BUILDING FOR THE FUTURE

HI-TECH PHARMACAL CO., INC.

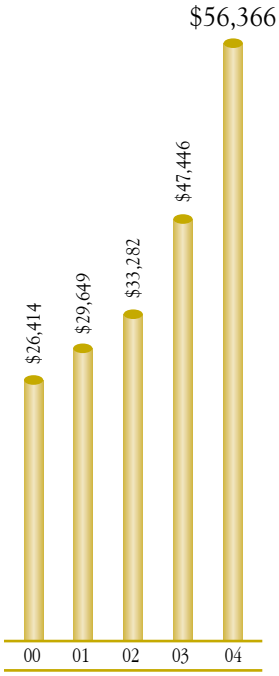
2004 ANNUAL REPORT

Our Mission:
Develop, manufacture and distribute high quality liquid, sterile and semi-solid generic pharmaceuticals at the most economical cost to the consumer.

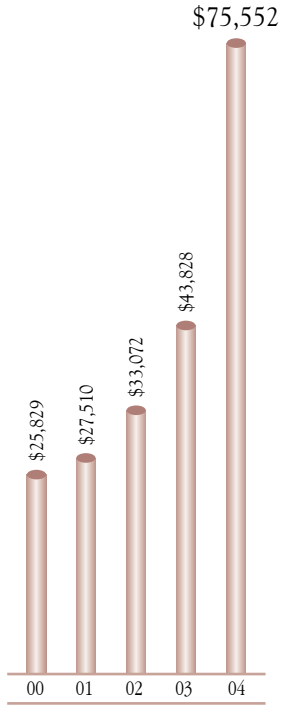
Help people with diabetes live healthier lives by providing pharmaceutical, nutritional and cosmetic products especially formulated to meet their needs.

To maintain the highest ethical standards while providing increased revenues, profits and shareholder value.

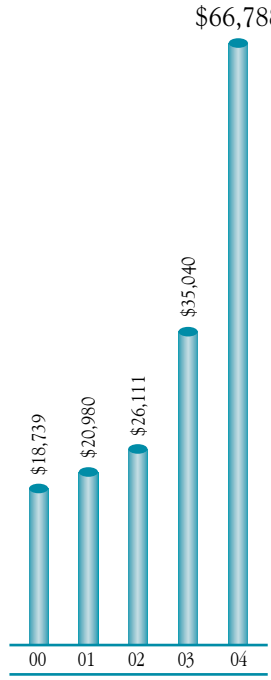
HI-TECH PHARMACAL RANKED NUMBER 90 ON FORTUNE MAGAZINE'S LIST OF THE NATION'S ONE HUNDRED FASTEST GROWING COMPANIES



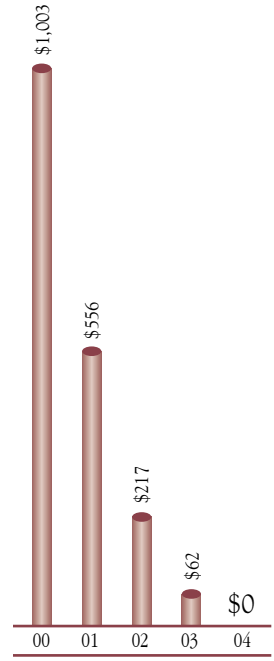
Sales
($ in thousands)



Total Assets
($ in thousands)



Stockholder's Equity
($ in thousands)



Total Debt
($ in thousands)

HI-TECH PHARMACAL ANNOUNCED RECORD SALES AND NET INCOME

Dear Shareholders:

We are pleased to announce another successful year for Hi-Tech Pharmacal. Last year our sales and income reached record highs. We launched five new products, received two final Abbreviated New Drug Application (ANDA) approvals and one tentative approval, increased our market share for several key prescription generic products, invested more aggressively in our research and development pipeline and expanded our facilities.

