share accordingly. The Company assesses the recoverability of long-lived assets and intangible assets whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Management estimates the Company's patents and property and equipment are not impaired. If these assets were considered impaired, the Company would recognize an impairment loss which would increase the Company's net loss and net loss per share accordingly. The Company assesses its exposure to current commitments and contingencies by advice of counsel. It should be noted that actual results may differ from these estimates under different assumptions or conditions.

### RESULTS OF CONSOLIDATED OPERATIONS

With respect to the following discussion and analyses and comparison of the results for the nine months ended December 31, 2004 vs. the nine months ended December 31, 2003, the year ended March 31, 2004 vs. the year ended March 31, 2003 and the year ended March 31, 2003 vs. the year ended March 31, 2002, please note that we are unable to provide a break-down of the specific costs associated with the research and development of each product on which we devoted resources because a significant portion of the costs are generally associated with salaries, laboratory supplies, laboratory and manufacturing expenses, utilities and similar expenses. We have not historically allocated these expenses to any particular product. In addition, we cannot estimate the additional costs and expenses that may be incurred in order to potentially complete the development of any product, nor can we estimate the amount of time that might be involved in such development because of the uncertainties associated with the development of controlled release drug delivery products as described in this Prospectus.

#### NINE MONTHS ENDED DECEMBER 31, 2004 VS. NINE MONTHS ENDED DECEMBER 31, 2003

Revenues for the nine months ended December 31, 2004 were \$151,450, all realized during the first six months of the period, of which \$150,000 was a non-refundable payment received from Purdue Pharma L.P. granting it the right to evaluate certain abuse resistance drug formulation technology of the Company. The Company was unable to generate any significant additional revenues under its existing customer contracts for the nine months ended December 31, 2004 or any revenues, other than \$30,000, during the year earlier nine month period 2003 due to inadequate funds and the resignation of the Company's principal scientific officers in 2003.

General and administrative expenses for the nine months ended December 31, 2004 were \$1,675,041, an increase of \$131,115 or (8.5%) from \$1,543,926 for the comparable period of the prior year, substantially due to the increases in

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salaries and staff, consulting fees and the write-off of a bad debt relating to accounts receivable.

Research and development expenses for the nine months ended December 31, 2004 were \$1,937,794, an increase of \$457,006, or approximately 30.9%, from \$1,480,788 for the comparable period of the prior year, primarily the result of increased research and development wages, consulting fees, lab and manufacturing supplies and raw materials.

Other expenses for the nine months ended December 31, 2004 were \$916,362, a decrease of \$782,575, or approximately 46.1%, from \$1,698,937 for the comparable period of the prior year, due to reductions of \$1,117,764 in charges related to the issuance of stock options and warrants and a charge of \$172,324 in the 2003 period related to the warrant exchange offer, offset partially by a charge relating to the repricing in the nine months ended December 31, 2004 of stock options in the amount of \$397,732.

As a result of the foregoing the Company's net loss for the nine months ended December 31, 2004 was \$4,649,827 compared to \$4,963,481 for the comparable period of the prior year.

### YEAR ENDED MARCH 31, 2004 VS. YEAR ENDED MARCH 31, 2003

Our auditor's report on the financial statements for these periods states that such financial statements have been prepared assuming that we will continue as a going concern. We have incurred a significant loss and negative cash flows during our fiscal year ended March 31, 2004 which have significantly decreased our working capital and increased our accumulated deficit. Our auditors have stated in their report that these conditions raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of the assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Our revenues for the year ended March 31, 2004 were \$258,250, a decrease of \$372,060, or approximately 59%, from the prior year. For the year ended March 31, 2003, revenues consisted of product formulation fees of \$187,810 earned in conjunction with our joint venture in ERL which terminated on September 30, 2002. Of our revenues for the years ended March 31, 2004 and March 31, 2003, \$108,500 and \$442,500, respectively, were research and development and testing fees earned in conjunction with our distinct development, license and manufacturing agreements.

General and administrative expenses for the year ended March 31, 2004 were \$2,549,846, an increase of \$691,777, or approximately 37% from the prior year. The increase was substantially due to increases in legal and consulting fees as well as approximately \$550,000 in expenses, including \$400,000 as compensation, resulting from a settlement of litigation instituted by our former President with respect to the termination of his employment agreement.

Research and development costs for the year ended March 31, 2004, were \$2,075,074, an increase of \$61,495 or approximately 3% from the prior year, primarily due to increased research and development wages, additional biostudies, laboratory supplies and raw materials used in our

research and development processes. We expect our research and development costs to continue to increase in future periods as a result of the ERL joint venture termination as we will be solely responsible to fund product development, which

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we will do from internal resources or through loans or investment by third parties.

Other expenses for the year ended March 31, 2004 were \$1,813,711, an increase of \$1,304,903, or approximately 256%, from the prior year. The increase was primarily due to charges related to the modification of a warrant exchange offer, the issuance of stock options and warrants valued at \$1,926,908 (an increase of \$1,664,020) and the reduction in interest income due to lower rates and compensating balances in the amount of \$72,927, partially offset by increases in sale of New Jersey tax losses of \$79,353 and the related settlement of a vendor litigation for \$150,000.

Our net loss for the year ended March 31, 2004 was \$6,514,217 as compared to \$4,061,422 in the prior year, an increase of approximately 60%, primarily due to the decrease in net revenues, and increases in research and development and administrative expenses, including increased charges of \$1,664,020 due to the issuance of stock options, warrants and the modification of warrant exchange offer.

### YEAR ENDED MARCH 31, 2003 VS. YEAR ENDED MARCH 31, 2002

Revenues for the year ended March 31, 2003 were \$630,310, a decrease of \$567,197 or approximately 47.4%, from the comparable prior year. For the years ended March 31, 2003 and 2002, revenues consisted of product formulation fees of \$187,810 and \$601,057, respectively, earned in conjunction with our joint venture in ERL, and research and development and testing fees of \$442,500 and \$593,000, respectively, earned in conjunction with our distinct development, license and manufacturing agreements. ERL had no revenue after our acquisition of Elan's interest in it on September 30, 2002. Elan's obligation to make payments to us or to ERL terminated upon the termination of the joint venture with Elan. The absence of payments from Elan will affect revenues for periods subsequent to September 30, 2002.

General and administrative expenses for the year ended March 31, 2003 were \$1,858,069, an increase of \$1,094,382, or approximately 143%, from the prior year, substantially due to increases in legal and consulting fees as well as approximately \$600,000 in expenses resulting from a consent solicitation and a proxy solicitation with regard to the election of our directors.

Research and development costs for the year ended March 31, 2003, were \$2,013,579, an increase of \$404,471, or approximately 25%, from the prior year, primarily the result of increased research and development wages, additional biostudies, laboratory supplies and raw materials used in our research and development processes. We expect our research and development costs to continue to increase as a result of the ERL joint venture termination as we will be solely responsible to fund product development, which we will do from internal resources or through loans or investment by third parties.

Other expenses for the year ended March 31, 2003 were \$580,482, an increase of \$112,774, or approximately 24%, from the prior year. A decrease of \$321,261 in equity loss in joint venture due to its termination was more than offset by charges related to the exchange of warrants and the expense of \$262,888 related to the issuance of stock options and the reduction of \$163,363 in interest income due to lower rates and compensating balances.

Our net loss for the year ended March 31, 2003 was \$4,061,422 as compared to \$1,774,527 in the prior year, an increase of 129%, primarily due to the decrease in net revenues, and an increase in research and development and

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administrative expenses associated with the consent solicitation and proxy solicitation with regard to the election of our directors. Our net loss included our 80.1% equity loss in ERL, which was \$186,379 and \$507,640, respectively, for the years ended March 31, 2003 and 2002. ERL's net loss for the years ended March 31, 2003 and 2002 was \$232,682 and \$633,642, respectively.

### MATERIAL CHANGES IN FINANCIAL CONDITION

The Company's working capital (total current assets less total current liabilities), which was \$1,289,764 as of March 31, 2004, increased to \$3,864,412 as of December 31, 2004, primarily due to net proceeds received from the sale of shares of Series A Preferred Stock (\$5,866,600) partially offset by the \$3,356,146 net cash loss from operations, exclusive of non-cash charges of \$1,293,680.

The Company experienced negative cash flows from operations of (\$3,610,066) for the nine months ended December 31, 2004, primarily due to the Company's net loss from operations of \$4,649,827, less non-cash charges of \$1,293,680, which included the charges of \$397,732 in connection with the repricing of stock options, \$325,558 in connection with the issuance of stock options, and \$241,010 in connection with the issuance of stock warrants.

Our working capital (total current assets less total current liabilities), which was \$2,950,513 as of March 31, 2003, decreased to \$1,289,764, approximately 56%, as of March 31, 2004, primarily due to our net loss from operations and deposits on equipment, partially offset by net proceeds of \$3,179,000 from the sale of Common Stock through a private placement and the receipt of \$30,000 from the exercise of stock options.

We experienced negative cash flow from operations of \$3,658,321 for the year ended March 31, 2004, primarily due to our net loss from operations of \$6,514,217 offset by non-cash charges of \$2,259,744. Non-cash charges included \$1,166,601 in connection with the issuance of stock options, a charge of \$587,983 in connection with the issuance of warrants, and a charge of \$172,324 related to the modification of a warrant exchange offer.

The Company completed a Good Manufacturing Practices ("GMP") batch for a product currently licensed with a pharmaceutical company under a development and license agreement entered into June 2001. The Company received \$30,000 in November 2003 under the Agreement and expects to complete two additional GMP batches in the near future under the terms of the licensing agreement. The Company expects to manufacture the product with revenues projected to be generated in the quarter of ending March 31, 2005 or shortly thereafter and anticipates the earning of additional milestone payments under the Agreement subject to completion of the GMP batches.

The Company recently entered into an agreement with Pivotal Development, L.L.C. pursuant to which the Company is to receive an aggregate of \$750,000 upon attaining certain milestones. Some of the milestones were achieved during the quarter ending March 31, 2004. No material revenues have resulted to date.

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No assurance can be given that the Company will consummate any of the transactions discussed above.

### LIQUIDITY AND CAPITAL RESOURCES

For the nine months ended December 31, 2004, the Company recorded positive cash flow and financed its operations through utilization of its

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existing cash. In October 2004, the Company raised net cash of \$5,866,600 from its private placement of its Series A Preferred Stock. The Company's working capital (current assets less current liabilities) at December 31, 2004 was \$3.8 million compared with working capital of \$1.3 million at March 31, 2004. Cash and cash equivalents at December 31, 2004 were \$4.6 million, an increase of \$2.5 million from the \$2.1 million at March 31, 2004.

For our fiscal year ended March 31, 2004 our operations did not generate positive cash flow. We have financed our operations primarily through the private sale of our equity securities. We had working capital of \$1.3 million at March 31, 2004 compared with \$3.0 million at March 31, 2003. Cash and cash equivalents at March 31, 2004 were \$2.1 million, a decrease of \$1.2 million from the \$3.3 million at March 31, 2003.

Net cash used in operating activities was \$3,658,000 during the year ended March 31, 2004, compared to \$2,573,000 for the year ended March 31, 2003. Net cash used in operating activities during the year ended March 31, 2004 resulted primarily from our net loss of \$6.5 million, offset in part by an increase in accounts payable and certain non-cash expenses. Net cash used in operating activities during the year ended March 31, 2003 resulted primarily from a net loss of \$4.1 million, offset in part by a reduction in accounts receivable from a joint venture and certain non-cash expenses.

Investing activities utilized net cash of \$495,000 and of \$469,000 during the years ended March 31, 2004 and March 31, 2003, respectively. Net cash used in investing activities during the year ended March 31, 2004 resulted primarily from equipment deposits, patent filings and an increase in restricted cash. Net cash used in investing activities during the year ended March 31, 2003 resulted primarily from the acquisition of property and equipment, offset in part by a decrease in restricted cash and the maturity of short term investments.

Financing activities provided net cash of \$2,994,000 during the year ended March 31, 2004 and utilized net cash of \$546,000 during the year ended March 31, 2003. Net cash provided by financing activities during the year ended March 31, 2004 resulted primarily from the issuance of common stock through a private placement offset by the repayment of indebtedness. Net cash used in financing activities during the year ended March 31, 2003 resulted from the repurchase of stock and the repayment of indebtedness, offset in part by the sale of common stock and warrants.

In order to conserve cash for the twelve months ending December 31, 2005, the Company intends to reduce costs by continuing the reduction of the number of products under active development to nine.

The Company purchased machinery and equipment amounting to approximately \$426,000 in the nine months ending December 31, 2004. This equipment was fully financed except for minor expenditures. No capital expenditures were made during the nine months ended December 31, 2003.

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Our capital expenditures aggregated \$398,580 and \$679,000 for the years ended March 31, 2004 and 2003, respectively. Such expenditures consisted primarily of the acquisition of property and equipment.

The Company had bonds of \$2,345,000 outstanding, as of December 31, 2004. The bonds bear interest at a rate of 7.75% per annum and are due on various dates between 2005 and thereafter. The bonds are secured by a first lien on the Company's facility in Northvale, New Jersey. Pursuant to the terms of the bonds, several restricted cash accounts have been established for the payment of bond



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principal and interest. Bond proceeds were utilized for the refinancing of the land and building the Company currently owns, the purchase of certain manufacturing equipment and related building improvements and the maintenance of a \$300,000 debt service reserve. All of the restricted cash, other than the debt service reserve, is expected to be expended within twelve months and is therefore categorized as a current asset on the Company's consolidated balance sheet as of December 31, 2004. Pursuant to the terms of the bond indenture agreement pursuant to which the bonds were issued, the Company is required to observe certain covenants, including covenants relating to the incurrence of additional indebtedness, the granting of liens and the maintenance of certain financial covenants. As of December 31, 2004 the Company was in compliance with the covenants contained in the bond indenture agreement.

On July 8, 2004, Elite Labs entered into a loan and financing agreement in order to finance the purchase of certain machinery and equipment. Elite Labs borrowed \$400,000 payable in 36 monthly installments of \$13,671, each, including principal and interest at 14% per annum. The first four and the last three months of scheduled payments are being held by the lender and were and will be applied to the principal balance when due. The loan is secured by two pieces of equipment and the guaranty of the Company. In addition, the Company issued to designees of the lender 50,000 warrants, which vest immediately, to purchase 50,000 shares of the Company's common stock at \$4.20 per share. If the loan is repaid within nine months, 15,000 warrants will be forfeited, but the lender will be entitled to a \$10,000 prepayment penalty. A charge for the cost of these warrants is reflected in the nine month period ended December 31, 2004.

The Company from time to time will consider potential strategic transactions including acquisitions, strategic alliances, joint ventures and licensing arrangements with other pharmaceutical companies. There can be no assurance that any such transaction will be available or consummated in the future.

In October 2004, the Company effected a private placement of 516,558 shares of its Series A Preferred Stock for gross proceeds of \$6,600,000, before payment of commission of \$623,520 and other expenses. All of the Series A Preferred Stock have been converted into an aggregate of 5,200,120 shares of Common Stock with 141,888 shares of the originally issued share mandatorily converted on March 7, 2005, pursuant to the Certificate of Incorporation as a result of the "market price" of the Common Stock, as defined for 30 consecutive trading days exceeding 300% of the per share conversion price. The Series A Preferred Shareholders were entitled to a preferential dividend of 8% per annum of the original issue price of \$12.30 per share payable on December 1 and June 1 of each year. The December 1, 2004 dividend of \$75,076 was paid by the issuance of 26,961 shares of Common Stock. The Company believes that the net proceeds of the placement will provide sufficient cash to fund the Company's operations and capital requirements through at least September 30, 2005.

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On November 15, 2004, Elite's partner, ECR, launched LODRANE 24(R), a once a day allergy product, utilizing Elite's extended release technology to provide for once daily dosing. Under its agreement with ECR, Elite is currently manufacturing commercial batches of LODRANE 24(R) in exchange for royalties on product revenues. No assurance can be given that any material royalties will be generated under this agreement.

### DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 65,000,000 shares of Common Stock, par value \$.01 per share, and 5,000,000 shares of Preferred Stock, par

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value \$.01 per share.

### PREFERRED STOCK

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

On October 6, 2004, pursuant to the authority of its Board of Directors, Elite filed with the Secretary of State of Delaware the Certificate of Designations, Preferences and Rights of Series A Preferred Stock (the "Series A Preferred Certificate") providing for 660,000 authorized shares (the Series A Preferred Shares).

In October 2004, the Company in a private placement issued in three tranches an aggregate of 516,558 Series A Convertible Preferred Shares and warrants expiring December 31, 2005 to purchase 2,592,792 shares of Common Stock and warrants expiring December 27, 2009 to purchase 2,950,588 shares of Common Stock. We issued 26,961 shares of Common Stock in payment of the \$75,076 dividend payable as of December 1, 2004. As of March 7, 2005 all of the 516,558 Series A Convertible Preferred Shares had been converted into an aggregate of 5,200,120 shares of Common Stock. The Series A Preferred Shares accrued dividends at the annual rate of \$0.984 per share (a rate of 8% per annum on the \$12.30 per share paid for the first tranche of the Series A Preferred Shares sold) payable at the Company's option, in cash or shares of Common Stock.

The Series A Preferred Shares as a class pursuant to its rights on February 15, 2005, the record date for the Annual Meeting of Stockholders held on April 15, 2005, elected one Director.

### COMMON STOCK

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

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

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

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The Common Stock is not entitled to preemptive rights and is not subject to conversion or redemption. Upon liquidation, dissolution or winding up of Elite, the remaining assets legally available for distribution to stockholders, after payment of claims or creditors, are distributable ratably among the holders of the Common Stock outstanding at that time. Each outstanding share of Common Stock is fully paid and nonassessable.

### 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

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an affiliate, who is an "interested stockholder" for a period of three years from the date that person became an interested stockholder unless:

- o the transaction resulting in a person becoming an interested stockholder, or the business combination, is approved by the board of directors of the corporation before the person becomes an interested stockholder,
- o the interested stockholder acquired 85% or more of the outstanding voting stock of the corporation in the same transaction that makes this person an interested stockholder, excluding shares owned by persons who are both officers and directors of the corporation, and the shares held by certain employee stock ownership plans, or
- o on or after the date the person becomes an interested stockholder, the business combination is approved by the corporation's board of directors and by the holders of at least 66-2/3% of the corporation's outstanding voting stock at an annual or special meeting, excluding the shares owned by the interested stockholder.