For the year ended April 30, 2004, the Company reported net sales of $56.4 million, an increase of 19% from net sales of $47.4 million for the year ended April 30, 2003. Net income increased 15% to $6.6 million or $0.74 per fully diluted share for the year ended April 30, 2004 compared to $5.7 million, or $0.74 per share, for the same period ended April 30, 2003.

Generic Pharmaceuticals

Generic pharmaceutical product sales grew by 23%, reaching a record of $50.3 million. Our core prescription products have continued their growth and we successfully launched our Urea 40% cream and lotion line which became a significant new product, gaining widespread distribution among leading chains and wholesalers. We continued our strong business with leading pharmacy chains, wholesalers, distributors and group purchasing organizations, while increasing our penetration of the managed care and hospital sectors. We are proud of the high quality products we produce and the service we provide to our customers. We enter our new fiscal year with strong relationships with our trading partners.

Research and Development

In fiscal 2004, our R&D spending increased 82% compared to the previous year, reaching $3.8 million. As a result, we have twenty products in active development, targeting brand sales of over $2.0 billion, including sterile ophthalmic products, oral solutions and suspensions and nasal sprays. We are working on a number of challenging projects requiring bioequivalence studies, and in some cases, clinical studies. These projects require higher investment that could potentially translate into significant rewards.

Last year we filed an ANDA submission for Levofloxacin ophthalmic solution under Paragraph IV certification. We are confident that we were first to file on this product, and we can potentially receive 180 days of marketing exclusivity upon successful completion of the patent litigation and FDA approval.

In order to enhance our new product development effort and bring talent to the Company, we hired Dr. Polireddy Dondeti as Sr. Director for Research & Development. Dr. Dondeti's years of experience in the liquid generic industry will enable him to provide the Company with the necessary leadership in an ever complex and competitive environment.

Our strategy for long term growth will continue to focus on liquid and semi-solid generic pharmaceuticals. There are tremendous market opportunities in specialty areas, such as ophthalmics and nasal sprays. In our search for less competitive and higher margin products, we intend to leverage our expertise in liquid and sterile manufacturing to focus on developing products with high barriers to entry and potentially limited competition.

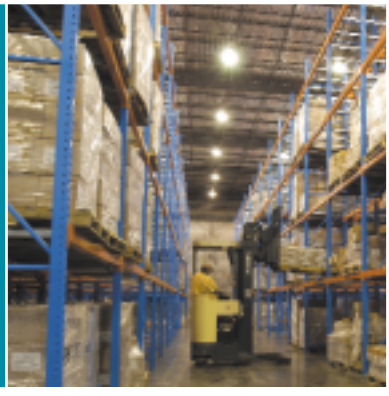
Branded Products

Health Care Products

The Health Care Products ("HCP") division had net sales of $6.1 million and $6.6 million for the year ended April 30, 2004 and 2003, respectively, a decrease of 9%. The decrease is primarily the result of previously exported Health Care products which were improperly returned to the domestic market during the first half of the fiscal year. We have taken the necessary steps to minimize the impact of this diversion and believe that its consequences are behind us. The Company's flagship Diabetic Tussin® line remains the leading sugar free cough syrup in the United States and was ranked by the Health & Beauty Aid Report as the sixth largest selling cough syrup in the general cough & cold category. To extend this brand, we plan to introduce a new Diabetic Tussin® Nite Time formula.

Another area of focus for HCP has been skin and foot care. HCP's fastest growing line is DiabetiDerm which grew by 46% primarily due to the strong sales of the DiabetiDerm Foot cream with L-Arginine. We plan to add new products targeting specific dermatological and podiatric conditions in people with diabetes. We also plan to expand our marketing reach through an aggressive telemarketing campaign and through promotion directly to physicians, pharmacists and diabetic educators.

We firmly believe that the diabetes market place continues to present vast opportunities for us, and we intend to stay focused on growing our existing brands.



IN FISCAL 2004, OUR R&D SPENDING INCREASED 82% COMPARED TO THE PREVIOUS YEAR, REACHING $3.8 MILLION

THE MARKET FOR LIQUID FORMULATIONS HAS BEEN EXPANDING AND WILL CONTINUE TO GROW DUE TO THE EXPANDING GERIATRIC POPULATION WHICH EXPERIENCES DIFFICULTIES WITH SWALLOWING TABLETS, CREATING ADDITIONAL DEMAND FOR ORAL SOLUTIONS AND SUSPENSIONS.

Naprelan® Acquisition

In addition to growing the line of over-the-counter brands, our growth strategy also includes building a portfolio of branded prescription products. In line with this strategy, we recently acquired Naprelan® from Elan Pharmaceuticals. Naprelan® is a non-steroidal anti-inflammatory agent that has been specifically formulated using Elan's patented IPDAS™ (Intestinal Protective Drug Absorption System) technology. Naprelan® offers the convenience of once-daily dosing and is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing, spondylitis, tendonitis, bursitis, acute gout, primary dysmenorrhea, and mild to moderate pain. The underlying extended release technology used in the formulation of Naprelan® is patent protected until 2014 and the product has only one generic competitor. We are excited about this acquisition and are actively seeking a marketing partner to maximize its potential.

Manufacturing Facilities

Manufacturing infrastructure plays a crucial role in the success of our business and we take pride in our facilities. We have continued to expand and modernize our facilities and equipment by adding two non-sterile filling lines, including a nasal spray line, and 12,500 square feet of warehouse space. We are currently expanding our narcotic manufacturing capacity, as well as our sterile packaging capability. We are confident that investing in high output and state of the art equipment will lead the Company to greater productivity and higher gross profit margins.

Senior Management

In May 2004, we announced the retirement of Mr. Arthur Goldberg, Vice President, Finance and Chief Financial Officer. Mr. Goldberg was with Hi-Tech for over 12 years, and we greatly appreciate his contribution to the Company's growth over these years. Hi-Tech also announced the appointment of Mr. William Peters as Vice President and Chief Financial Officer of the Company. He joined the Company in September 2003 as Vice President, Corporate Development and has demonstrated broad knowledge of corporate finance and an understanding of the issues, opportunities and challenges facing the pharmaceutical industry. I am confident that his background and experience will help us to further grow the business and build shareholder value.

Building Blocks for Future Growth

I strongly believe that our Company has all the necessary building blocks in place to ensure its successful and sustainable growth in the future.

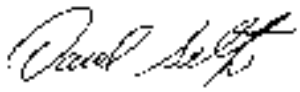
The market for liquid formulations has been expanding and will continue to grow due to the expanding geriatric population which experiences difficulties with swallowing tablets, creating additional demand for oral solutions and suspensions. Another significant factor driving the growth of the liquid market is patent expirations for nasal sprays and ophthalmic products.

As one of the leading manufacturers of liquid pharmaceutical products, Hi-Tech is very well positioned to capitalize on these opportunities. As a result of dramatically increased research & development spending, we have built an exciting pipeline including several products that we hope to be first to file. Our strong balance sheet creates additional opportunities for us to enhance our business through licensing agreements and acquisitions.

We are very confident in our business model and recently announced the authorization by our Board of Directors to repurchase up to $10 million of the Company's common stock, in addition to the $2 million, authorized for repurchase in Fiscal 2004, which was recently completed.

Behind our Company's growth and achievements are dedicated employees, and we are committed to investing in one of our most important resources – our people. I am excited about our Company's prospects for the future and eager to work with our management team to increase stockholder value.

I sincerely thank you for your continued confidence and support.



David Seltzer
President and Chief Executive Officer

U.S. Securities and Exchange Commission

Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For fiscal year ended April 30, 2004

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

Commission File Number 0-20424

Hi-Tech Pharmacal Co., Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**11-2638720**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

369 Bayview Avenue, Amityville, New York 11701
(Address of principal executive offices, including zip code)

(631) 789-8228
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 par value
(Title of Class)

Name of each exchange on which registered: NASDAQ

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act): Yes ☒ No ☐

The registrant's revenues for its most recent fiscal year ended April 30, 2004 were $56,366,000.