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

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

### PRICE RANGE OF OUR COMMON STOCK AND DIVIDEND POLICY

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

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### COMMON STOCK

| QUARTER ENDED:                               | HIGH   | LOW    |
|--|--------|--------|
| FISCAL YEAR                                  |        |        |
| ENDING MARCH 31, 2005:                       |        |        |
| March 31, 2005 (through March 23, 2005)..... | \$4.79 | \$3.20 |
| December 31, 2004.....                       | \$4.01 | \$1.20 |
| September 30, 2004.....                      | \$2.35 | \$1.05 |
| June 30, 2004.....                           | \$4.31 | \$2.15 |
| FISCAL YEAR                                  |        |        |
| ENDING MARCH 31, 2004:                       |        |        |
| March 31, 2004.....                          | \$3.80 | \$2.40 |
| December 31, 2003.....                       | \$3.30 | \$2.70 |
| September 30, 2003.....                      | \$3.49 | \$2.05 |
| June 30, 2003 .....                          | \$3.45 | \$1.34 |

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### FISCAL YEAR

ENDING MARCH 31, 2003:

|                         |        |        |
|-------------------------|--------|--------|
| March 31, 2003.....     | \$2.20 | \$1.45 |
| December 31, 2002.....  | \$3.15 | \$1.80 |
| September 30, 2002..... | \$5.25 | \$2.41 |
| June 30, 2002.....      | \$7.75 | \$4.50 |

### FISCAL YEAR

ENDING MARCH 31, 2002:

|                         |         |        |
|-------------------------|---------|--------|
| March 31, 2002.....     | \$8.30  | \$5.65 |
| December 31, 2001.....  | \$7.75  | \$5.90 |
| September 30, 2001..... | \$11.50 | \$5.10 |
| June 30, 2001.....      | \$11.45 | \$4.85 |

On April [\_\_\_], 2005, the last sale price of our Common Stock, as reported by the American Stock Exchange, was \$[\_\_\_] per share.

We have never paid cash dividends on our capital stock. On December 1, 2004, the Company issued 26,961 shares of Common Stock in payment of the \$75,076 dividend payable on its Series A Preferred Shares. [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 table below sets forth the names and ages, as of February 28, 2005, of each of the Directors and the period during which each such person has served on the Board of Directors of the Company.

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| NAME AND BUSINESS ADDRESS   | AGE | DIRECTOR SINCE |
|---|-----|----------------|
| Bernard Berk<br>c/o Elite Pharmaceuticals Inc.<br>165 Ludlow Avenue,<br>Northvale, NJ 07647 | 55  | 2004           |
| Edward Neugeboren*<br>36 New Norwalk Road<br>New Canaan, CT 06840                           | 35  | 2005           |
| Dr. Barry Dash<br>168 Wood Road<br>Englewood Cliffs, NJ 07632                               | 73  | 2005           |
| Dr. Melvin H. Van Woert<br>752 Ridgewood Road<br>Millburn, NJ 07061                         | 74  | 2005           |

\* Mr. Neugeboren was designated by a representative of the Series A Preferred Shares

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

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held the position indicated for at least the past five years.

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

Mr. Edward Neugeboren has been a managing partner of IndiGo Ventures LLC, an investment-banking firm based in New York since January 2003. From May 2001 to January 2004, Mr. Neugeboren was a managing partner of Third Ridge Capital Management, LLC, a U.S. equity hedge fund. He was from October 2000 to April 2001 the Chief Administrative Officer of Soceron, an emerging Silicon Alley based media software company and from 1988 to 2000 the Chief Administrative Officer and director of Equity Research Operations at Lehman Brothers. He was deputy director of Equity Research at UBS Warburg, formerly Warburg, Dillon Read, from 1996 to 1998 and director of Equity Research Operations from 1995 to 1996. Mr. Neugeboren began his career in 1992 as an equity research analyst covering the specialty pharmaceuticals industry, constituting generic drugs and drug delivery, at Dillon Read & Co., Kidder, Peabody & Co. and Furman Selz, Inc. Mr. Neugeboren is a Director of KineMed, Inc. a platform based drug development and advanced medical diagnostics company based in San Francisco, California.

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Dr. Barry Dash has been since 1995 President and Managing Member of Dash Associates, L.L.C., an independent consultant to the pharmaceutical and health and beauty aid industries. From 1983 to 1996 he was employed by American Home Products Corporation, its Whitehall-Robins Healthcare Division, initially as Vice President of Scientific Affairs, then Senior Vice President of Scientific Affairs and then Senior Vice President of Advanced Technologies during which time he personally supervised six separate departments: Medical and Clinical Affairs, Regulatory Affairs, Technical Affairs, Research and Development, Analytical R&D and Quality Management/Q.C. He had previously been employed by the Whitehall Robins Healthcare Division from 1960 to 1976, during which time he served as Director of Product Development Research, Assistant Vice President of Product Development and Vice President of Scientific Affairs. Dr. Dash had been employed by J.B. Williams Company (Nabisco Brands, Inc.) from 1978 to 1982, during which time he helped introduce more than 14 national and test market brands. From 1976 to 1978 he was Vice President, Director of Laboratories of the Consumer Products Division of American Can Company. He is a director of GeoPharma, Inc. Dr. Dash holds a Ph.D. from the University of Florida and M.S. and B.S. degrees from Columbia University at which he was Assistant Professor at the College of Pharmaceutical Sciences from 1956 to 1960. He is a member of the American Pharmaceutical Association, The American Association for the Advancement of Science and the Society of Cosmetic Chemist.

Dr. Melvin H. Van Woert, a neurologist has been since 1974, a member of the staff of Mount Sinai Medical Center where he has been a Professor of the Department of Neurology and Pharmacology at Mount Sinai School of Medicine since 1978. Dr. Van Woert had been a consultant for Neuropharmacological Drug Products to the Food and Drug Administration from 1974 to 1980; Associate Editor for the Journal of the Neurological Sciences; a Member of the Editorial Board of Journal of Clinical Neuropharmacology; and Medical Director of National Organization for Rare Disorders for which he received in 1993 the Humanitarian Award. His other

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awards include the U.S. Public Health Service Award for Exceptional Achievement in Orphan Products Development and the National Myoclonus Foundation Award. He has authored and co-authored more than 150 articles appearing in pharmacological, medical and other professional journals or publications.

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

### COMMITTEES

The Board of Directors has an Audit Committee and, since March 2004, a Nominating Committee. The Board has no other standing committees. The Audit Committee members commencing April 15, 2005 are Edward Neugeboren, Dr. Barry Dash and Dr. Melvin H. Van Woert, with Drs. Dash and Van Woert replacing former Directors, Harmon Aronson and Eric L. Sichel. The Company's Board of Directors has adopted a written charter for the Audit Committee, a copy of which was included as an appendix to the Company's proxy statement sent to stockholders in connection with the annual meeting of stockholders held October 11, 2001.

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

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The Nominating Committee is authorized to select the nominees of the Board of Directors for election as directors. The members are Bernard Berk, Dr. Barry Dash and Dr. Melvin H. Van Woert.

### 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. John A. Moore, a Director until January 24, 2005, 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 are Bernard Berk and Mark I. Gittelman. Executive officers, except for Mr. Berk who has a long term employment agreement, serve until the next annual meeting of directors and until their successors have been duly elected and qualified. There are no family relationships between any of our directors and executive officers.

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

Mark I. Gittelman, age 45, CPA, the Chief Financial Officer, Secretary and Treasurer of the Company, is the President of Gittelman & Co., P.C., an accounting firm in Clifton, New Jersey. Prior to forming Gittelman & Co., P.C. in 1984, he worked as a certified public accountant with the international

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accounting firm of KPMG Peat Marwick, LLP. Mr. Gittelman holds a B.S. in accounting from New York University and a Masters of Science in Taxation from Farleigh Dickinson University. He is a Certified Public Accountant licensed in New Jersey and New York, and is a member of the American Institute of Certified Public Accountants ("AICPA"), and the New Jersey State and New York States Societies of CPAs. Other than Elite Labs, no company with which Mr. Gittelman was affiliated in the past was a parent, subsidiary or other affiliate of the Company.

The Company entered into a three-year employment agreement effective July 23, 2003 with Mr. Berk providing for (i) his 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 the \$2.01 per share to vest on consummation of a "strategic transaction" while he is employed as Chief Executive Officer. The consummation of such transaction will result in the increase of his base annual salary to \$310,140 effective with the consummation. A strategic transaction is defined as any one of the following transactions provided that the net value of the consideration to the Company or its stockholders determined in good faith by the Board of Directors is at least \$10,000,000: (i) the sale of all or substantially all

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of the assets of the Company, (ii) a merger or consolidation or business combination, or (iii) the sale by the Company of debt or equity securities.

Either party upon notice may terminate Mr. Berk's employment except that a termination by the Company without cause or because of his permanent disability or a termination by him for cause will result in severance pay in the form of the continuation of his base salary for the balance of the term or two years, whichever is longer, less in the event of termination for permanent disability the amount of payments under a disability insurance policy maintained by the Company. The Company is also to continue to pay during the foregoing period the premiums for life and disability insurance policies. Furthermore, in the event that Mr. Berk terminates his employment following a "change of control" event he is to receive, payable in 24 monthly installments, an amount which will depend on the fair value of the consideration determined in good faith by the Board of Directors received by the Company or stockholders from the "change of control" event less related expenses ("Net Fair Value") -- \$500,000 if the Net Fair Value is \$10 million or less; the greater of \$500,000 or twice his then base annual salary, if the Net Fair Value is greater than \$10,000,000 but not more than \$20 million, or \$1,000,000 if the Net Fair Value is greater than \$20,000,000. A "change of control" event is (i) a merger or consolidation in which securities possessing more than 50% of the voting power is issued to persons other than the holders of voting securities of the Company immediately prior to the event, (ii) the sale, transfer or disposition of all or substantially all the assets of the Company, or (iii) the sale by the Company of securities to a third party.

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

### 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

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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                          |
|---|--------------------------|---------------|--------------|---|-----------------------------------|-------------------------------|
| (a)<br>Name and Principal<br>Position   | (b)<br>Fiscal<br>Year(1) | (c)<br>Salary | (d)<br>Bonus | (e)<br>Other Annual<br>Compensa-<br>tion(5) | (f)<br>Restricted<br>Stock Awards | (g)<br>Secur<br>Under<br>Opti |
| Bernard Berk,<br>President and Chief<br>Executive Officer                         | 2003-04                  | \$ 166,667    | --           | --  | --                                | 300,0                         |
| Atul M. Mehta,<br>Ph.D., former<br>President and<br>Chief Executive<br>Officer(2) | 2003-04                  | \$ 53,684     | --           | \$ 3,040                                    | --                                |                               |
|   | 2002-03                  | \$ 330,140    | --           | \$ 3,040                                    | --                                |                               |
|   | 2001-02                  | \$ 272,855    | --           | \$ 83,856                                   | --                                | 50,0                          |

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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 June 3, 2003.

(3) As part of a settlement of a litigation between Dr. Mehta and the Company the expiration dates of options granted to him prior to April 1, 2001 to purchase 770,000 shares were extended in April 2004 to June 30, 2005 (subsequently by agreement reduced to 670,000 options with the expiration date extended to December 31, 2007).

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

(5) Other Annual Compensation represents use of a Company car, premiums paid by the Company for life insurance on Dr. Mehta's life for the benefit of his wife and the purchase price of \$80,856 for options acquired from Dr. Mehta.

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

The Board of Directors in January 2005 adopted, and the stockholders of



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the Company approved on April 15, 2005, an amendment to the Company's Stock Option Plan (the "Plan") to increase the number of shares subject to the Plan from 1,500,000 to 4,000,000 shares. The Plan authorizes the grant of options to employees and directors of the Company or its subsidiaries and individuals performing consulting services to the Company or a subsidiary.

As of March 15, 2005, options to purchase 402,000 shares of Common Stock were granted under the Plan; no options granted under the Plan have been exercised.

Pursuant to the Plan, the Board on June 22, 2004 granted options to purchase 220,900 shares of Common Stock at \$2.34 per share under the Plan to current employees who held options with exercise prices higher than the options to be granted; with the optionees surrendering the options containing the higher exercise price. No options granted prior to the stockholder approval in substitution of previously granted options were made to any officer or director of the Company.

To the extent any of the options granted or to be granted under the Plan expire or terminate without being exercised they may be subject to future grants under the Plan.

The following table sets forth information regarding options previously granted by the Company (exclusive of warrants previously sold along with shares of Common Stock in private placements by the Company) and options, included in the foregoing, granted under the Plan to each of the Company's executive officers named under the Executive Officer Compensation Table under "Executive Compensation", all current executive officers as a group, all current directors who are not executive officers as a group and all employees other than executive officers as a group:

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| NAME AND POSITION  | NUMBER OF<br>STOCK OPTIONS<br>PREVIOUSLY GRANTED* | NUMBER OF<br>OPTIONS GRANTED<br>UNDER THE PLAN* |
|--|---|---|
| Atul Mehta, former President and<br>Chief Executive Officer (1)..... | 670,000   | --  |
| Bernard Berk .....   | 630,000 (1)                                       | 30,000  |
| Executive Officer Group (2 persons).....                             | 640,000   | 30,000  |
| Non-Executive Directors Group (4 persons)...                         | 270,000   | 90,000  |
| Non-Executive Officer Employee Group<br>(13 persons).....            | 403,050   | 282,000   |

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\* Given effect to the cancellation of options upon the grant of a like number of options granted under the Plan.

(1) The options include 300,000 options which may not be exercised prior to the occurrence of a "strategic event". See "Executive Officers".

The Plan may not be amended to increase the maximum number of shares which may be granted under the Plan (except under the anti-dilution provisions contained therein) or to change the class of persons to whom options may be granted without the affirmative vote of holders of the Company's Common Stock.

The Plan permits the Company to grant both incentive stock options ("Incentive Stock Options" or "ISOs") within the meaning of Section 422 of the Code, and other options which do not qualify as Incentive Stock Options (the

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"Non-Qualified Options").

Unless earlier terminated by the Board of Directors, the Plan (but not outstanding options) terminates on March 1, 2014, after which no further awards may be granted under the Plan. The Plan is administered by the full Board of Directors or, at the Board's discretion, by a committee of the Board consisting of at least two persons who are "disinterested persons" defined under Rule 16b-2(c)(ii) under the Securities Exchange Act of 1934, as amended (the "Committee"). As of February 15, 2005, the Board has not appointed a Committee.

Recipients of options under the Plan ("Optionees") are selected by the Board or the Committee. The Board or Committee determines the terms of each option grant including (1) the purchase price of shares subject to options, (2) the dates on which options become exercisable and (3) the expiration date of each option (which may not exceed ten years from the date of grant). The minimum per share purchase price of options granted under the Plan for Incentive Stock Options is the fair market value (as defined in the Plan) or for Nonqualified Options is 85% of Fair Market Value of one share of the Common Stock on the date the option is granted.

### 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:

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| NAME              | NUMBER OF<br>SHARES<br>UNDERLYING<br>OPTIONS<br>GRANTED | % OF TOTAL<br>OPTIONS<br>GRANTED TO<br>EMPLOYEES IN<br>FISCAL YEAR | EXERCISE<br>PRICE | EXPIRATION<br>DATE | POTENTIAL R<br>VALUE<br>ASSUMED A<br>RATES OF STO<br>APPRECIATI<br>OPTION<br>5%<br>-- |
|-------------------|---|--|-------------------|--------------------|---|
| Bernard Berk      | 300,000 (1)   | 41.4%  | \$2.01            | 6/2/13             | \$982,223   |
| Atul M. Mehta (2) | --  | --   | --                | --                 | --  |

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

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

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

| NAME  | NUMBER OF SHARES<br>UNDERLYING UNEXERCISED<br>OPTIONS AT YEAR-END* | VALUE OF UNEXERCISED<br>IN-THE-MONEY OPTIONS<br>AT YEAR-END (1) |
|-------|--|---|
| ----- | -----  | -----   |

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|                   | EXERCISABLE<br>----- | UNEXERCISABLE<br>----- | EXERCISABLE<br>----- | UNEXERCISABLE<br>----- |
|-------------------|----------------------|------------------------|----------------------|------------------------|
| Atul M. Mehta (2) | 270,000*             | --                     | \$0                  | --                     |
|                   | 100,000              | --                     | \$0                  | --                     |
|                   | 100,000              | --                     | \$48,000             | --                     |
|                   | 100,000              | --                     | \$98,000             | --                     |
|                   | 100,000              | --                     | \$148,000            | --                     |
|                   | 100,000              | --                     | \$198,000            | --                     |
| Bernard Berk (3)  | 300,000              | 300,000                | \$291,000            | \$291,000              |

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

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

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

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Company is a party to an agreement dated February 26, 1998 whereby fees are paid to Gittelman & Co., P.C., a firm wholly owned by Mark I. Gittelman, the Company's Chief Financial Officer, Secretary and Treasurer, in consideration for services rendered by the firm as

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internal accountant and financial and management consultant. The firm's services include the services rendered by Mr. Gittelman in his capacity as Chief Financial Officer, Treasurer and Secretary. For the fiscal years ended March 31, 2004, 2003 and 2002, the fees paid by the Company under the agreement were \$168,750, \$167,544 and \$91,260, respectively. The services rendered by the firm to the Company averaged 128, 127 and 69 hours per month, respectively, of which an average of 30 hours per month were services rendered by him in his capacity as an officer of the Company.

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

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

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 15, 2005 by (i) each director and named executive officer, (ii) each beneficial holder of at least 5% of the outstanding shares of Common Stock, and (iii) all executive officers and directors as a group. On April 15, 2005 there were outstanding 17,957,345 shares of Common Stock.