The aggregate market value of the voting stock held by non-affiliates of the registrant as of October 31, 2003, the last business day of the registrant's most recently completed second fiscal quarter, was $123,385,000, based upon the closing price of the common stock

on that date, as reported by NASDAQ. Shares of common stock known to be owned by directors and executive officers of the registrant subject to Section 16 of the Securities Exchange Act of 1934 are not included in the computation. No determination has been made that such persons are “affiliates” within the meaning of Rule 12b-2 under the Exchange Act.

The number of shares of common stock of the registrant outstanding as of July 12, 2004 was 8,388,552.

DOCUMENTS INCORPORATED BY REFERENCE: None

HI-TECH PHARMACAL CO., INC.
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FOR THE YEAR ENDED APRIL 30, 2004

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K and certain information incorporated herein by reference contains forward-looking statements within the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report on Form 10-K, other than statements that are purely historical, are forward-looking statements. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates" and similar expressions also identify forward-looking statements. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, without limitation, statements regarding operating results, product development, marketing initiatives, business plans and anticipated trends. The forward-looking statements in this Annual Report on Form 10-K are based on information available to the Company on the date hereof. The Company assumes no obligation to update any forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS.

General

Hi-Tech Pharmacal Co., Inc. ("Hi-Tech", the "Company", which may be referred to as "we", "us" or "our") a Delaware corporation, incorporated in April 1983, is a growing specialty manufacturer and marketer of prescription, over-the-counter and nutritional products.

We develop, manufacture and market generic and branded products. Most of our generic products are prescription items and include oral solutions and suspensions, as well as topical creams and ointments. We also specialize in the manufacture of products in our state of the art sterile facility capable of producing liquid ophthalmic, otic and inhalation products. Our Health Care Products Division markets a line of branded products primarily for people with diabetes, including Diabetic Tussin®, DiabetiDerm®, DiabetiSweet®, DiabetiTrim® and Multi-betic®.

Our customers include chain drug stores, drug wholesalers, managed care purchasing organizations, certain Federal government agencies, generic distributors, mass merchandisers, and mail-order pharmacies. Some of our key customers include Walgreens, McKesson Corporation, Cardinal Health, Inc., CVS, AmeriSourceBergen Corporation and Wal-Mart. We produce a wide range of products for various disease states, including asthma, bronchial disorders, dermatological disorders, allergies, pain, stomach, oral care, neurological disorders and other conditions.

We currently market more than 100 products to over 100 customers. For the fiscal year ended April 30, 2004 sales of generic pharmaceuticals represented 89% of total sales and branded products represented 11% of total sales.

Recent Approvals and Product Launches

We have 29 prescription products approved for marketing by the Food and Drug Administration (the "FDA"). In addition, we have six products submitted to the FDA and pending approval, and approximately 20 products in various stages of development.

We received Abbreviated New Drug Application ("ANDA") approvals for the following products in fiscal 2004:

- Lidocaine 2.5% and Prilocaine 2.5% topical cream (the generic equivalent of Emla® from AstraZeneca), indicated as a topical anesthetic for local analgesia used in dermatological procedures in adults and children in hospitals and doctor's offices
- Midazolam HCL Syrup 2mg (base)/ml (the generic equivalent of midazolam HCL Syrup from Roxane), indicated for use in pediatric patients for sedation, anxiolysis and amnesia prior to diagnostic, therapeutic or endoscopic procedures or before induction of anesthesia

Additionally, we received tentative ANDA approval for the following product in fiscal 2004 and, in May 2004, received final approval upon patent expiration of the brand product:

- Ofloxacin Ophthalmic Solution USP, 0.3% (the generic equivalent of Ocuflox® from Allergan), indicated for the treatment of bacterial infections

In our fiscal 2004, we launched the following products:

- Urea 40% Cream and Lotion (the generic equivalent of Carmol 40® from Bradley and Vanamide® from Dermik)
- Prednisolone Sodium Phosphate Oral Solution (the generic equivalent of Pediapred® from Celltech)
- Prednisolone Syrup (the generic equivalent of Prelone® from Muro)
- Lidocaine/Prilocaine Topical Cream (the generic equivalent of Emla® from AstraZeneca)
- Promethazine Plain (the generic equivalent of Phenergan® from Wyeth)