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

| NAME AND ADDRESS   | NUMBER<br>OF SHARES | PERCENTAGE<br>OF CLASS |
|--|---------------------|------------------------|
| DIRECTORS AND NAMED EXECUTIVE OFFICERS   |                     |                        |
| Bernard Berk, Chairman of the Board<br>and Chief Executive Officer*  | 756,000 (1)         | 4.1%                   |
| Edward Neugeboren, Director*   | 188,094 (2)         | 1.0%                   |
| Dr. Barry Dash, Director   | --                  | --                     |
| Dr. Melvin H. Van Woert  | --                  | --                     |
| Mark I. Gittelman, Chief Financial Officer,<br>Treasurer and Secretary<br>300 Colfax Avenue<br>Clifton, New Jersey 07013 | 10,000 (3)          | **                     |
| All Directors and Officers as a group  | 954,094 (4)         | 5.1%                   |
| 5% BENEFICIAL OWNERS   |                     |                        |
| SAC Capital Associates LLC<br>P.O. Box 58<br>Victoria House, The Valley<br>Antigua, BVI                                  | 1,147,418 (5)       | 6.1%                   |
| Jerome Belson<br>495 Broadway<br>New York, New York 10012  | 969,000 (6)         | 5.3%                   |

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

\*\* Less than 1% of outstanding shares

(1) Includes options to purchase 630,000 shares, of which options to purchase 300,000 shares are not exercisable until occurrence of a "strategic event" as defined in his employment agreement.

(2) Includes 147,263 shares issuable upon exercise of warrants but does not

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include 20,325 shares issuable upon exercise of warrants held by his father.

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- (3) Comprised of options to purchase 10,000 shares
- (4) Includes options and warrants to purchase an aggregate of 787,263 shares.
- (5) Includes 813,010 shares issuable upon exercise of warrants.
- (6) Includes (i) warrants to purchase 281,000 shares of Common Stock, (ii) 53,900 shares held by Maxine Belson, wife of Jerome Belson, (iii) 63,300 held by other members of his family, and (iv) 50,000 shares held by the Jerome Belson Foundation.

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

Other than the Stock Option Plan, the Company does not have any compensation plans or arrangements benefiting employees or non-employees under which equity securities of the Company are authorized for issuance in exchange for consideration in the form of goods or services.

### OFFER TO CLASS B AND CLASS C WARRANTHOLDERS

Each of the Class B and the Class C Warrants is nontransferable except by operation of law and entitles the holder to purchase one share of Common Stock on or before November 30, 2005 at a price of \$5.00 per share. The exercise price is subject to adjustment for stock dividends, stock splits or combination of the Common Stock.

The Class C Warrants were issued by the Company in exchange for all the outstanding Class A Warrants. To the extent a Class A Warrant Holder did not submit the holder's Class A Warrants for exchange such Class A Warrants are deemed to be Class C Warrants.

The shares issuable upon exercise of the Class B Warrants and Class C Warrants are offered by the Company pursuant to this Prospectus. Exercise of the Warrants may be effected by delivering the Warrants with the exercise portion of the Warrant fully executed to the Company's Warrant Agent, Jersey Transfer & Trust Company, 201 Bloomfield Avenue, P.O. Box 36, Verona, New Jersey 07044 with cash or a check in the amount of the full exercise price.

### LEGAL MATTERS

Reitler Brown & Rosenblatt LLC, New York, New York, as counsel to the Company will pass upon whether the shares of Common Stock when issued upon exercise of the Class B and Class C Warrants will be 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, March 31, 2003 and March 31, 2002, incorporated by reference in this prospectus, have been audited by Miller, Ellin & Company, LLP, New York, New York, independent certified public accountants, as indicated in its report with respect thereto, and is incorporated by reference in this prospectus in reliance upon its report given upon the authority of said firm as experts in accounting and auditing.

ELITE PHARMACEUTICALS INC.  
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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEET  
(UNAUDITED)

ASSETS

|   | DECEMBER 31, 2004 |
|---|-------------------|
|   | -----             |
| CURRENT ASSETS:                           |                   |
| Cash and cash equivalents                 | \$ 4,564,948      |
| Accounts receivable, net                  | --                |
| Restricted cash                           | 116,645           |
| Prepaid expenses and other current assets | 54,833            |
|   | -----             |

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|   |              |
|---|--------------|
| Total current assets  | 4,736,426    |
|   | -----        |
| PROPERTY AND EQUIPMENT, net of accumulated<br>depreciation and amortization | 4,273,898    |
|   | -----        |
| INTANGIBLE ASSETS - net of accumulated amortization                         | 83,791       |
|   | -----        |
| OTHER ASSETS:   |              |
| Prepaid expenses  | 41,013       |
| Deposit on equipment  | --           |
| Restricted cash - debt service reserve                                      | 300,000      |
| Restricted cash - note payable  | --           |
| EDA bond offering costs, net of accumulated amortization<br>of \$67,058     | 127,502      |
|   | -----        |
| Total other assets  | 468,515      |
|   | -----        |
| Total assets  | \$ 9,562,630 |
|   | =====        |

The accompanying notes are an integral part  
of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEET  
(UNAUDITED)

LIABILITIES AND STOCKHOLDERS' EQUITY

|                                       |                   |
|---------------------------------------|-------------------|
|                                       | DECEMBER 31, 2004 |
|                                       | -----             |
| CURRENT LIABILITIES:                  |                   |
| Current portion - note payable        | \$ 130,000        |
| Current portion of EDA bonds          | 165,000           |
| Accounts payable and accrued expenses | 595,014           |
|                                       | -----             |
| Total current liabilities             | 890,014           |
|                                       | -----             |
| LONG TERM LIABILITIES:                |                   |
| Note payable - net of current portion | 205,051           |
| EDA bonds - net of current portion    | 2,180,000         |
|                                       | -----             |
| Total long-term liabilities           | 2,385,051         |
|                                       | -----             |

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|   |              |
|---|--------------|
| Total liabilities                               | 3,275,065    |
|   | -----        |
| COMMITMENTS AND CONTINGENCIES                   |              |
| STOCKHOLDERS' EQUITY:                           |              |
| Preferred stock - \$. 01 par value;             |              |
| Series A 8% Convertible Preferred Stock         |              |
| Authorized 660,000 shares,                      |              |
| aggregate liquidation preference of \$5,303,662 | 4,312        |
| Common stock - \$.01 par value;                 |              |
| Authorized - 65,000,000 shares                  |              |
| Issued and outstanding - 13,111,547 shares,     | 131,115      |
| Additional paid-in capital                      | 46,289,033   |
| Accumulated deficit                             | (39,830,054) |
|   | -----        |
|   | 6,594,406    |
| Treasury stock, at cost (100,000 shares)        | (306,841)    |
|   | -----        |
| Total stockholders' equity                      | 6,287,565    |
|   | -----        |
| Total liabilities and stockholders' equity      | \$ 9,562,630 |
|   | =====        |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

|                               | NINE MONTHS ENDED<br>DECEMBER 31, |             |
|-------------------------------|-----------------------------------|-------------|
|                               | 2004                              | 2003        |
|                               | -----                             | -----       |
| REVENUES                      | \$ 151,450                        | \$ 30,000   |
|                               | -----                             | -----       |
| COST OF OPERATIONS:           |                                   |             |
| Research and development      | 1,937,794                         | 1,480,788   |
| General and administrative    | 1,675,041                         | 1,543,926   |
| Depreciation and amortization | 271,080                           | 268,830     |
|                               | -----                             | -----       |
|                               | 3,883,915                         | 3,293,544   |
|                               | -----                             | -----       |
| LOSS FROM OPERATIONS          | (3,732,465)                       | (3,263,544) |
|                               | -----                             | -----       |
| OTHER INCOME (EXPENSES):      |                                   |             |
| Interest income               | 18,842                            | 16,469      |
| Litigation settlement         | --                                | 150,000     |
| Sale of New Jersey tax losses | 205,792                           | 151,027     |
| Interest expense              | (176,696)                         | (159,777)   |



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|   |                |                |
|---|----------------|----------------|
| Expenses relating to issuance of stock options          | (325,558)      | (1,096,349)    |
| Expenses relating to issuance of stock warrants         | (241,010)      | (587,983)      |
| Expenses relating to repricing of stock options         | (397,732)      | --             |
| Expenses relating to warrant exchange offer             | --             | (172,324)      |
|   | -----          | -----          |
|   | (916,362)      | (1,698,937)    |
|   | -----          | -----          |
| LOSS BEFORE PROVISION FOR INCOME TAXES                  | (4,648,827)    | (4,962,481)    |
| PROVISION FOR INCOME TAXES                              | 1,000          | 1,000          |
|   | -----          | -----          |
| NET LOSS  | (4,649,827)    | (4,963,481)    |
| Preferred stock dividends                               | (75,076)       | --             |
|   | -----          | -----          |
| NET LOSS ATTRIBUTABLE TO COMMON<br>SHAREHOLDERS         | \$ (4,724,903) | \$ (4,963,481) |
|   | =====          | =====          |
| BASIC AND DILUTED LOSS PER COMMON SHARE                 | \$ (.39)       | \$ (.46)       |
|   | =====          | =====          |
| WEIGHTED AVERAGE NUMBER OF<br>COMMON SHARES OUTSTANDING | 12,231,405     | 10,829,626     |
|   | =====          | =====          |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THE NINE MONTHS ENDED DECEMBER 31, 2004  
(UNAUDITED)

|  | SERIES A 8%<br>CONVERTIBLE<br>PREFERRED STOCK |        | COMMON STOCK |           | ADDITIONAL<br>PAID-IN<br>CAPITAL | TREA<br>ST |
|--|---|--------|--------------|-----------|----------------------------------|------------|
|  | SHARES  | AMOUNT | SHARES       | AMOUNT    |                                  |            |
| BALANCE AT MARCH 31, 2004 (AUDITED)  | --  | \$ --  | 12,204,426   | \$122,044 | \$39,338,140                     | \$ (30     |
| Series A 8% convertible<br>preferred shares and warrants<br>issued in connection with<br>private placement | 516,558                                       | 5,166  |              |           | 5,861,434                        |            |
| Common shares issued in<br>connection with consulting<br>agreement   | --  | --     | 26,500       | 265       | 58,035                           |            |

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|  |          |         |            |           |              |                |
|--|----------|---------|------------|-----------|--------------|----------------|
| Preferred shares converted to common shares                                | (85,366) | (854)   | 853,660    | 8,537     | (7,683)      |                |
| Expenses related to issuance of stock options                              | --       | --      | --         | --        | 325,558      |                |
| Expenses related to issuance of stock warrants                             | --       | --      | --         | --        | 241,010      |                |
| Expenses related to repricing of stock options                             | --       | --      | --         | --        | 397,732      |                |
| Common stock issued as dividend on Series A 8% convertible preferred stock | --       | --      | 26,961     | 269       | 74,807       |                |
| NET LOSS FOR NINE MONTHS ENDED DECEMBER 31, 2004                           | --       | --      | --         | --        | --           |                |
| BALANCE AT DECEMBER 31, 2004 (Unaudited)                                   | 431,192  | \$4,312 | 13,111,547 | \$131,115 | \$46,289,033 | \$(30,000,000) |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

|   | NINE MONTHS<br>DECEMBER 31 |                |
|---|----------------------------|----------------|
|   | 2004                       | 2003           |
| CASH FLOWS FROM OPERATING ACTIVITIES:                                   |                            |                |
| Net loss  | \$ (4,649,827)             | \$ (4,649,827) |
| Adjustments to reconcile net loss to cash used in operating activities: |                            |                |
| Depreciation and amortization   | 271,080                    | 271,080        |
| Expenses related to issuance of stock options                           | 325,558                    | 325,558        |
| Expenses related to issuance of stock warrants                          | 241,010                    | 241,010        |
| Expenses related to repricing of stock options                          | 397,732                    | 397,732        |
| Expenses related to modification of warrant exchange offer              | --                         | --             |
| Expenses related to issuance of common stock                            | 58,300                     | 58,300         |
| Changes in assets and liabilities:                                      |                            |                |
| Accounts and accrued interest receivable                                | 153,250                    | 153,250        |
| Prepaid expenses and other current assets                               | 83,059                     | 83,059         |
| Accounts payable, accrued expenses and other current liabilities        | (490,228)                  | (490,228)      |
| NET CASH USED IN OPERATING ACTIVITIES                                   | (3,610,066)                | (3,610,066)    |

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|   |    |              |
|---|----|--------------|
| CASH FLOWS FROM INVESTING ACTIVITIES:   |    |              |
| Purchase of equipment   |    | (27,843)     |
| Purchase of patent  |    | --           |
| Restricted cash   |    | 312,350      |
|   |    | -----        |
| NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES                                     |    | 284,507      |
|   |    | -----        |
| CASH FLOWS FROM FINANCING ACTIVITIES:   |    |              |
| Net proceeds from issuance of Securities  |    | 5,866,600    |
| Principal bank note payments  |    | (225,000)    |
| Proceeds from equipment loan  |    | 400,000      |
| Principal equipment note payments   |    | (64,989)     |
| Principal repayments of NJEDA Bonds   |    | (150,000)    |
| Prepaid interest  |    | (41,013)     |
|   |    | -----        |
| NET CASH PROVIDED BY FINANCING ACTIVITIES   |    | 5,785,638    |
|   |    | -----        |
| NET CHANGE IN OPERATING CASH AND CASH EQUIVALENTS                                       |    | 2,460,079    |
| OPERATING CASH AND CASH EQUIVALENTS - beginning of period                               |    | 2,104,869    |
|   |    | -----        |
| OPERATING CASH AND CASH EQUIVALENTS - end of period                                     |    | \$ 4,564,948 |
|   |    | =====        |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:                                      |    |              |
| Cash paid for interest  | \$ | 132,231      |
| Cash received for income taxes  |    | 204,792      |
| SCHEDULE OF NON-CASH FINANCING ACTIVITIES:  |    |              |
| Preferred Stock dividends of \$75,076 paid by issuance of 26,961 shares of Common Stock | \$ | 75,076       |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
 CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
 NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
 (UNAUDITED)

NOTE 1 - BASIS OF PRESENTATION

The information includes the results of operations of Elite Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively the "Company") including its wholly-owned subsidiaries, Elite Laboratories, Inc. ("Elite Labs"), Elite Research Ltd. ("ERL") and Elite Research, Inc. ("ERI"), for the periods ended December 31, 2004 and December 31, 2003. As of December 31, 2004, the financial statements of all entities are consolidated and all significant intercompany accounts are eliminated upon consolidation. The accompanying unaudited consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and

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Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary for a fair presentation of the consolidated financial position, results of operations and cash flows of the Company for the periods presented have been included.

The financial results for the interim periods are not necessarily indicative of the results to be expected for the full year or future interim periods.

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted for interim financial statement presentation and should be read in conjunction with the consolidated financial statements and notes included elsewhere for the year ended March 31, 2004. There have been no changes in significant accounting policies since March 31, 2004.

The Company does not anticipate being profitable for fiscal year 2005; therefore a current provision for income tax was not established for the nine months ended December 31, 2004. Only the minimum corporation tax liability required for state purposes is reflected.

### NOTE 2 - STOCKHOLDERS' EQUITY

The shareholders at the Annual Meeting of Stockholders adjourned to July 21, 2004, approved the amendment to the Certificate of Incorporation increasing the number of authorized shares of capital stock from 25,000,000 of Common Stock to 65,000,000 shares of Common Stock and 5,000,000 shares of Preferred Stock, each with a par value of \$.01 per share.

#### SERIES A 8% CONVERTIBLE PREFERRED STOCK TRANSACTION

In October 2004, the Company completed a private placement through Indigo Securities LLC, the Placement Agent, for aggregate gross proceeds of \$6,600,000 of 516,558 shares of Series A Preferred Stock, par value \$0.01 per share ("Preferred Shares") convertible into 5,165,580 shares of Common Stock. The Preferred Shares were accompanied by warrants to purchase an aggregate of 5,165,580 shares of Common Stock at exercise prices ranging from \$1.54 to \$1.84 per share. See Note 4 - "Subsequent Events" for the conversion of all the originally issued 516,558 shares into shares of Common Stock.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

### NOTE 2 - STOCKHOLDERS' EQUITY (Continued)

#### SERIES A 8% CONVERTIBLE PREFERRED STOCK TRANSACTION (Continued)

The holders of the Preferred Shares were entitled to dividends at the rate of 8% of the original issue price of \$12.30 per share payable on December 1 and June 1 of each year in cash or shares of Common Stock.

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Holder s were entitled to elect one Director, and ten votes per share, and vote with the Common Stockholders as one class on all other matters. Each Preferred Share was convertible into ten shares of Common Stock at a rate of \$1.23 into \$12.30 plus dividends to the date of conversion. The purchaser of the Preferred Shares (the "INVESTORS") received for each Preferred Share acquired two Common Stock Purchase Warrants, one exercisable on or prior to December 31, 2005 ("SHORT-TERM WARRANTS") and the other exercisable on or prior to December 28, 2009 ("LONG-TERM WARRANTS"). Each warrant represents the right to purchase five shares of Common Stock.

The private placement was effected in three tranches. The first tranche involved the sale on October 6, 2004 of 379,122 Preferred Shares at a price of \$12.30 per share convertible into an aggregate of 3,791,220 shares of Common Stock accompanied by Short-Term Warrants and Long-Term Warrants to purchase at \$1.54 per share an aggregate of 3,791,220 shares of Common Stock. The second tranche involved the sale on October 12, 2004 of 119,286 Preferred Shares at a price of \$14.00 per share convertible into 1,192,860 shares of Common Stock accompanied by Short-Term and Long-Term Warrants to purchase an aggregate of 1,192,860 shares of Common Stock at a price of \$1.75 per share. The third tranche involved the sale on October 26, 2004 of 18,150 Preferred Shares at a price of \$14.70 per share convertible into 181,500 shares of Common Stock accompanied by Short Term and Long Term Warrants to purchase at a price of \$1.84 per share an aggregate of 181,500 shares of Common Stock.

Pursuant to the Placement Agent Agreement, the Company issued to the Placement Agent and its designees Long Term Warrants to purchase 357,495 shares of Common Stock at \$1.23 per share, 119,286 shares of Common Stock at a price of \$1.40 per share, and 18,150 shares of Common Stock at a price of \$1.47 per share, respectively. The Company paid commissions aggregating \$633,510 and also paid legal fees and expenses of the Agent's counsel of \$75,000 and legal fees and expenses of one counsel for the investors in the private placement of \$25,000.