Top Products

Our top 5 selling generic products in fiscal 2004 were:

- Urea 40% Cream and Lotion (the generic equivalent of Carmol 40® from Bradley and Vanamide™ from Dermik)
- Sulfamethoxazole & Trimethoprim (the generic equivalent of Bactrim® from Roche)
- Promethazine products including Plain, Codeine and Dextromethorphan varieties (the generic equivalent of Phenergan® from Wyeth)
- Albuterol Solution for Inhalation and Syrup (the generic equivalent of Proventil® from Schering)
- Lactulose Solution (various)

Health Care Products Division

Our Health Care Products Division ("HCP") is a leading marketer of branded products that include over-the-counter, nutritional, and prescription products, primarily for people with diabetes. The Company's leading brand, Diabetic Tussin®, is available in several formulations, including DM, Maximum Strength, EX, Allergy and Cough Drops. HCP also markets dermatological products for people with diabetes under the brand name

DiabetiDerm®. This is our fastest growing brand and includes DiabetiDerm® Foot Rejuvenating Cream, DiabetiDerm® Cream and DiabetiDerm® Lotion. HCP also markets Multi-betic®, a daily multi-vitamin and mineral supplement formula, DiabetiSweet®, a unique sugar substitute which is aspartame free and heat stable for baking and cooking. In 2004, HCP introduced, through a licensing agreement with Medifast, DiabetiTrim® shake, a formula that provides the essential nutrients to assist diabetics to stay fit and maintain a healthy lifestyle. HCP expanded the DiabetiTrim® line with the introduction of DiabetiTrim® nutritional bars.

The Company also markets Diabetic Tussin-C®, a prescription formulation for severe coughs, through a marketing arrangement with Syncom Pharmaceuticals.

Growth Strategy

Management believes that growth in the generic pharmaceutical industry is driven by several factors which should continue in the coming years. These factors include:

- The aging of the U.S. population
- Efforts by federal and state governments, employers, third-party payors and consumers to control health care costs
- Increased acceptance of generic products by physicians, pharmacists and consumers
- The increasing number of branded pharmaceutical products that have lost or will lose patent protection

Management hopes to exploit these macroeconomic trends by making strategic decisions which will result in the Company's growth. Our growth strategy is based on the following:

- Increase market share for our core prescription generic products by adding new customers and adding products at existing customers
- Increase the number of new product introductions by expanding our research and development efforts and increasing our ANDA submissions
- Leverage our manufacturing capabilities primarily focusing on the development of liquid and semi-solid dosage forms and products requiring sterile manufacturing
- Continue to develop and license branded products with a focus on niche markets, such as diabetes care and related areas, such as podiatry
- Acquire products and businesses that management believes can contribute to the Company's growth strategy

Product Development Strategy

We have identified over $3 billion of brand name drugs in the liquid, sterile, and semi-solid dosage forms which will lose patent protection over the next five years. We are currently developing drugs with branded sales of over $2 billion and plan to take advantage of this opportunity.

Our product development strategy focuses on products in the following areas:

- Drugs with significant volume and high annual sales
- Products that are difficult to bring to market and more likely to face limited competition, enabling us to earn higher margins for a longer period of time. These opportunities include nasal sprays and sterile products, including ophthalmics
- Products that will have limited competition due to smaller market size but can generate long term revenues

Research and Development

The Company obtains new generic pharmaceutical products primarily through internal product development and from strategic arrangements with other pharmaceutical companies.

For the fiscal years ended April 30, 2004 and 2003, total R&D expenditures were $3,820,000 and $2,095,000, respectively. The increase is primarily the result of increased costs of product development including bioequivalency studies and other services performed by outside laboratories. The Company has entered into agreements for two studies on a product Hi-Tech has under current development. The total commitment under the agreements is $2.1 million which is expected to be paid by April 30, 2005.