The Company at its expense registered under the Securities Act of 1933 (the "ACT") for resale the shares of Common Stock issuable upon conversion of the Preferred Shares, exercise of the warrants (including the Placement Agent's warrants) and as payment of dividends on the Preferred Shares.

The Preferred Shares and warrants were sold by Registrant pursuant to the exemption from registration afforded by Section 4(2) of the Act and Registration D thereunder.

In the private placement Dr. Charan Behl, the Company's Chief Scientific Advisor, purchased at \$12.30 per share 20,000 Preferred Shares and received warrants to purchase 200,000 shares of Common Stock. His payment consisted of \$16,675 in cash and the release of the Company's obligation of \$229,325 due to Dr. Behl for consulting fees for services rendered through September 30, 2004.

The December 1, 2004 dividends in the amount of \$75,076 were paid by issuance of 26,961 shares of Common Stock. By December 31, 2004, 85,366 shares of Series A Preferred Stock were converted into 853,660 shares of Common Stock.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

### NOTE 2 - STOCKHOLDERS' EQUITY (Continued)

#### COMMON STOCK TRANSACTION

On July 6, 2004, the Company issued 26,500 shares of Common Stock and agreed to pay \$10,000 per month to a corporation in consideration for the rendering for a six-month period of investor relation consulting services, including the distribution of the Company's press releases, the provision of related strategic advice and the inclusion of the Company on the consultant's website. The Company agreed to provide the holder with "piggy-back" registration rights with respect to the shares.

#### DECEMBER 2003 PRIVATE PLACEMENT

The Company completed in December 2003 a private placement of 1,645,000 shares of its common stock at \$2.00 per share, exempt from registration pursuant to Section 4(2) and Regulation D under the Act. In connection with the offering, the Company paid a cash commission of \$75,000 to First Montauk Group Inc., as Placement Agent and issued to the agent a five year warrant to purchase 50,000 shares of Company's common stock at a price of \$2.00 per share. Legal fees approximating \$36,000 were also incurred in connection with this private placement. Pursuant to its agreement with the purchasers, the Company at its expense registered 1,580,000 of the shares issued and the shares issuable upon exercise of the warrant under the Act

#### TREASURY STOCK TRANSACTIONS

The Company purchased prior to March 31, 2003, in the open market, 100,000 shares of common stock for a total consideration of \$306,841 pursuant to the authorization by the Board of Directors on June 27, 2002.

#### WARRANTS AND OPTIONS

On July 20, 2004, the Company issued five-year warrants to purchase 50,000 shares of Common Stock at a price of \$3.00 per share to an individual in consideration of his agreement to render financial consulting services. See Note 4 - "Subsequent Events".

On July 8, 2004, Elite Labs, to finance the purchase of certain machinery and equipment, borrowed \$400,000 and designees of the lender received warrants which vested immediately, to purchase an aggregate of 50,000 shares of the Company's common stock at \$4.20 per share.

On June 3, 2004, the Company granted five-year warrants to purchase 100,000 shares of Common Stock at a price of \$2.50 per share to a corporation as consideration for financial consulting services.

The per share weighted-average fair value of the above mentioned warrants under this subcaption ranged from \$.83 - \$1.50 using the Black-Scholes warrant pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 80.34; risk free interest rate of 3.0% and expected lives of 10 years.

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In June 2004, the stockholders of the Company approved the adoption by the Board of Directors of the Company's 2004 Stock Option Plan (the "2004 Plan"). The Plan reserves 1,500,000 shares of Common Stock for grant by the Board of Directors of incentive or nonqualified stock options to officers, employees, or directors of and consultants to the Company.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

NOTE 2 - STOCKHOLDERS' EQUITY (Continued)

WARRANTS AND OPTIONS (Continued)

On June 22, 2004, the Company granted under its 2004 Stock Option Plan, 120,000 options to Directors and 123,300 options to employees to purchase an aggregate of 243,300 shares of Common Stock at a price of \$2.34 per share. The 120,000 options granted under the 2004 Plan to members of the Board of Directors expire ten years from the date of issuance and are fully vested. The per share weighted-average fair value of the 243,300 options amounted to \$1.91 using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 76.69%; risk free interest rate of 4.0%; and expected lives of ten years. The Company has taken a charge of \$229,632 for the nine-months ended December 31, 2004, which represents the fair value of the vested options, utilizing the Black-Scholes options pricing model on the grant date.

The 120,000 options granted to employees were in replacement of previously granted options containing exercise prices greater than \$2.34 per share. On the same date the stockholders approved amendments made previously by the Board of Directors to outstanding warrants and options including the repricing of options to purchase 420,000 shares of which options to purchase 330,000 shares were held by Directors of the Company. Accordingly, during the nine months ended December 31, 2004 options with respect to an aggregate of 543,300 options were repriced (treating the options granted in lieu of outstanding options as repriced options). The new options have exercise prices between \$2.21 and \$2.34 per share. 162,300 options are vested and 381,000 options are in various stages of three year vesting periods. The options expire ten years from date of issuance. The per share weighted-average fair value of options repriced during the nine months ended December 31, 2004, ranged from \$1.51 - \$1.91 using the Black-Scholes options pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 76.69%; risk-free interest rate of 4.0%; and expected lives of ten years. The Company has taken a charge of \$397,732 for the nine months ended December 31, 2004 which represents the fair value of the options vested, utilizing the Black-Scholes options pricing model on each grant date.

The following table illustrates the effect on net loss and loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all outstanding and unvested awards in each period presented:

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|   | NINE MONTHS ENDED DECEMBER |                |
|---|----------------------------|----------------|
|   | 2004                       | 2003           |
| Net loss as reported  | \$ (4,649,827)             | \$ (4,963,481) |
| Add: Stock-based compensation expense included in reported net loss, net of related tax effects                             | 964,300                    | 1,684,332      |
| Deduct: Total stock-based compensation expense determined under fair value method for all awards net of related tax effects | (1,005,571)                | (2,344,940)    |
| Pro-forma net loss  | (4,691,098)                | (5,624,089)    |
| Loss per share as reported  | (.38)                      | (.46)          |
| Pro-forma loss per share  | (.38)                      | (.52)          |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

NOTE 2 - STOCKHOLDERS' EQUITY (Continued)

WARRANTS AND OPTIONS (Continued)

At December 31, 2004, Elite had outstanding 2,377,050 options with exercise prices ranging from \$1.00 to \$3.00 and 8,514,750 warrants (exclusive of the Short Term Warrants and the Long Term Warrants) with exercise prices ranging from \$2.00 to \$5.00; each option and warrant representing the right to purchase one share of common stock.

CLASS A WARRANT EXCHANGE OFFER

On October 23, 2002, the Company entered into a Settlement Agreement with various parties in order to end a Consent Solicitation contest and various legal actions initiated by the Company. The agreement provided, among other things, an agreement to commence an exchange offer (the "Exchange Offer") whereby holders of the Company's Class A Warrants which expired on November 30, 2002 (the "Old Warrants") had the opportunity to exchange those warrants for new warrants (the "Class C Warrants") upon payment to the Company of \$.10 per share of common stock issuable upon the exercise of the old warrants. In September 2003 the Company discontinued the Exchange offer and issued the Class C Warrants to the record holders as of November 30, 2002 of the Class A Warrants without requiring any cash payment.

Class C Warrants are exercisable for the same number of shares of common stock as the Class A Warrants at an exercise price of \$5.00 per share, and expire on November 30, 2005. They are not transferable except pursuant to operation of law.



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During the year ended March 31, 2003, the Company expensed \$242,338 relating to the Exchange Offer, which represents the fair value of the Class C Warrants,. The per share weighted-average fair value of each warrant on the date of grant was \$1.10 using the Black-Scholes option pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 73.77%; risk-free interest rate of 2.88%; and expected lives of 3 years. The elimination of the \$0.10 per share fee resulted in an additional charge of \$172,324 during the year ended March 31, 2004.

For the year ended March 31, 2003 the Company incurred legal fees and other costs amounting to approximately \$100,000, in connection with the Exchange Offer, which was charged to additional paid-in capital.

### NOTE 3 - COMMITMENTS AND CONTINGENCIES

#### SETTLEMENT OF LITIGATION WITH ATUL M. MEHTA

The Company had an employment agreement ("Employment Agreement") with its former President/CEO, Dr. Atul M. Mehta ("Mehta").

On June 3, 2003, Mehta resigned from all positions that he held with the Company, while reserving his rights under his Employment Agreement and under common law. On July 3, 2003, Mehta instituted litigation against the Company and one of its directors in the Superior Court of New Jersey, alleging, among other things, the breach of his Employment Agreement and defamation, and claiming that he is entitled to receive his salary through June 6, 2006. The Company made certain counter claims against Mehta.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

### NOTE 3 - COMMITMENTS AND CONTINGENCIES (Continued)

#### SETTLEMENT OF LITIGATION WITH ATUL M. MEHTA (Continued)

Under a settlement agreement, dated April 21, 2004, Mehta relinquished any rights to the Company's patents and intellectual properties and agreed to certain non-disclosure and certain limited non-competition covenants. The Company paid Mehta \$400,000 and certain expense reimbursements, and received a short-term option for the Company or its designees to acquire all of the shares of the common stock of the Company held by Mehta and his affiliates at \$2.00 per share. The Company paid \$100,000 into escrow which was released to Mehta because the option was not exercised in full. As part of the settlement, the Company extended expiration dates of certain options to purchase 770,000 shares of common stock at prices ranging from \$1.00 to \$10.00 per share held by Mehta and also provided him with certain "piggyback" registration rights with respect to shares underlying his options. The Company entered into an agreement dated October 7, 2004 with Mehta pursuant to which 100,000 of the \$10.00 options were terminated, the expiration dates of the other 670,000 options were extended from June 13, 2005 to December 31, 2007 and the exercise price of 170,000 options were reduced from \$10.00 to \$2.34 per share. The agreement also obligates the Company to bear Mehta's legal and other expenses

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for the two year period from the litigation settlement will not exceed \$50,000.

### REFERRAL AGREEMENT WITH RELATED PARTY

In January 2002, the Company entered into a Referral Agreement with one of its directors (Referring Party) whereby the Company is to pay the Referring Party a fee based upon payments received by the Company from sales of products, development fees, licensing fees and royalties generated as a direct result of the Referring Party identifying customers for the Company. These amounts are to be reduced by the cost of goods sold directly incurred in the manufacturing or development of products as well as any direct expenses associated with these efforts. The Referral Agreement has no expiration date.

The Company committed to pay the Referring Party a referral fee each year as follows:

| PERCENTAGE OF<br>REFERRAL BASE | REFERRAL BASE<br>FROM | TO          |
|--------------------------------|-----------------------|-------------|
| 5%                             | \$ 0                  | \$1,000,000 |
| 4%                             | 1,000,000             | 2,000,000   |
| 3%                             | 2,000,000             | 3,000,000   |
| 2%                             | 3,000,000             | 4,000,000   |
| 1%                             | 4,000,000             | 5,000,000   |

As of December 31, 2004, no referral fee payments were required to be made under this agreement.

### COLLABORATIVE AGREEMENTS

On December 18, 2003, the Company and Pivotal Development, L.L.C. entered into an agreement to develop a controlled release product utilizing Elite's proprietary drug delivery technology. The product is a generic equivalent to a drug losing patent exclusivity with addressable market revenues of approximately \$150 million per year. The agreement also provides an option to develop a controlled release NDA product.

Under the collaboration agreement, Pivotal Development will be responsible for taking the Elite formulation through clinical development and the FDA regulatory approval process. The partners are to seek a license during the development cycle from a pharmaceutical company, which has the resources to effectively market the product and share the cost of defending the product against any lawsuits.

Elite and Pivotal are to bear costs in their respective areas of responsibility. In addition Pivotal is to pay Elite \$750,000 upon attainment of certain milestones outlined in the agreement.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

NOTE 3 - COMMITMENTS AND CONTINGENCIES (Continued)

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### COLLABORATIVE AGREEMENTS (Continued)

Pivotal did not raise the capital required to move forward with the development agreement and did not go forward under the terms of the agreement. Elite is attempting to identify other partners for this project.

In June 2001, the Company entered into two separate and distinct development and license agreements with another pharmaceutical company, ECR Pharmaceuticals, Inc. ("ECR"). The Company is developing two drug compounds for the partner in exchange for certain payments and royalties. The Company also reserves the right to manufacture the compounds. On November 15, 2004, ECR announced that it launched LODRANE 24, utilizing Elite's exclusive extended release technology, for once daily dosing. The Company is currently manufacturing commercial batches for promotion by ECR for which Elite will receive a royalty on product revenues. No amounts were earned under the agreements during the nine month period ended December 31, 2004 or 2003 respectively.

On September 13, 2002, the Company, entered into a manufacturing agreement with Ethypharm S.A. ("Ethypharm"). Under the terms of this agreement, the Company initiated the manufacturing of a new prescription drug product for Ethypharm. The Company received an upfront manufacturing fee for the first phase of the technology transfer and billed an additional amount upon the completion of the first phase of manufacturing.

The Company is entitled to receive additional fees in advance for the final phase of the manufacturing. In addition, if and when FDA approval is obtained and if requested by Ethypharm, the Company will manufacture commercial batches of the product on terms to be agreed upon. There were no amounts earned in the nine month periods ended December 31, 2004 and 2003.

### EMPLOYMENT AGREEMENT

On July 23, 2003, the Company appointed Bernard Berk as its Chief Executive Officer and President and entered into an employment agreement with him. The initial term of this agreement is three years. Pursuant to the agreement:

- Mr. Berk is entitled to receive a base salary of \$200,000 per annum, subject to increase to \$330,140 if and when the Company consummates a Strategic Transaction (as defined in the employment agreement).
- The Company confirmed its grant to Mr. Berk on June 3, 2003 of options to purchase 300,000 shares of the Company's common stock at \$2.01 per share. All of these options are vested.
- The Company granted Mr. Berk options to purchase an additional 300,000 shares of its common stock, with an exercise price equal to \$2.15, the closing price of the Company's common stock on the date of grant. These options will vest solely upon consummation of a Strategic Transaction, as defined.

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NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

### NOTE 3 - COMMITMENTS AND CONTINGENCIES (Continued)

#### EMPLOYMENT AGREEMENT (Continued)

- Mr. Berk will be entitled to receive severance in accordance with the employment agreement if he is terminated without cause or because of his death or permanent disability or if he terminates his employment for good reason or as a result of a "change of control" as defined. The severance will be payable in accordance with the terms of his employment agreement.

On May 14, 2004, the Company's Board of Directors appointed Bernard Berk to the position of Chairman of the Board of Directors.

#### CONSULTING AGREEMENTS

On July 3, 2003, the Company entered into an agreement with Leerink Swann & Company to provide a Valuation and a Fairness Opinion in order for the Company to complete a proposed acquisition (subsequently not effected) for which the Company paid a non-refundable retainer fee of \$50,000. If and when the Board of Directors requests a Fairness Opinion, Leerink's compensation is to be \$50,000. No amounts were expensed in the nine month period ended December 31, 2004 and 2003.

The Company entered into one year consulting agreements with each of Saggi Capital Corp. and Bridge Ventures Inc. on November 4, 2003. The consultant's services include advice with respect to overall strategic planning, financing opportunities, acquisition policy, commercial and investment banking relationships and stockholder matters. In consideration of the consultant's agreement to provide services, the Company pays each consultant \$75,000 in monthly installments of \$6,250 and issued to each consultant a warrant to purchase 100,000 shares of the Company's common stock at a price of \$2.00 per share. Each agreement was extended for an additional year until November 4, 2005 at a cash fee of \$6,250 per month.

On June 3, 2004, the Company agreed to engage a company to provide consulting services and issued in connection therewith a five-year warrant to purchase 100,000 shares of common stock at a price of \$2.50 per share.

On July 20, 2004, the Company agreed to engage an individual to provide financial consulting services and issued in connection therewith a three-year warrant to purchase 50,000 shares of common stock at a price of \$3.00 per share. Pursuant to the rules of the American Stock Exchange, the issuance of the warrants is to be presented for ratification by shareholders at the next Annual Meeting.

For the nine month periods ended December 31, 2004 and 2003, consulting expenses under these agreements amounted to an aggregate of \$30,000 and \$120,000, respectively.

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NINE MONTHS ENDED DECEMBER 31, 2004 AND 2003  
(UNAUDITED)

### NOTE 4 - SUBSEQUENT EVENTS

Effective January 24, 2005, Mr. John Moore resigned as a director of the Company and a member of its Audit and Nominating Committee and was replaced by Mr. Edward Neugeboren who was appointed pursuant to the Certificate of Designation of the Series A Preferred Stock by the Placement Agent of the private placement in which the shares were sold as the agent of the Preferred Shareholders. He was appointed by the Board of Directors to the Audit and Nominating Committees.

As of March 7, 2005, all of the originally issued 516,558 shares of Series A Convertible Preferred Stock had been converted (431,192 shares subsequent to December 31, 2004) into 5,200,120 shares of common stock.

During the period January 1, 2005 through March 7, 2005, the Company issued 203,050 shares of common stock upon exercise of short-term warrants.

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### REPORT OF REGISTERED PUBLIC ACCOUNTING FIRM

To Elite Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Elite Pharmaceuticals, Inc. and Subsidiaries (the "Company") as of March 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the years ended March 31, 2004, 2003 and 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Elite Pharmaceuticals, Inc. and Subsidiaries as of March 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2004, 2003 and 2002 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As shown in the financial statements, the Company has experienced significant losses and negative cash flows, resulting in decreased working capital and accumulated deficits. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are described in Note 2.