We have six ANDA applications pending at the FDA that address over $300 million in annual product sales in the United States according to IMS Health. One of the ANDA submissions was submitted under a Paragraph IV Certification. In August 2003, the FDA accepted for filing our ANDA submission for a bioequivalent version of Quixin® ophthalmic solution 0.5% which is used for the treatment of bacterial infections and is currently being marketed by Santen Inc. under a license from Daiichi Pharmaceutical Co., Ltd. On December 18, 2003, Daiichi Pharmaceutical Co., Ltd. filed a complaint against the Company in the United States District Court for the District of New Jersey alleging infringement of its patent for the drug. The Company believes it has meritorious defenses to the allegations in the Complaint. The Company has a partner responsible for the legal defense in this litigation. See Section "Legal Proceedings."

Customers and Marketing

We market our products to chain drug stores, drug wholesalers, managed care purchasing organizations, certain Federal government agencies, generic distributors, mass merchandisers and mail order pharmacies. We sell our generic products to over 100 active accounts located throughout the United States. For the fiscal year ended April 30, 2004, Walgreens and McKesson Corporation accounted for net sales of approximately 14% and 11%, respectively. These customers represented approximately 31% of the outstanding accounts receivable at April 30, 2004. Our top five customers accounted for approximately 47% and 46% of the Company's total sales for each of the fiscal years ended April 30, 2004 and 2003, respectively. If any of our top five customers discontinues or substantially reduces its purchases from the Company, it may have a material adverse effect on our business and financial condition. We believe, however, that we have good relationships with our customers.

We utilize our state of the art manufacturing facilities and laboratories to offer contract manufacturing, which includes research and development programs, to our existing as well as potential customers.

Consistent with industry practice, we have a return policy that allows our customers to return product within a specified period. We have arrangements with certain indirect customers to establish contract pricing for certain products. The indirect customer then independently selects a wholesaler from which to actually purchase the products at these contracted prices. We provide a chargeback credit to our wholesale customers for the difference between our invoice price to the wholesaler and the indirect customer's contract price.

We market our products using various marketing strategies, which include professional and consumer sampling programs, telemarketing efforts, coupon promotions and more contemporary packaging to improve point-of-purchase impact, media and trade and consumer journal advertising. We use trade journals to introduce new

products as well as telemarketing to gain awareness of our generic products among pharmacies and buyers. We have expanded our marketing strategy with programs to include marketing ventures with several companies selling popular non-competing diabetic medications, pharmacy programs and via the Internet using our website. As part of our marketing strategy, we place increasing emphasis on the Internet which we view as a very efficient tool in educating and reaching out to millions of people with diabetes. Our website is registered under the domain name diabeticproducts.com and is linked to other diabetic based websites.

Health Care Products currently employs 5 full time employees in sales and marketing and 2 independent commission sales representative organizations. We have also developed a telemarketing effort which targets diabetic educators and pharmacists.

We are focused on growth, will continue to develop new branded and generic products and also will devise new marketing strategies to penetrate our markets. In order to maximize our potential growth and shareholder value, we are seeking to complement this internal effort by acquiring products for future marketing, as well as licensing rights to proprietary products and technologies for development and commercialization. We will place increasing emphasis on establishing co-development and co-marketing agreements with strategic partners.

In June 2004 we acquired the rights to Naprelan® from Elan Pharmaceuticals and are currently exploring various marketing arrangements for this product. Naprelan® is a non-steroidal anti-inflammatory agent that has been specially formulated using Elan's patented IPDAS™ (Intestinal Protective Drug Absorption System) technology. Naprelan® offers the convenience of once-daily dosing and is indicated in the treatment of rheumatoid arthritis, osteoarthritis, ankylosing, spondylitis, tendonitis, bursitis, acute gout, primary dysmenorrhea and mild to moderate pain.