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/s/ Miller, Ellin & Company, LLP  
 CERTIFIED PUBLIC ACCOUNTANTS

New York, New York  
 June 8, 2004, except for  
 the fourth and fifth paragraphs of  
 Note 13, as to which  
 the date is June 24, 2004

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2004 AND 2003

ASSETS

|   | 2004        | 2003        |
|---|-------------|-------------|
|   | -----       | -----       |
| CURRENT ASSETS:   |             |             |
| Cash and cash equivalents   | \$2,104,869 | \$3,264,081 |
| Accounts and accrued interest receivable  | 153,250     | 4,681       |
| Restricted cash   | 203,995     | 99,380      |
| Prepaid expenses and other current assets   | 137,892     | 132,092     |
|   | -----       | -----       |
| Total current assets  | 2,600,006   | 3,500,234   |
|   | -----       | -----       |
| PROPERTY AND EQUIPMENT- net of accumulated<br>depreciation and amortization                           | 4,090,250   | 4,390,553   |
|   | -----       | -----       |
| INTANGIBLE ASSETS - net of accumulated amortization   | 102,196     | 104,842     |
|   | -----       | -----       |
| OTHER ASSETS:   |             |             |
| Deposit on equipment  | 398,580     | --          |
| Restricted cash - debt service  | 300,000     | 300,000     |
| Restricted cash - note payable  | 225,000     | 250,000     |
| EDA bond offering costs, net of accumulated<br>amortization of \$60,458 and \$47,267,<br>respectively | 137,402     | 150,593     |
|   | -----       | -----       |
| Total other assets  | 1,060,982   | 700,593     |

|             |             |
|-------------|-------------|
| \$7,853,434 | \$8,696,222 |
| =====       | =====       |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

MARCH 31, 2004 AND 2003  
(CONTINUED)

LIABILITIES AND STOCKHOLDERS' EQUITY

|                                       | 2004         | 2003         |
|---------------------------------------|--------------|--------------|
|                                       | -----        | -----        |
| <b>CURRENT LIABILITIES:</b>           |              |              |
| Current portion - Note payable        | \$ 75,000    | \$ 75,000    |
| Current portion of EDA bonds          | 150,000      | 140,000      |
| Accounts payable and accrued expenses | 1,085,242    | 334,721      |
|                                       | -----        | -----        |
| Total current liabilities             | 1,310,242    | 549,721      |
|                                       | -----        | -----        |
| <b>LONG TERM LIABILITIES:</b>         |              |              |
| Note payable - net of current portion |              |              |
| EDA bonds - net of current portion    | 150,000      | 225,000      |
|                                       | 2,345,000    | 2,495,000    |
|                                       | -----        | -----        |
| Total long-term liabilities           | 2,495,000    | 2,720,000    |
|                                       | -----        | -----        |
| <b>COMMITMENTS AND CONTINGENCIES</b>  |              |              |
| <b>STOCKHOLDERS' EQUITY:</b>          |              |              |
| Common stock - \$.01 par value;       |              |              |
| Authorized - 25,000,000 shares        |              |              |
| Issued and outstanding - 12,204,423   |              |              |
| and 10,544,423 in 2004 and 2003,      |              |              |
| respectively                          | 122,044      | 105,444      |
| Additional paid-in capital            | 39,338,140   | 34,218,832   |
| Accumulated deficit                   | (35,105,151) | (28,590,934) |
|                                       | -----        | -----        |
|                                       | 4,355,033    | 5,733,342    |
| Treasury stock                        | (306,841)    | (306,841)    |
|                                       | -----        | -----        |
| Total stockholders' equity            | 4,048,192    | 5,426,501    |
|                                       | -----        | -----        |

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|  |              |              |
|--|--------------|--------------|
| Total liabilities and stockholders' equity | \$ 7,853,434 | \$ 8,696,222 |
|  | =====        | =====        |

The accompanying notes are an integral part  
of the consolidated financial statements.

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## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS

|   | YEARS ENDED MARCH 31, |                |                |
|---|-----------------------|----------------|----------------|
|   | 2004                  | 2003           | 2002           |
| REVENUES:                                     |                       |                |                |
| Research and development                      | \$ 258,250            | \$ 442,500     | \$ 593,000     |
| Product formulation fees                      | --                    | 187,810        | 601,057        |
| Consulting and test fees                      | --                    | --             | 3,450          |
|   | -----                 | -----          | -----          |
| Total revenues                                | 258,250               | 630,310        | 1,197,507      |
|   | -----                 | -----          | -----          |
| OPERATING EXPENSES:                           |                       |                |                |
| Research and development                      | 2,075,074             | 2,013,579      | 1,609,108      |
| General and administrative                    | 2,549,846             | 1,858,069      | 763,687        |
| Depreciation and amortization                 | 332,836               | 310,876        | 266,919        |
|   | -----                 | -----          | -----          |
|   | 4,957,756             | 4,182,524      | 2,639,714      |
|   | -----                 | -----          | -----          |
| LOSS FROM OPERATIONS                          | (4,699,506)           | (3,552,214)    | (1,442,207)    |
|   | -----                 | -----          | -----          |
| OTHER INCOME (EXPENSES):                      |                       |                |                |
| Interest income                               | 23,765                | 96,692         | 260,055        |
| Litigation Settlement                         | 150,000               | --             | --             |
| Sale of NJ Tax Losses                         | 151,027               | 71,674         | 137,818        |
| Interest expense                              | (211,595)             | (227,907)      | (220,123)      |
| Equity in loss of joint venture               | --                    | (186,379)      | (507,640)      |
| Charge relating to issuance of stock options  | (1,166,601)           | (20,550)       | --             |
| Charge relating of issuance of stock warrants | (587,983)             | --             | --             |
| Charge relating to warrant exchange offer     | (172,324)             | (242,338)      | --             |
|   | -----                 | -----          | -----          |
|   | (1,813,711)           | (508,808)      | (329,890)      |
|   | -----                 | -----          | -----          |
| LOSS BEFORE PROVISION FOR INCOME TAXES        | (6,513,217)           | (4,061,022)    | (1,772,097)    |
| PROVISION FOR INCOME TAXES                    | 1,000                 | 400            | 2,430          |
|   | -----                 | -----          | -----          |
| NET LOSS                                      | \$ (6,514,217)        | \$ (4,061,422) | \$ (1,774,527) |



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|  | =====      | =====      | =====     |
|--|------------|------------|-----------|
| BASIC AND DILUTED LOSS PER COMMON SHARE              | \$ (0.58)  | \$ (0.40)  | \$ (0.19) |
| WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING | 11,168,618 | 10,069,991 | 9,561,299 |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

|  | PREFERRED STOCK |           | COMMON STOCK |          | ADDITIONAL PAID-IN CAPITAL | TREASURY STOCK |        |
|--|-----------------|-----------|--------------|----------|----------------------------|----------------|--------|
|  | SHARES          | AMOUNT    | SHARES       | AMOUNT   |                            | SHARES         | AMOUNT |
| BALANCE AT APRIL 1, 2001   | --              | \$ --     | 9,376,389    | \$93,764 | \$18,071,503               | --             | \$ --  |
| Issuance of shares through exercise of warrants                              | --              | --        | 298,179      | 2,981    | 1,301,606                  | --             | --     |
| Issuance of shares and warrants through exercise of placement agent warrants | --              | --        | 16,272       | 163      | 58,416                     | --             | --     |
| Issuance of shares and warrants through exercise of options                  | --              | --        | 20,000       | 200      | 37,939                     | --             | --     |
| Issuance of Series B convertible exchangeable preferred stock                | 200,000         | 200,000   | --           | --       | --                         | --             | --     |
| Dividends declared - Series A preferred stock                                | --              | --        | --           | --       | --                         | --             | --     |
| Net loss for year ended March 31, 2002                                       | --              | --        | --           | --       | --                         | --             | --     |
| BALANCE AT MARCH 31, 2002  | 200,000         | \$200,000 | 9,710,840    | \$97,108 | \$19,469,464               | --             | \$ --  |

The accompanying notes are an integral part of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

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CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

|   | PREFERRED STOCK |            | COMMON STOCK |           | ADDITIONAL<br>PAID-IN<br>CAPITAL | TREASURY STOCK |             |
|---|-----------------|------------|--------------|-----------|----------------------------------|----------------|-------------|
|   | SHARES          | AMOUNT     | SHARES       | AMOUNT    |                                  | SHARES         | AMOUNT      |
| BALANCE AT APRIL 1, 2002  | 200,000         | \$ 200,000 | 9,710,840    | \$ 97,108 | \$19,469,464                     | --             | \$          |
| Issuance of shares<br>through exercise of<br>warrants                                 | --              | --         | 2,603        | 26        | 13,004                           |                |             |
| Issuance of shares and<br>warrants through<br>exercise of placement<br>agent warrants | --              | --         | 14,670       | 147       | 52,666                           |                |             |
| Issuance of convertible<br>exchangeable preferred<br>stock                            | 559,000         | 559,000    | --           | --        | --                               |                |             |
| Dividends - declared -<br>Series B preferred stock                                    | --              | --         | --           | --        | --                               |                |             |
| Dividends - declared -<br>Series A preferred stock                                    | --              | --         | --           | --        | --                               | --             | --          |
| Preferred stock issued to<br>satisfy accrued dividends                                | 14,000          | 14,000     | --           | --        | --                               |                |             |
| Conversion of convertible<br>exchangeable preferred<br>stock into common stock        | (773,000)       | (773,000)  | 816,310      | 8,163     | 14,520,810                       | --             |             |
| Purchase of treasury stock  | --              | --         | (100,000)    | --        | --                               | 100,000        | (30,000)    |
| Charge relating to<br>exchange of warrants  | --              | --         | --           | --        | 242,338                          |                |             |
| Charge relating to issuance<br>of stock options                                       | --              | --         | --           | --        | 20,550                           |                |             |
| Fees relating to Warrant<br>Exchange Offer  | --              | --         | --           | --        | (100,000)                        |                |             |
| Net loss for the year ended<br>March 31, 2003   | --              | --         | --           | --        | --                               | --             | --          |
| BALANCE AT MARCH 31, 2003   | --              | \$ --      | 10,444,423   | \$105,444 | \$34,218,832                     | 100,000        | \$ (30,000) |

The accompanying notes are an integral part  
of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

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|   | PREFERRED STOCK |        | COMMON STOCK |           | ADDITIONAL<br>PAID-IN<br>CAPITAL | TREASURY ST |       |
|---|-----------------|--------|--------------|-----------|----------------------------------|-------------|-------|
|   | SHARES          | AMOUNT | SHARES       | AMOUNT    |                                  | SHARES      | AMO   |
| BALANCE AT APRIL 1, 2003                      | --              | \$ --  | 10,444,423   | \$105,444 | \$34,218,832                     | 100,000     | \$(30 |
| Modification of warrant<br>exchange offer     | --              | --     | --           | --        | 172,324                          | --          | --    |
| Issuance of stock options                     | --              | --     | --           | --        | 1,166,601                        | --          | --    |
| Issuance of stock warrants                    | --              | --     | --           | --        | 587,983                          | --          | --    |
| Proceeds from exercising<br>stock options     | --              | --     | 15,000       | 150       | 29,850                           | --          | --    |
| Net proceeds from private<br>placement        | --              | --     | 1,645,000    | 16,450    | 3,162,550                        | --          | --    |
| Net loss for the year<br>ended March 31, 2004 | --              | --     | --           | --        | --                               | --          | --    |
| BALANCE AT MARCH 31, 2004                     | --              | \$ --  | 12,104,423   | \$122,044 | \$39,338,140                     | 100,000     | \$(30 |

The accompanying notes are an integral part  
of the consolidated financial statements.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

|   | YEARS ENDE    |       |
|---|---------------|-------|
|   | 2004          | 2     |
| CASH FLOWS FROM OPERATING ACTIVITIES:                                   |               |       |
| Net loss  | \$(6,514,217) | \$(4, |
| Adjustments to reconcile net loss to cash used in operating activities: |               |       |
| Write off of accounts receivable and patents                            | --            | --    |
| Depreciation and amortization   | 332,836       | --    |
| Charge relating to Warrant Exchange Offer                               | 172,324       | --    |
| Charge relating to issuance of stock options                            | 1,166,601     | --    |
| Charge relating to issuance of stock warrants                           | 587,983       | --    |
| Equity in loss of joint venture   | --            | --    |
| Changes in assets and liabilities:                                      |               |       |
| Contract revenue receivable   | (148,569)     | --    |
| Prepaid expenses and other current assets                               | (5,800)       | --    |

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|  |              |             |
|--|--------------|-------------|
| Amount receivable from Joint Venture   | --           |             |
| Accounts payable and accrued expenses and other current Liabilities  | 750,521      |             |
|  | -----        |             |
| NET CASH (USED IN) OPERATING ACTIVITIES  | (3,658,321)  | (2,-----)   |
|  | -----        |             |
| CASH FLOWS FROM INVESTING ACTIVITIES:  |              |             |
| (Purchases) redemptions of short-term investments  | --           |             |
| Payments for patent and trademark filings  | (16,696)     |             |
| Restricted cash  | (79,615)     |             |
| Receivable from sale of New Jersey tax losses  | --           |             |
| Payment of deposit for manufacturing equipment   | (398,580)    |             |
| Purchases of property and equipment  | --           |             |
|  | -----        |             |
| NET CASH (USED IN) INVESTING ACTIVITIES  | (494,891)    | (-----)     |
|  | -----        |             |
| CASH FLOWS FROM FINANCING ACTIVITIES:  |              |             |
| Fees relating to Warrant Exchange Offer  | --           |             |
| Proceeds under bank note   | --           |             |
| Principal repayments of bank note  | (75,000)     |             |
| Purchase of treasury stock   | --           |             |
| Proceeds from issuance of common stock and warrants  | 3,209,000    |             |
| Principal repayments of EDA bonds  | (140,000)    |             |
|  | -----        |             |
| NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES  | 2,994,000    | (-----)     |
|  | -----        |             |
| NET CHANGE IN CASH AND CASH EQUIVALENTS  | (1,159,212)  | (3,-----)   |
| CASH AND CASH EQUIVALENTS - beginning of period  | 3,264,081    | 6,-----)    |
|  | -----        |             |
| CASH AND CASH EQUIVALENTS - end of period  | \$ 2,104,869 | \$ 3,-----) |
|  | =====        | =====)      |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:   |              |             |
| Cash paid for interest   | \$ 214,199   | \$          |
| Cash paid (received) for income taxes  | (150,027)    |             |
| SCHEDULES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:  |              |             |
| Utilization of equipment deposit towards purchase of equipment   | \$ --        | \$          |
| Issuance of Preferred Stock (including stock dividend payable of \$14,000 and subscription receivable of \$67,000) for interest in joint venture | --           |             |
| Conversion of preferred stock to common stock  | --           |             |
| Conversion of preferred stock to additional paid in capital  | --           | 14,         |
| Satisfaction of amounts due to joint venture   | --           |             |
| Reduction in (addition to) investment in joint venture   | --           |             |
| Dividends accrued on preferred stock   | --           |             |

The accompanying notes are an integral part of the consolidated financial statements.

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## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

### NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include the accounts of Elite Pharmaceuticals, Inc. and its wholly-owned subsidiaries, (the "Company"). All significant intercompany accounts and transactions have been eliminated in consolidation.

The Company consolidates all entities that it controls. The Company did not consolidate companies it did not control. The Company used the equity method to account for its investments in companies in which it did not have the ability to exercise significant influence over operating and financial policies.

#### NATURE OF BUSINESS

Elite Pharmaceuticals, Inc. ("Elite") was incorporated on October 1, 1997 under the laws of the State of Delaware, and its wholly-owned subsidiary Elite Laboratories, Inc. ("Elite Labs") was incorporated on August 23, 1990 under the laws of the State of Delaware, in order to engage in research and development activities for the purpose of obtaining Food and Drug Administration approval, and, thereafter, commercially exploiting generic and new controlled-release pharmaceutical products. The Company also engages in contract research and development on behalf of other pharmaceutical companies.

On October 24, 1997, Elite merged with Prologica International, Inc. ("Prologica") a Pennsylvania corporation, a publicly traded inactive corporation, with Elite surviving the merger. In addition, Elite Labs merged with a wholly-owned subsidiary of Prologica, with the Company's subsidiary surviving this merger. The former shareholders of the Company's subsidiary exchanged all of their shares of Class A voting common stock for shares of the Company's voting common stock in a tax free reorganization under Internal Revenue Code Section 368. The result of the merger activity qualified as a reverse acquisition. In connection with the reverse acquisition, options exercisable for shares of Class A voting and Class B nonvoting common stock of the Company's subsidiary were exchanged for options exercisable for shares of the Company's voting common stock.

On September 30, 2002, the Company acquired from Elan Corporation, plc and Elan International Services, Ltd. (together "Elan") Elan's 19.9% interest in Elite Research, Ltd. ("ERL"), a joint venture formed between the Company and Elan where the Company's interest originally was 80.1%.

On December 31, 2002, the Company entered into an agreement of merger whereby ERL (a Bermuda Corporation) was merged into a new Delaware Corporation, Elite Research, Inc. ("ERI"), a wholly-owned subsidiary of the Company. As a result of the merger, ERI became the owner of all of the assets and liabilities of ERL. The merger was accounted for as a tax free reorganization.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

## NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### CASH AND CASH EQUIVALENTS

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks and money market instruments. The Company places its cash and cash equivalents with high-quality, U.S. financial institutions and, to date, has not experienced losses on any of its balances.

### PROPERTY AND EQUIPMENT

Property and equipment are stated at cost. Depreciation is provided on the straight-line method based on the estimated useful lives of the respective assets which range from five to forty years. Major repairs or improvements are capitalized. Minor replacements and maintenance and repairs which do not improve or extend asset lives are expensed currently.

Upon retirement or other disposition of assets, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is recorded.

### IMPAIRMENT OF LONG-LIVED ASSETS

The Company periodically evaluates the fair value of long-lived assets whenever events or changes in circumstances indicate that its carrying amounts may not be recoverable. Accordingly, any impairment of value will be recognized when the carrying amount of a long-lived asset exceeds its fair value in accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." Management has determined that no impairment of long-lived assets has occurred.

### RESEARCH AND DEVELOPMENT

Research and development expenditures are charged to expense as incurred.

### PATENTS AND TRADEMARKS

Effective April 1, 2002, the Company adopted the provisions of SFAS No. 142, "Goodwill and Other Intangible Assets." The adoption of SFAS No. 142 required an initial impairment assessment involving a comparison of the fair value of patents and trademarks to current carrying value. No impairment was determined to exist. The Company reviews such trademarks and patents with definite lives for impairment to ensure they are appropriately valued if conditions exist that may indicate the carrying value may not be recoverable. Such conditions may include an economic downturn or a change in the assessment of future operations.

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Costs incurred for the application of patents and trademarks are capitalized and amortized on the straight-line method, based on their estimated useful lives ranging from five to fifteen years, commencing upon approval of the patent and trademarks. These costs are charged to expense if the patent or trademark is unsuccessful.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

##### CONCENTRATION OF CREDIT RISK

The Company derives substantially all of its revenues from contracts with other pharmaceutical companies, subject to licensing and research and development agreements.

The Company maintains cash balances in its bank, which, at times, may exceed the limits of the Federal Deposit Insurance Corp.

The Company extends credit to its customers pursuant to contract terms in the normal course of business and performs ongoing credit evaluations. As of March 31, 2004 and 2003, no allowance for doubtful accounts was considered necessary, based on historical trends, economic conditions and the credit worthiness of customers. Amounts are written off when they are deemed uncollectible. The Company has not experienced significant write-offs.

##### USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, the recognition of revenue and the fair value of intangible assets and stock-based awards.

##### INCOME TAXES

The Company adopted SFAS No. 109, "Accounting for Income Taxes," which requires the use of the liability method of accounting for income taxes. The liability method measures deferred income taxes by applying enacted statutory rates in effect at the balance sheet date to the differences between the tax bases of assets and liabilities and their reported amounts in the financial statements. The resulting deferred tax assets or liabilities are adjusted to reflect changes in tax laws as they occur.

##### LOSS PER COMMON SHARE

Net loss per common share is calculated by dividing net loss by the

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weighted average number of shares outstanding during each period presented. Common stock equivalents, consisting of options, warrants and convertible securities, have not been included, as their effect would be antidilutive. For the three years ended March 31, 2004, 2003 and 2002 the following potentially dilutive securities were not included in the computation of diluted loss per share:

|                              | 2004      |                                 | 2003      |                                 |     |
|------------------------------|-----------|---------------------------------|-----------|---------------------------------|-----|
|                              | SHARES    | WEIGHTED-AVERAGE EXERCISE PRICE | SHARES    | WEIGHTED-AVERAGE EXERCISE PRICE | SH  |
| Stock options                | 2,417,050 | \$ 3.70                         | 2,266,850 | \$ 5.74                         | 2,0 |
| Warrants                     | 2,654,239 | \$ 4.72                         | 733,752   | \$ 12.33                        | 2,6 |
| Convertible preferred shares | --        | --                              | --        | --                              | 8   |
|                              | 5,071,289 |                                 | 3,000,602 |                                 | 5,5 |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

REVENUE RECOGNITION

Revenues derived from providing research and development services under contracts with other pharmaceutical companies are recognized when earned. These contracts provide for non-refundable upfront and milestone payments. Because no discrete earnings event has occurred when the upfront payment is received, that amount is deferred until the achievement of a defined milestone. Each nonrefundable milestone payment is recognized as revenue when the performance criteria for that milestone has been met. Under each contract, the milestones are defined, substantive effort is required to achieve the milestone, the amount of the non-refundable milestone payment is reasonable commensurate with the effort expended, and achievement of the milestone is reasonably assured.

Revenues earned by licensing certain pharmaceutical products developed by Elite are recognized at the beginning of a license term when Elite's customer has legal right to the use of the product. To date, no revenues have been earned by licensing products and there are no continuing obligations under any licensing agreements.

INVESTMENT IN JOINT VENTURE

The equity method of accounting was used to account for the Company's



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investment in its joint venture with Elan. Under the equity method, the Company recognized its share in the net earnings or losses of the joint venture as they occurred. While Elite owned 100% of the outstanding common stock of ERL, Elite's equity in the loss of ERL was based on 100% of ERL's losses, less the amounts funded by Elan. Elan funded 19.9% of ERL's losses. Once Elite's investment was reduced to zero, further losses were recognized to the extent of Elite's commitment to fund the losses. The joint venture was terminated effective September 30, 2002, as further discussed in Note 7.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

##### TREASURY STOCK

The Company records common shares purchased and held in treasury at cost.

##### STOCK-BASED COMPENSATION

Under various qualified and non-qualified plans, the Company may grant stock options to officers, selected employees, as well as members of the board of directors and advisory board members, as further described in Note 11. Effective April 1, 2002, the Company adopted the fair value recognition provisions of SFAS No. 123, "Accounting for Stock-Based Compensation" and selected the prospective method of adoption described in SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of SFAS No. 123." Prior to April 1, 2002, the Company measured stock-based compensation for its employee compensation plans using the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations. No stock-based employee compensation expense for stock options was reflected in net loss for the year ended March 31, 2002 as all stock options granted under those plans had an exercise price equal to the fair market value of the underlying common stock on the date of grant.

During the years ended March 31, 2003 and 2004 the Company issued 210,000 and 1,024,000, respectively options to purchase common stock to employees and to members of the board of directors. The options have an exercise price ranging from \$2.01 to \$5.00 per share and all vest over three years except 610,000 shares issued in 2004 which vested upon grant date. The options expire between five and ten years from the date of grant. The Company has recorded compensation expense of \$20,550 and \$1,166,601 for the years ended March 31, 2003 and 2004 which represents the fair value of the options vested, utilizing the Black-Scholes options pricing model on each grant date.

On June 22, 2004 the Company's Stockholders approved the 2004 Stock Option Plan and ratified the amendments of the terms of outstanding options and warrants, including the repricing of options to certain

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Directors and employees (See Note 13). The Company will record a significant compensation expense in future periods, based on the fair value of the options after reflecting the repricing and amendments to the terms of the options.

The following table illustrates the effect on net loss and loss per share as if the Company had applied the fair value recognition provisions of SFAS No. 123 to all outstanding and unvested awards in each year presented:

|  | 2004          | 2003          |
|--|---------------|---------------|
| Net loss as reported   | \$(6,514,217) | \$(4,061,422) |
| Add: Stock-based compensation expense included in reported net loss, net of related tax effects                              | 1,166,601     | 20,550        |
| Deduct: Total stock-based compensation expense determined under fair value method for all awards, net of related tax effects | (865,255)     | (1,070,651)   |
| Pro forma net loss   | (6,212,871)   | (5,111,523)   |
| Loss per share as reported   | (0.58)        | (0.40)        |
| Pro-forma loss per share   | (0.56)        | (0.51)        |

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 1 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

##### FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts of current assets and liabilities approximate fair value due to the short-term nature of these instruments. The carrying amounts of noncurrent assets are reasonable estimates of their fair values based on management's evaluation of future cash flows. The long-term liabilities are carried at amounts that approximate fair value based on borrowing rates available to the Company for obligations with similar terms, degrees of risk and remaining maturities.

##### RECLASSIFICATIONS

Certain accounts and amounts in the 2003 and 2002 financial statements have been reclassified in order to conform with the 2004 presentation. These reclassifications have no effect on net income.

#### NOTE 2 - MANAGEMENT'S LIQUIDITY PLANS

The Company reported net losses of \$6,514,217, \$4,061,422 and \$1,774,527 for the fiscal years ended March 31, 2004, 2003 and 2002,

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respectively. At March 31, 2004, the Company 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. The Company has not generated any significant revenue to date.

In an effort to reduce costs in fiscal 2003, the Company has reduced the number of products being actively developed from approximately fifteen to six. The six products that continue in development were deemed by management to be the most suitable for continued development given the Company's limited resources. The Company has also settled certain litigation with its former CEO which will significantly reduce its legal fees.

The primary strategy remains to develop the Company's oral control release pharmaceutical products, with emphasis in the area of pain management, for FDA approval, and once developed, to commercially exploit these products either by licensing or through the development of collaborations with strategic partners.

The Company also retained an investment banking firm in fiscal 2003 to assist the Company in connection with potential strategic transactions, including acquisitions. The Company may receive additional cash proceeds from the exercise of outstanding options and warrants, as well as through the continued sale of its New Jersey State tax losses. However, there is no assurance that any options or warrants will be exercised, that any sale of tax losses will be completed or that the Company will be able to raise additional capital.

In the event Purdue Pharma L.P. proceeds with its option to license the Company's Oxycodone product pursuant to the option agreement entered into on May 14, 2004 (See Note 13), the terms of the licensing agreement provide for the Company to receive significant milestone payments on or before March 31, 2005.

See Note 13 for information as to the Company's efforts to effect a financing of equipment purchases and a private placement of shares of its Common Stock. No representation can be made that the efforts will be successful or that if successful that the resulting proceeds will be material.

There is also no assurance that the Company's current business strategies will be successfully implemented or that it will raise the necessary funds to allow it to continue its operations. Management believes that cost reductions already implemented will reduce losses in the future, and with the Company's existing working capital levels, anticipates that the Company will be able to continue its operations at least through the end of fiscal year 2005, assuming it is successful in consummating the transactions discussed above.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

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### NOTE 3 - PROPERTY AND EQUIPMENT

Property and equipment at March 31, 2004 and 2003 consists of the following:

|  | 2004        | 2003        |
|--|-------------|-------------|
|  | -----       | -----       |
| Laboratory manufacturing, and<br>warehouse equipment | \$3,140,250 | \$3,140,250 |
| Office equipment                                     | 32,981      | 32,981      |
| Furniture and fixtures                               | 51,781      | 51,781      |
| Land, building and improvements                      | 2,097,668   | 2,097,668   |
| Equipment under capital lease                        | 168,179     | 168,179     |
|  | -----       | -----       |
|  | 5,490,859   | 5,490,859   |
| Less: Accumulated depreciation<br>and amortization   | 1,400,609   | 1,100,306   |
|  | -----       | -----       |
|  | \$4,090,250 | \$4,390,553 |
|  | =====       | =====       |

Depreciation and amortization expense amounted to \$300,303, \$278,348 and \$249,338 for the years ended March 31, 2004, 2003 and 2002, respectively. The Company's obligations under capital leases were satisfied prior to March 31, 2003.

### NOTE 4 - INTANGIBLE ASSETS

Intangible assets at March 31, 2004 and 2003, consist of the following:

|                                | 2004       | 2003       |
|--------------------------------|------------|------------|
|                                | -----      | -----      |
| Patents                        | \$ 145,830 | \$ 129,134 |
| Trademarks                     | 8,120      | 8,120      |
|                                | -----      | -----      |
|                                | 153,950    | 137,254    |
| Less: Accumulated amortization | 51,754     | 32,412     |
|                                | -----      | -----      |
|                                | \$ 102,196 | \$ 104,842 |
|                                | =====      | =====      |

Amortization of intangible assets amounted to \$19,342, \$19,344 and \$4,390 for the years ended March 31, 2004, 2003 and 2002, respectively.

Aggregate amortization expense of intangible assets for the next five fiscal years is estimated to be as follows:

YEARS ENDING MARCH 31,

|      |           |
|------|-----------|
| 2005 | \$ 19,340 |
| 2006 | 19,340    |
| 2007 | 19,340    |
| 2008 | 19,340    |
| 2009 | 8,140     |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 5 - NOTE PAYABLE

On February 26, 2002, the Company closed a bank loan totaling \$375,000 to finance the purchase and installation of machinery and equipment. Interest is fixed at 5.70% per annum calculated on a 360-day year. The loan is due in 60 equal monthly installments of \$6,250 plus interest, with the first payment commencing on April 1, 2002, and is secured by the machinery and equipment purchased under this facility and a certificate of deposit in the amount of \$225,000 held as collateral. This certificate of deposit has been classified as noncurrent restricted cash. The note payable consists of the following at March 31:

|   | 2004       | 2003       |
|---|------------|------------|
|   | -----      | -----      |
| Bank note payable                               | \$ 225,000 | \$ 300,000 |
| Current portion                                 | (75,000)   | (75,000)   |
|   | -----      | -----      |
| Long-term portion, net of<br>current maturities | \$ 150,000 | \$ 225,000 |
|   | =====      | =====      |

Future principal maturities under this loan are as follows:

YEARS ENDING MARCH 31,

|      |            |
|------|------------|
| 2005 | \$ 75,000  |
| 2006 | 75,000     |
| 2007 | 75,000     |
|      | -----      |
|      | \$ 225,000 |

NOTE 6 - BOND FINANCING OFFERING

On September 2, 1999, the Company completed the issuance of tax exempt bonds by the New Jersey Economic Development Authority. The aggregate principal proceeds of the fifteen year term bonds were \$3,000,000. Interest on the bonds accrues at 7.75% per annum. The proceeds, net of offering costs of \$60,000, are being used by the Company to refinance the land and building it currently owns, and for the purchase of certain manufacturing equipment and related building improvements.

Offering costs in connection with the bond issuance totaled \$197,860, including the \$60,000 mentioned above which were paid from bond proceeds. Offering costs included underwriter fees equal to \$90,000 (three percent (3%) of the par amount of the bonds).

The bonds are collateralized by a first lien on the building, which includes property and equipment.

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Several restricted cash accounts are maintained in connection with the issuance of these bonds. These include amounts restricted for payment of bond principal and interest, for the refinancing of the land and building the Company currently owns, for the purchase of certain manufacturing equipment and related building improvements as well as the maintenance of a \$300,000 Debt Service Reserve.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 6 - BOND FINANCING OFFERING (CONTINUED)

All restricted accounts other than the \$300,000 Debt Service Reserve are expected to be expended within twelve months and are therefore categorized as current assets. Bond financing consisted of the following at March 31:

|   | 2004        | 2003        |
|---|-------------|-------------|
|   | -----       | -----       |
| EDA Bonds                                       | \$2,495,000 | \$2,635,000 |
| Current portion                                 | (150,000)   | (140,000)   |
|   | -----       | -----       |
| Long term portion, net of<br>current maturities | \$2,345,000 | \$2,495,000 |
|   | =====       | =====       |

FUTURE PRINCIPAL MATURITIES REQUIRED UNDER THE BOND AGREEMENT ARE AS FOLLOWS:

YEARS ENDING MARCH 31,

|            |              |
|------------|--------------|
| 2005       | \$ 150,000   |
| 2006       | 165,000      |
| 2007       | 175,000      |
| 2008       | 190,000      |
| 2009       | 205,000      |
| Thereafter | 1,610,000    |
|            | -----        |
|            | \$ 2,495,000 |
|            | =====        |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

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### NOTE 7 - JOINT VENTURE ACTIVITIES

In October 2000, the Company entered into a joint development and operating agreement with Elan Corporation, plc, and Elan International Services, Ltd. (together "Elan") to develop products using drug delivery technologies and expertise of both companies. This joint venture, Elite Research, Ltd. ("ERL"), a Bermuda corporation, was initially owned 80.1% by the Company and 19.9% by Elan. ERL was to fund its research through capital contributions from its partners based on the partners' respective ownership percentage. ERL subcontracted research and development efforts to the Company, Elan and others. It was anticipated that the Company would provide most of the formulation and development work. The Company had commenced work for three products. The joint venture terminated on September 30, 2002. For the years ended March 31, 2003 and 2002, the Company charged \$187,810 and \$601,057, respectively, to ERL which was reflected in product formulation fees. Intercompany profits and losses were eliminated.

ERL was initially capitalized with \$15,000,000 which included the issuance of 6,000 voting common shares, par value \$1.00 per share, and 6,000 non-voting convertible preferred shares, par value \$1.00 per share. All of the voting shares were held by the Company, with the non-voting convertible preferred shares held by both the Company and Elan, being split 3,612 shares and 2,388 shares, respectively. Elite's and Elan's respective ownership in ERL did not change during the term of the joint venture.

While the Company initially owned 80.1% of the outstanding capital stock (100% of the outstanding common stock) of ERL until September 30, 2002, Elan and its subsidiaries retained significant minority investor rights that were considered "participating rights" as defined in the Emerging Issues Task Force Consensus No. 96-16. Accordingly, the Company did not consolidate the financial statements of ERL until September 30, 2002 but instead accounted for its investment in ERL under the equity method of accounting until the Joint Venture was terminated, effective September 30, 2002.

For the year ended March 31, 2002 and the period beginning April 1, 2002 through September 30, 2002, ERL recognized net losses of \$633,642 and \$232,742, respectively, and the Company recognized 80.1% of these losses, or \$507,640 and \$186,379, respectively. The product formulation fees \$187,810 and \$601,057 earned by the Company for services rendered to ERL for the years ended March 31, 2003 and 2002, respectively, are included in ERL's expenses. During fiscal year 2001, ERL paid \$15,000,000 to Elan for a license providing ERL non-exclusive rights to use certain Elan in-process drug delivery technologies. The Elan technology rights acquired relate to very early stage technology that, in the opinion of management, have not reached technological feasibility and have no future alternative uses. Through the date of its termination, ERL completed in-vivo (pilot clinical trial) on the first product and began formulation and development of two additional products.

During fiscal year 2003, the Company consummated a termination agreement (the "Termination Agreement") with Elan to acquire all of Elan's interest in ERL. As further discussed in Note 10, the joint venture was terminated effective September 30, 2002.

ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 7 - JOINT VENTURE ACTIVITIES (CONTINUED)

Under the Termination Agreement, among other things, the Company acquired all proprietary, development and commercial rights for the worldwide markets for the products developed by ERL. In exchange for the assignment, ERL agreed to pay Elan a royalty on certain revenues that may be realized from the once-a-day Oxycodone product that has been developed by ERL. Effective October 1, 2002, the Company is solely responsible to fund ERL's product development.

The Company did not pay, nor did Elan receive any cash consideration under the Termination Agreement. Furthermore, the Company has the exclusive rights to the proprietary, development and commercial rights for the worldwide markets for two other products developed by ERL. The Company is not required to pay Elan royalties on revenues that may be realized from these products.

The Company accounted for this acquisition by consolidating ERL as a wholly-owned subsidiary as of September 30, 2002. As more specifically described in Note 10, Elan converted 773,000 shares of Series B Preferred Stock, according to their terms, into 52,089 shares of the Company's common stock. This resulted in an increase in common stock of \$521 and an increase in additional paid in capital of \$772,479. As a result, the Series B Preferred Stock was eliminated.

As further disclosed in Note 10, the acquisition resulted in the conversion of 13,756 shares of Series A Preferred Stock into 764,221 shares of Elite's common stock in accordance with their terms. The Company accounted for this conversion by increasing common stock in the amount of \$7,642 and by a corresponding increase in additional paid in capital of \$13,748,332. As a result, the Series A Preferred Stock was eliminated.

As a result of the Termination Agreement, ERL became a wholly-owned subsidiary of the Company as of September 30, 2002. Elan retained certain securities of Elite it had obtained in connection with the joint venture and transferred other such securities to a third-party, as further discussed in Note 10.

The following is a condensed balance sheet of ERL on September 30, 2002 (the date of acquisition):

CURRENT ASSETS

|              |          |
|--------------|----------|
| Cash         | \$ 1,084 |
|              | -----    |
| Total assets | \$ 1,084 |
|              | =====    |



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CURRENT LIABILITIES

|                       |           |
|-----------------------|-----------|
| Accounts payable      | \$ 84,597 |
|                       | -----     |
| Total liabilities     | 84,597    |
| Shareholders' deficit | (83,513)  |
|                       | -----     |
|                       | \$ 1,084  |
|                       | =====     |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 7 - JOINT VENTURE ACTIVITIES (CONTINUED)

The following are unaudited pro-forma consolidated results of operations for the years ended March 31, 2003 and 2002, assuming the acquisition was completed on April 1, 2001.

|   | YEAR ENDED MARCH 31, |                |
|---|----------------------|----------------|
|   | 2003                 | 2002           |
|   | -----                | -----          |
|   | (Unaudited)          | (Unaudited)    |
| Revenue   | \$ 442,500           | \$ 596,450     |
| Proforma net (loss) available to common shareholders                                | \$ (4,107,785)       | \$ (1,900,529) |
| Proforma net (loss) available to common shareholders per share -- basic and diluted | \$ (0.40)            | \$ (0.19)      |

Unaudited pro-forma data may not be indicative of the results that would have been obtained had these events actually occurred at the beginning of the periods presented, nor does it intend to be a projection of future results.

NOTE 8 - INCOME TAXES

The components of the provision for income taxes are as follows:

|          | YEAR ENDED MARCH 31, |       |       |
|----------|----------------------|-------|-------|
|          | 2004                 | 2003  | 2002  |
|          | -----                | ----- | ----- |
| Federal: |                      |       |       |
| Current  | \$ --                | \$ -- | \$ -- |
| Deferred | --                   | --    | --    |

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|          |          |        |          |
|----------|----------|--------|----------|
|          | -----    | -----  | -----    |
|          | --       | --     | --       |
|          | -----    | -----  | -----    |
| State:   |          |        |          |
| Current  | 1,000    | 400    | 2,430    |
| Deferred | --       | --     | --       |
|          | -----    | -----  | -----    |
|          | 1,000    | 400    | 2,430    |
|          | -----    | -----  | -----    |
|          | \$ 1,000 | \$ 400 | \$ 2,430 |
|          | =====    | =====  | =====    |

In the year ended March 31, 2001, the Company received approval for the sale of \$4,872,267 of New Jersey net operating losses under the Technology Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority (NJEDA). The total tax benefit approved for receipt by the Company during the year ended March 31, 2002 was \$368,343 of which \$222,211 and \$146,132 was received in 2002 and in 2003, respectively.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 8 - INCOME TAXES (CONTINUED)

During the year ended March 31, 2003, the Company received approval for the sale of an additional \$1,822,989 of New Jersey net-operating losses under the Technology Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority (NJEDA). The total tax benefit approved for receipt by the Company during the year ended March 31, 2003 was \$137,818, of which \$71,741 was received in November 2002. The remaining balance of \$66,077 was received in 2003.

During the year ended March 31, 2004, the Company received approval for the sale of an additional \$1,928,817 of New Jersey net-operating losses under the Technology Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority (NJEDA). The total tax benefit received during the year ended March 31, 2004 was \$151,027 and is recorded as other income in the accompanying financial statements.

The major components of deferred tax assets at March 31, 2004 and 2003 are as follows:

|                                   |              |              |
|-----------------------------------|--------------|--------------|
|                                   | 2004         | 2003         |
|                                   | -----        | -----        |
| Net operating loss carry forwards | \$ 6,736,336 | \$ 4,486,167 |
| Valuation allowance               | (6,736,336)  | (4,486,167)  |
|                                   | -----        | -----        |
|                                   | \$ --        | \$ --        |
|                                   | =====        | =====        |

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At March 31, 2004, a 100% valuation allowance is provided, as it is uncertain if the deferred tax assets will be utilized. The valuation allowance increased during 2004, 2003 and 2002 by \$2,250,169, \$1,357,792 and \$304,375, respectively.

At March 31, 2004, for federal income tax purposes, the Company has unused net operating loss carry forwards of approximately \$20,518,995 expiring in 2007 through 2015. For state tax purposes, the Company has \$11,011,302 of unused net operating losses, which are net of the \$9,539,503 of New Jersey net-operating losses sold, as discussed above.

### NOTE 9 - COMMITMENTS AND CONTINGENCIES

#### EMPLOYMENT AGREEMENTS

The Company had an employment agreement ("Employment Agreement") with its former President/CEO, Atul M. Mehta.

On June 3, 2003, Dr. Mehta resigned from all positions that he held with the Company, while reserving his rights under his Employment Agreement and under common law. On July 3, 2003, Dr. Mehta instituted litigation against Elite and one of its directors, in the Superior Court of New Jersey, for, among other things, allegedly breaching his Employment Agreement and for defamation, and claims that he is entitled to receive his salary through June 6, 2006.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

### NOTE 9 - COMMITMENTS AND CONTINGENCIES (CONTINUED)

#### Employment Agreements

The Company and Dr. Mehta settled their litigation subsequent to March 31, 2004 (See Note 13). The Company accrued \$400,000 for compensation owed to Dr. Mehta as of March 31, 2004, in accordance with the settlement agreement.

On July 23, 2003, the Company entered into an agreement with its new Chief Executive Officer, Bernard Berk. The initial terms of this agreement is three years. Pursuant to this agreement:

- Mr. Berk is entitled to receive a base salary of \$200,000 per annum, subject to increase to \$330,140 if and when the Company consummates a Strategic Transaction (as defined in the employment agreement);
- The Company confirmed its grant to Mr. Berk on June 3, 2003 of options to purchase 300,000 shares of the Company's common stock at \$2.01 per share. All of these options are vested.

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- The Company granted Mr. Berk options to purchase an additional 300,000 shares of its common stock, with an exercise price equal to \$2.15, the closing price of the Company's common stock on the date of grant. These options will vest solely upon consummation of a Strategic Transaction.
- Mr. Berk will be appointed as a director of the Company if he is serving as its Chief Executive Officer following the consummation of a Strategic Transaction.
- Mr. Berk will be entitled to receive severance in accordance with the employment agreement if he is terminated without cause or because of his death or permanent disability or if he terminates his employment for good reason or following a "change-of-control". The severance will be payable in accordance with the terms of his employment agreement.

### CONSULTING AGREEMENTS

The Company entered into one year consulting agreements with each of Saggi Capital Corp. and Bridge Ventures Inc. on November 4, 2003. The consultants' services will include, but not be limited to, advice with respect to overall strategic planning, financing opportunities, acquisition policy, commercial and investment banking relationships and stockholders matters. In consideration of each consultant's services, the Company agrees to pay it \$75,000 payable in monthly installments of \$6,250 and to issue to the consultant a warrant to purchase 100,000 shares of the Company's common stock. For the year ended March 31, 2004, consulting expenses under both agreements aggregated \$30,000 plus approximately \$470,000 attributable to the issuance of warrants.

On July 3, 2003, the Company entered into an agreement with Leerink Swann & Company to provide a Valuation and a Fairness Opinion in order for the Company to complete a proposed acquisition for which it received a non-refundable retainer fee of \$50,000. If and when the Board of Directors requests a Fairness Opinion, Leerink's compensation shall be \$50,000. For the year ended March 31, 2004, consulting expenses under this agreement amounted to the \$50,000 non-refundable retainer fee.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 9 - COMMITMENTS AND CONTINGENCIES (CONTINUED)

##### REFERRAL AGREEMENTS

On January 29, 2002, the Company entered into a Referral Agreement with a Director (Referring Party) whereby Elite will pay the Referring Party a fee based upon payments received by Elite from sales of products, development fees, licensing fees and royalties generated as a direct result of the Referring Party identifying customers for

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Elite. These amounts shall be reduced by the cost of goods sold directly incurred in the manufacturing or development of products as well as any direct expenses associated with these efforts. Elite will pay Referring Party a referral fee each year equal to:

| PERCENTAGE OF REFERRAL<br>BASE<br>---- | FROM<br>---- | TO<br>--     |
|--|--------------|--------------|
| 5%                                     | \$ 0         | \$ 1,000,000 |
| 4%                                     | 1,000,000    | 2,000,000    |
| 3%                                     | 2,000,000    | 3,000,000    |
| 2%                                     | 3,000,000    | 4,000,000    |
| 1%                                     | 4,000,000    | 5,000,000    |

No amounts had been earned through March 31, 2004.

On August 1, 1998, the Company entered into a consulting agreement (the "1998 Agreement") with a company owned by a Director for the purpose of providing management, marketing and financial consulting services for an unspecified term. Terms of the agreement provided for a nonrefundable monthly fee of \$2,000. This compensation was applied against amounts due pursuant to a business referral agreement entered into on April 8, 1997 (the "1997 Agreement") with the same party.

Terms of the 1997 Agreement provided for payments by the Company based upon a formula, as defined, for an unspecified term. On November 14, 2000, the Company amended its 1997 Agreement to provide certain consulting services for the period beginning November 1, 2000 through October 31, 2003. The Company previously advanced \$20,000 under the 1997 Agreement in addition to a payment of \$50,000 made during the year ended March 31, 2001. The 1997 Agreement called for 25 monthly installments of \$3,200 beginning on December 1, 2001.

Consulting expense under the 1997 and 1998 Agreements amounted to \$28,800, \$38,400 and \$12,800 for the years ended March 31, 2004, 2003 and 2002, respectively. The agreement terminated on November 30, 2003.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 9 - COMMITMENTS AND CONTINGENCIES (CONTINUED)

##### COLLABORATIVE AGREEMENTS

On December 18, 2003, the Company and Pivotal Development, L.L.C. entered into an agreement to develop a controlled release product utilizing Elite's proprietary drug delivery technology. The product is a generic equivalent to a drug losing patent exclusivity with addressable market revenues of approximately \$150 million per year. The agreement will also provide an option to develop a controlled release NDA product.

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Under the collaboration agreement, Pivotal Development will be responsible for taking the Elite formulation through clinical development and the FDA regulatory approval process. The partners will seek a license during the development cycle from a pharmaceutical company which has the resources to effectively market the product and share the cost of defining the product against any lawsuits.

Elite and Pivotal will bear costs in their respective areas of responsibility. In addition, Pivotal shall pay Elite \$750,000 upon attainment of certain milestones outlined in the agreement.

In June 2001, the Company entered into two separate and distinct development and license agreements with another pharmaceutical company ("partner"). The Company is developing two drug compounds for the partner in exchange for certain payments and royalties. The Company also reserves the right to manufacture the compounds. The Company received \$250,000 and \$300,000, respectively, on these two agreements, which were earned during the year ended March 31, 2002. The Company is currently proceeding with the development and formulation for both products as specified in the development agreements. During the years ended March 31, 2004 and 2003, the Company earned revenues of \$105,000 and \$85,000, respectively, for additional development and formulation for both products.

On September 13, 2002, the Company, entered into a manufacturing agreement with Ethypharm S.A. ("Ethypharm"). Under the terms of this agreement, the Company has initiated the manufacturing of a new prescription drug product for Ethypharm. The Company received an upfront manufacturing fee for the first phase of the technology transfer and billed an additional amount upon the completion of the first phase of manufacturing. The Company is entitled to receive additional fees in advance for the final phase of the manufacturing. In addition, if and when FDA approval is obtained and if requested by Ethypharm, the Company will manufacture commercial batches of the product on terms to be agreed upon. As of March 31, 2004, the Company billed and earned revenues of \$280,000 under this agreement, all of which was billed and earned during the year ended March 31, 2003, in accordance with the substantive milestone method of revenue recognition. Under this method, the milestone payments are considered to be payments received for the accomplishment of a discrete, substantive earnings event. Accordingly, the non-refundable milestone payments are recognized in full when the milestone is achieved. In addition to milestone payments, the Company billed and recognized \$75,000 in additional revenues as a result of the manufacturing and delivery of additional batches during the year ended March 31, 2003.

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 10 - STOCKHOLDERS' EQUITY (DEFICIT)

TREASURY STOCK TRANSACTIONS

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At a special meeting of the Company's Board of Directors held on June 27, 2002, the Board authorized the Company to purchase up to 100,000 shares of its common stock in the open market no later than December 31, 2002. As of March 31, 2003, the Company had purchased 100,000 shares of common stock for total consideration of \$306,841.

### PUBLIC OFFERINGS

In July 1998 the Company filed a registration statement on Form SB-2 under the Securities Act of 1933, as amended, for the purpose of registering securities previously sold to and held by various corporations and individuals. The Company did not receive any proceeds upon filing of this Form SB-2. The securities registered consisted of 3,725,000 shares of the Company's \$.01 par value common stock, including 1,525,000 redeemable common stock purchase warrants.

In March 2000, the Company filed a registration statement on Form SB-2 under the Securities Act of 1933, as amended, for the purpose of registering securities previously sold to and held by various corporations and individuals. The Company did not receive any proceeds upon filing of this Form SB-2. The securities registered consisted of 3,297,539 shares of the Company's \$.01 par value common stock, 2,022,537 underlying Class A and Class B common stock purchase warrants, and 317,250 Class A common stock purchase warrants.

### PRIVATE PLACEMENT OFFERINGS

In a private placement offering dated May 17, 1999, the Company raised \$4,462,500 from the sale of 12.75 units of its securities; each unit consisting of 100,000 shares of common stock of the Company and 50,000 warrants, each warrant entitling the holder to purchase one share of common stock at an exercise price of \$5.00 per share during the five year period commencing with the date of closing of the private placement (June 16, 1999). The price per unit was \$350,000. This resulted in the issuance of 1,275,000 shares of common stock and 637,500 warrants to purchase common stock, at an exercise price of \$5.00 per share.

In a private placement offering concluded in December 2003 the Company sold 1,645,000 shares of Common Stock for aggregate proceeds of \$3,290,000. It paid a cash commission of \$75,000 to the Placement Agent and issued to the agent and its associates five year warrants to purchase 50,000 shares of Common Stock at a price of \$2.00 per share. The Company granted to the purchasers and the Placement Agent piggyback registration rights.

### PREFERRED STOCK

As further discussed in Note 7, on October 16, 2000, Elite entered into an agreement (the "Joint Venture Agreement") with Elan International Services, Ltd. and Elan Corporation, plc. (together "Elan"), under which the parties formed a joint venture, Elite Research, Ltd. ("ERL"). Under the terms of the Joint Venture Agreement, 409,165 shares of the Company's common stock and 12,015 shares of a newly created Series A Convertible Exchangeable Preferred Stock ("Series A Preferred Stock") were issued to Elan for consideration of \$5,000,000 and \$12,015,000, respectively. Proceeds from the sale of the Series A Preferred Stock were used to fund the Company's 80.1% share of ERL, as further discussed in Note 7.

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## ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 10 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

##### PREFERRED STOCK (CONTINUED)

The Series A Preferred Stock accrued a dividend of 7% per annum, compounded annually and payable in shares of Series A Preferred Stock. Dividends accrued and compounded annually beginning on October 16, 2001. As of September 30, 2002 (the termination date of the Joint Venture), the Company had accrued dividends of \$1,740,973 on the Series A Preferred Stock. During the year ended March 31, 2003, the Company issued preferred stock to satisfy accrued dividends.

On October 17, 2000, the Company authorized 7,250,000 shares of newly created Series B Preferred Stock of which 4,806,000 was designated for issuance to Elan for a total consideration of \$4,806,000. These shares were issuable from time to time to fund the Company's 80.1% portion of capital contributions to ERL and for funding of the research and development activities for ERL.

The Series B Preferred Stock accrued a dividend of 7% per annum of the original issue price, compounded on each succeeding twelve month anniversary of the first issuance and payable solely by the issuance of additional shares of Series B Preferred Stock, at a price per share equal to the original issue price. Dividends were accrued and compounded commencing one year after issuance. As of September 30, 2002 (the termination date of the joint venture), the Company had accrued dividends of \$14,000 on the Series B Preferred Stock. During the year ended March 31, 2003, the Company issued preferred stock to satisfy accrued dividends.

During the fiscal year ended March 31, 2003, the Company made capital contributions to ERL in the amount of \$573,000. These contributions were financed by the proceeds from the issuance to Elan of 573,000 shares of Series B Preferred Stock. These contributions were in addition to a capital contribution in the amount of \$200,000 made by the Company to ERL during the fiscal year ended March 31, 2002.

##### JOINT-VENTURE TERMINATION

In addition to the issuance of shares as described above, on October 17, 2000 the Company issued to Elan 100,000 warrants to purchase the Company's common stock at an exercise price of \$18 per share. The warrants are exercisable at any time on or before October 17, 2005. Subject to a Termination Agreement between the Company and Elan dated September 30, 2002, the Company acquired Elan's 19.9% interest in ERL, and Elan transferred its warrants and its 12,015 shares of Series A Preferred Stock to a third party along with accrued dividends of 1,741 shares. On November 6, 2002, under a transfer and assignment among the Company, Elan and a third party purchaser, all 13,756 shares of Series A Preferred Stock have been converted, according to their terms, into 764,221 shares of the Company's common stock using the \$18 per share



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price. Elan retained 409,165 shares of the Company's common stock and 773,000 shares of Series B Preferred Stock, the latter of which was converted into 52,089 shares of the Company's common stock. Both of the Series A and Series B preferred stock were converted into the Company's common stock in accordance with their terms. The warrants remain unexercised at March 31, 2004.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 10 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

##### JOINT-VENTURE TERMINATION (CONTINUED)

For the period of one year after the issuance of the above shares of common stock, Elan and the third party purchaser have the right to require registration under the Securities Act of 1933, as amended ("the Securities Act") of all or part of these securities. All registration expenses would be borne by the requesting party. Elan and the third party purchaser also have the right to piggyback registration if at any time the Company proposes to register shares of its common stock under the Securities Act.

##### WARRANTS

To date, the Company has authorized the issuance of common stock purchase warrants, with terms of five to six years, to various corporations and individuals, in connection with the sale of securities, loan agreements and consulting agreements. Exercise prices range from \$2.00 to \$18.00 per warrant. The warrants expire at various times through October 17, 2005.

A summary of warrant activity for the fiscal years indicated below were as follows:

|  | 2004      | 2003        | 2002      |
|--|-----------|-------------|-----------|
|  | -----     | -----       | -----     |
| Beginning balance  | 733,752   | 2,669,477   | 2,983,928 |
| Warrants issued  | 200,000   | --          | --        |
| Warrants issued pursuant to<br>Placement Agent Agreement | 50,000    | 8,136       | 2,260     |
| Placement Agent Warrants Exercised                       | --        | (158,652)   | (24,408)  |
| Class C Warrants   | 1,723,237 | --          | --        |
| Warrants exercised or expired                            | (52,750)  | (1,829,957) | (298,179) |
|  | -----     | -----       | -----     |
| Ending balance   | 2,654,239 | 733,752     | 2,669,477 |
|  | =====     | =====       | =====     |

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### CLASS A WARRANT EXCHANGE OFFER

On October 23, 2002, the Company entered into a Settlement Agreement with various parties in order to end a Consent Solicitation and various litigation initiated by the Company. The Agreement provided, among other things, an agreement to commence an exchange offer (the "Exchange Offer") whereby holders of the Company's Class A Warrants which expired on November 30, 2002 (the "Old Warrants") had the opportunity to exchange those warrants for new warrants (the "Class C Warrants") upon payment to the Company of \$0.10 per share of common stock issuable upon the exercise of the old warrants. In September 2003 the Company issued Class C Warrants to the record holders as of November 30, 2002 of the Old Warrants without requiring any cash payment.

Each Class C Warrant is exercisable for the same number of shares of common stock as the Old Warrants at an exercise price of \$5.00 per share, and expires on November 30, 2005. The Class C Warrants are not transferable except pursuant to operation of law.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

#### NOTE 10 - STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)

##### CLASS A WARRANT EXCHANGE OFFER (CONTINUED)

During the year ending March 31, 2003, the Company expensed \$242,338 relating to the Exchange Offer, which represents the fair value of the Class C Warrants. The per share weighted-average fair value of each warrant on the date of grant was \$1.10 using the Black-Scholes option pricing model with the following weighted-average assumptions: no dividend yield; expected volatility of 73.77%; risk-free interest rate of 2.88%; and expected lives of 3 years. The elimination of the \$0.10 per share fee resulted in an additional charge of \$172,324 during the year ended March 31, 2004.

For the year ended March 31, 2003 the Company incurred legal fees and other costs amounting to approximately \$100,000, in connection with the Exchange Offer, which has been charged to additional paid-in capital.

#### NOTE 11 - STOCK OPTION PLANS

Under various plans, the Company may grant stock options to officers, selected employees, as well as members of the board of directors and advisory board members. All options have generally been granted at a price equal to or greater than the fair market value of the Company's common stock at the date of grant. Generally, options are granted with a vesting period of up to three years and expire ten years from the date of grant. Transactions under the various stock option and

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incentive plans for the years indicated were as follows:

|                                  | 2004      |                                 | 2003      |                                 | 2002      |                                 |
|----------------------------------|-----------|---------------------------------|-----------|---------------------------------|-----------|---------------------------------|
|                                  | OPTIONS   | AVERAGE WEIGHTED EXERCISE PRICE | OPTIONS   | AVERAGE WEIGHTED EXERCISE PRICE | OPTIONS   | AVERAGE WEIGHTED EXERCISE PRICE |
| Outstanding at beginning of year | 2,266,850 | \$5.74                          | 2,056,850 | \$5.82                          | 2,009,064 | \$5.64                          |
| Granted                          | 1,024,000 | 2.23                            | 210,000   | 5.00                            | 113,000   | 9.22                            |
| Exercised                        | (15,000)  | 2.00                            | --        | --                              | (20,000)  | 6.00                            |
| Expired                          | (858,800) | 7.38                            | --        | --                              | (25,000)  | 7.80                            |
| Purchased for retirement         | --        | --                              | --        | --                              | (20,214)  | 4.00                            |
| Outstanding at end of year       | 2,417,050 | \$3.70                          | 2,266,850 | \$5.74                          | 2,056,850 | \$5.82                          |

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ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

NOTE 11 - STOCK OPTION PLANS (CONTINUED)

The following table summarizes information about stock options outstanding at March 31, 2004:

| RANGE OF EXERCISE PRICE | Options OUTSTANDING | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS) | WEIGHTED-AVERAGE EXERCISE PRICE | OPTIONS EXERCISABLE | WEIGHTED AVERAGE EXERCISABLE PRICE |
|-------------------------|---------------------|---|---------------------------------|---------------------|------------------------------------|
| \$1.00 - \$2.00         | 503,750             | 1.40  | \$ 1.70                         | 503,750             | \$ 1.70                            |
| 2.01 - 4.00             | 1,209,000           | 5.47  | 2.20                            | 810,000             | 2.20                               |
| 4.01 - 6.00             | 311,000             | 8.15  | 5.55                            | 156,000             | 5.55                               |
| 6.01 - 8.00             | 60,300              | 6.75  | 6.50                            | 60,300              | 6.50                               |
| 8.01 - 10.00            | 333,000             | 6.27  | 10.00                           | 122,000             | 10.00                              |
| \$1.00 - 10.00          | 2,417,050           | 5.11  | \$ 3.10                         | 1,652,080           | \$ 3.10                            |

The per share weighted-average fair value of each option granted during fiscal 2004, 2003 and 2002 ranged from \$1.03 to \$2.68, \$1.28, and \$8.38, respectively, on the date of grant using the Black-Scholes options pricing model with the following weighted-average assumptions; no dividend yield; expected volatility ranging from 75.47% to 77.97%, 75.40%, and 76.69% for fiscal years 2004, 2003, and 2002, respectively; risk-free interest rate of 4.0% in 2004, 4.0% in 2003 and rates ranging from 4.55% to 4.875% in 2002, and expected lives

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ranging from five to ten years.

### NOTE 12 - MAJOR CUSTOMERS

For the years ended March 31, 2004, 2003, 2002 revenues from major customers are as follows:

|            | 2004   | 2003   | 2002   |
|------------|--------|--------|--------|
|            | -----  | -----  | -----  |
| Customer A | --     | 29.79% | 50.19% |
| Customer B | --     | 56.32% | --     |
| Customer C | 40.70% | 13.49% | --     |
| Customer D | 59.30% | --     | --     |

Customer A represents ERL, a joint-venture until September 30, 2002, when it became a wholly-owned subsidiary of the Company, as further discussed in Note 7. Its revenues after September 30, 2002, are eliminated in consolidation.

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### ELITE PHARMACEUTICALS, INC. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

MARCH 31, 2004, 2003 AND 2002

### NOTE 13 - SUBSEQUENT EVENTS

On April 21, 2004, the Company settled the litigation between Dr. Atul Mehta, its former president and chief executive officer of the Company. Under the settlement agreement, Dr. Mehta relinquished any rights to the Company's patents and intellectual properties and agreed to certain non-disclosure and certain limited non-competition covenants. The Company agreed to pay Dr. Mehta \$400,000 and certain expense reimbursements in accordance with the settlement agreement, and received a short term option for the Company or its designees to acquire all of the shares of the common stock of the Company held by Dr. Mehta and his affiliates at \$2.00 per share. The Company paid \$100,000 into escrow which will be released to Dr. Mehta if the Company option is not exercised within 90 days. As part of the settlement, the Company extended expiration dates of certain options to purchase 770,000 shares of Common Stock held by Dr. Mehta and also provided him with certain "piggyback" registration rights with respect to shares underlying his options.

On May 10, 2004, Elite Labs entered into an agreement with Purdue Pharma L.P. ("Purdue") through which Purdue was granted the exclusive right to evaluate certain abuse resistance drug formulation technology of the Company and an exclusive option to negotiate a license to develop and commercialize oxycodone products under the Company's technology. The Company's proprietary abuse resistance technology is designed to discourage and reduce abuse of narcotic analgesic medications by making the products more difficult to abuse when crushed, damaged or otherwise manipulated.

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On May 14, 2004, the Company's Board of Directors appointed Bernard Berk, its Chief Executive Officer and President, to the additional position of Chairman of the Board of Directors.

On June 22, 2004 the Company's stockholders approved the 2004 Stock Option Plan providing for grants of incentive and nonqualified stock options with respect to 1,500,000 shares including shares which are to be subject to options to be granted to employees in replacement of outstanding options held by them. The stockholders also ratified the amendments of terms of outstanding options and warrants including the repricing of options with respect to 420,000 shares which will result in a significant charge to earnings. A proposal to amend the Certificate of Incorporation of the Company to increase the authorized 25,000,000 shares of Common Stock to 65,000,000 shares of Common Stock and 5,000,000 shares of Preferred stock is to be considered at the adjourned meeting scheduled to be held on July 19, 2004.

Elite Labs is currently negotiating an agreement with a financial institution to finance the purchase of certain machinery and equipment and to recast the outstanding balance due to a bank in the approximate amount of \$212,000. Under the terms of the proposed agreement, Elite Labs is to borrow \$612,000 payable in 36 monthly installments of \$20,917, including principal plus interest at 14% per annum. The proposed agreement is to provide that (i) the loan will be secured by two pieces of equipment and the guaranty of the Company, (ii) restricted cash currently held as collateral under the note payable in the amount of \$225,000 is to be released to the lender, of which \$125,500 is to be utilized to prepay the first six monthly payments under the loan and (iii) the balance is to be held as a security deposit which is to be released if the Company raises certain proceeds from the sale of its securities or other licensing fees. No assurance can be given that the proposed agreement will be executed or if the agreement is executed that the agreement will provide the foregoing terms.

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### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

##### ITEM 13. Other Expenses of Issuance and Distribution

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

|                                    | AMOUNT<br>TO BE PAID*<br>----- |
|------------------------------------|--------------------------------|
| SEC Registration Fee .....         | \$ 1,413.68                    |
| Legal Fees and Expenses .....      | \$ *                           |
| Accounting Fees and Expenses ..... | \$ *                           |
| Printing Expenses .....            | \$ *                           |
| Miscellaneous .....                | \$ *                           |
| Total .....                        | \$ *                           |

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\* To be provided by amendment

### ITEM 14. 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 correspondingly eliminated or limited, without further stockholder action.

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

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

### ITEM 15. Recent Sales Of Unregistered Securities

In December 2002 the Company issued its Class C Warrants in exchange for all the outstanding Class A Warrants. The Class C Warrants were the same as the Class A Warrants except they are nontransferable except by law, contain an exercise price of \$5.00 per share and expire November 30, 2005. The Company also agreed to the amendment of its outstanding Class B Warrants to provide the same terms as the Class C Warrants

The Company completed in December 2003 a private placement of 1,645,000 shares of its Common Stock at \$2.00 per share. In connection with the offering, the Company paid a cash commission of \$75,000 to First Montauk Group Inc., as Placement Agent and issued to the agent a five year warrant to purchase 50,000 shares of Company's common stock at a price of \$2.00 per share. Legal fees approximating \$36,000 were also incurred in connection with this private placement. Pursuant to its agreement with the purchasers, the Company at its expense registered under the Act for reoffering the shares issued and shares which may be acquired upon exercise of the warrants.

The Company in October 2004 issued its Series A Preferred Shares and the Short Term and Long Term Warrants in a private placement effected in three

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tranches, the first involving the sale of 379,122 Series A Preferred Shares at a price of \$12.30 per share convertible into 3,791,220 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 3,791,220 shares at a price of \$1.54 per share, the second tranche involving the sale of 119,286 Series A Preferred Shares at a price of \$14.00 per share convertible into 1,192,860 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 1,192,860 shares of Common Stock at a price of \$1.75 per share, and the third involving the sale of 18,150 Series A Preferred Shares at a price of \$14.70 per share convertible into 181,500 shares of Common Stock and the issuance of Short Term and Long Term Warrants to purchase an aggregate of 181,500 shares of Common Stock at a price of \$1.84 per share. The Company paid Indigo Securities Inc., the Placement Agent, and selected dealers cash commissions aggregating \$633,510.70 and issued to them Long Term Warrants to purchase 357,495 shares of Common Stock at a price of \$1.23 per share, 119,286 shares of Common Stock at a price of \$1.40 per share and 18,150 shares of Common Stock at a price of \$1.47 per share. Pursuant to its agreement with the purchasers in the private placement the Company registered at its expense under the Securities Act of 1933, as amended, for reoffering the shares of Common Stock acquired upon conversion of the Series A Preferred Shares and shares of Common Stock which may be acquired upon exercise of the Long Term Warrants and Short Term Warrants.

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On June 3, 2004, the Company granted five year warrants to purchase 100,000 shares of Common Stock at a price of \$2.50 per share to D. H. Blair Investment Banking Corp. as consideration for financial consulting services.

On July 6, 2004, the Company issued 26,500 shares of Common Stock to CEOcast, Inc. in partial consideration for rendering during a nine-month period investor relation consulting services and agreed to provide the holder with "piggy-back" registration rights.

On July 8, 2004, the Company issued three year warrants to purchase an aggregate of 50,000 shares of Common Stock at a price of \$4.20 per share to designees of a lender in connection with the refinancing of the outstanding equipment loan, with the provision that warrants to purchase 15,000 shares will be cancelled in the event of the repayment in full of the new loan within nine months, in which event the Company is to pay \$10,000 to the lender as a prepayment penalty.

On July 20, 2004, the Company issued to Mr. Jason Lyons five-year warrants to purchase 50,000 shares of Common Stock at a price of \$3.00 per share in consideration of his agreement to render financial consulting services. Ratification of the issuance of the warrants will be sought at the Company's next Annual Meeting of Stockholders.

CEOcast, Inc. and each of the warrant holders has agreed that no transfer of the shares, warrants or any shares acquired upon exercise of the warrants will be made unless such transfer is registered under the Act or exempt from registration under the Act.

In the opinion of the Company, the issuance of the foregoing securities were exempt from registration under the Act by virtue of Section 4(2) of the Act, except for the exchange of Class C Warrants for Class A Warrants which was exempt from registration under the Act by virtue of Section 3(a)(9) of the Act.

ITEM 16. Exhibits and Financial Statement Schedule

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### (a) Exhibits

- 4.1 Certificate of Incorporation, together with all amendments thereto, incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-4, Registration No. 333-101686 filed with the Commission on December 6, 2002 and Exhibit 3.1 to Registrant's Current Report on Form 8-K\*.
- 4.1(a) Certificate of Designation of Series A Preferred Stock, incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K\*
- 4.2 By-laws of Elite, as amended. Incorporated by reference to Exhibit 3.1 to Elite's Registration Statement on Form SB-2, Registration No. 333-90633, made effective on February 28, 2000.
- 4.3 Form of Common Stock certificate, incorporated by reference to Exhibit 4.1 to Elite's Registration Statement on Form SB-2, Registration No. 333-90633, made effective on February 28, 2000.
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- 4.4 Form of Class B Warrant, incorporated by reference to Exhibit 4.3 to Registrant's Annual Report on Form 10-K for the year ended March 31, 2004.
- 4.5 Form of Class C Warrant, incorporated by reference to Exhibit 4.2 to Registrant's Annual Report on Form 10-K for the year ended March 31, 2004.
- 4.6 2004 Stock Option Plan, incorporated by reference to Schedule 14A with respect to Annual Meeting of Stockholders held on June 22, 2004.
- 4.7 Amendment to Stock Option Plan approved by Stockholders on April 15, 2005.
- 5.1 Opinion of Reitler Brown & Rosenblatt LLC.\*\*\*
- 6.1 Employment Agreement dated as of July 23, 2003 between Bernard Berk and the Registrant incorporated by reference to Exhibit 10.6 to Report on Form 10-Q for three months ended June 30, 2003 (the "June 30, 2003 10Q Report")
- 6.2(a) Option Agreement between Bernard Berk and the Company dated as of July 23, 2003 incorporated by reference to Exhibit 10.7 to the June 30, 2003 10Q Report.
- 6.2(b) Option Agreement between Bernard Berk and the Company dated as of July 23, 2003 incorporated by reference to Exhibit 10.8 to the June 30, 2003 10Q Report.
- 6.3 Product Development, Manufacturing and Distribution Agreement dated March 30, 2005.\*\*
- 6.4 Engagement letter dated February 26, 1998 between Gittelman & Co. P.C. and the Company incorporated by reference to Exhibit 6.4 to Registrant's Annual Report on Form 10-K for the year ended March 31, 2004.
- 21.0 Subsidiaries of the Registrant.



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- 23.1 Consent of Miller, Ellin & Company LLP.
- 23.2 Consent of KPMG.\*\*\*
- 23.3 Consent of Reitler Brown & Rosenblatt LLC (included in Exhibit 5.1 above)
- 24.1 Power of Attorney (included on Signature page).

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

\*\* Registrant has requested confidential treatment with respect to this Exhibit. In the event that the Securities and Exchange Commission should deny such request in whole or in part, such exhibit or the relevant portions thereof shall be filed by amendment.

\*\*\* To be filed by amendment

(b) Schedules to Financial Statements None

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;

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

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

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

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be

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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

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

(c) (1)

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

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

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### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has

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duly caused this registration statement to be signed, in the Borough of Northvale, State of New Jersey, on April 26, 2005.

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: April 26, 2005                   /s/ Bernard Berk  
-----  
Bernard Berk  
Chief Executive Officer and  
Chairman of the Board of Directors

Dated: April 26, 2005                   /s/ Mark I. Gittleman  
-----  
Mark I. Gittelman  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: April     , 2005                   -----  
Edward Neugeboren  
Director

Dated: April 26, 2005                   /s/ Barry Dash  
-----  
Barry Dash  
Director

Dated: April 26, 2005                   /s/ Melvin Van Woert  
-----

Director