Manufacturing

Our manufacturing facilities are designed to be flexible in order to allow for the low cost production of a variety of products of different dosages, sizes, packagings and quantities while maintaining a high level of quality and customer service. This flexible production capability allows us to adjust on-line production in order to meet customer requirements. In the fiscal year ended April 30, 2004, we added one high speed sterile filler bringing the number of sterile fillers to three and subsequently added two high speed non-sterile filling lines bringing our total to eight.

Facilities

We are operating from five buildings owned by the company on one site in Amityville, New York, totaling approximately 153,500 square feet. The Company is currently constructing additional production space on our existing property to meet our anticipated sales growth requirements.

Raw Materials/Active Pharmaceutical Ingredients

The active compounds for our products, also called active pharmaceutical ingredients or APIs, are purchased from specialized manufacturers and are essential to our business and success. API manufacturers are required to file a Drug Master File with the FDA. Each individual API must be approved by the FDA as part of the ANDA approval process. API manufacturers are also regularly inspected by the FDA.

In some cases, the raw materials used to manufacture pharmaceutical products are only available from a single FDA-approved supplier. Even when more than one supplier exists, the Company may elect to list, and in most cases has only listed, one supplier in its applications with the FDA. Any change in a supplier not previously approved must then be submitted through a formal approval process with the FDA.

It is crucial for the business to select suppliers that meet Current Good Manufacturing Procesess ("cGMP") requirements, are reliable and offer competitive prices. We are proactive in maintaining good relationships with our API suppliers because we believe that these relationships allow us to save crucial time and be cost competitive. For new products in development, the timely selection of the right API suppliers who have access to cutting-edge chemical and process technologies, and in some cases offer proprietary and patented methods for chemical synthesis and manufacturing processes, can potentially give us a significant advantage over our competitors.

We believe we have good, cooperative working relationships with our suppliers and are not experiencing any difficulty in obtaining raw materials. If a supplier were unable to supply us, we believe we could locate an alternative supplier. However, any change in suppliers of a raw material could cause significant delays and cost increases in the manufacture of such product.

Competition

The market for generic pharmaceuticals is highly competitive. Our direct competition consists of numerous generic drug manufacturers, many of which have greater financial and other resources than we do. If one or more other generic pharmaceutical manufacturers significantly reduce their prices in an effort to gain market share, our profitability or market position could be adversely affected. Competition is based principally on price, quality of products, customer service levels, reputation and marketing support.

Seasonality

We experience seasonal variations in the demand for our cough and cold products. Therefore, no one quarter's performance can be used to indicate a full year results. Our revenues are typically lower during the first and fourth quarters of our fiscal year. We expect this seasonality to continue in the future.

Government Regulation

FDA Oversight

Our products and facilities are subject to regulation by a number of Federal and state governmental agencies. The FDA, in particular, maintains oversight of our manufacturing process as well as the distribution of our products. Facilities, procedures, operations and/or testing of products are subject to periodic inspection by the FDA, the Drug Enforcement Administration and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Certain of our suppliers are subject to similar regulations and periodic inspections. We have had several FDA inspections including our most recent which took place in April 2004. We believe the issues cited during the inspection were adequately addressed by the Company.

A sponsor of a New Drug Application ("NDA") is required to identify in its application any patent that claims the drug or a use of the drug, which is the subject of the application. Upon NDA approval, the FDA lists the approved drug product and these patents in the Orange Book.

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent, market exclusivity, during which the FDA cannot approve an application for a bioequivalent product. If the listed drug is a new chemical entity, the FDA may not accept an ANDA for a bioequivalent product for up to five years following approval of the NDA for the new chemical entity. If it is not a new chemical entity but the holder of the NDA conducted clinical trials essential to approval of the NDA or a supplement thereto, the FDA may not approve an ANDA for a bioequivalent product before expiration of three years. Certain other periods of exclusivity may be available if the listed drug is indicated for treatment of a rare disease or is studied for pediatric indications.

The FDA has extensive enforcement powers, including the power to seize noncomplying products, to seek court action to prohibit their sale and to seek criminal penalties for noncomplying manufacturers. Although it has no statutory power to force the recall of products, the FDA usually accomplishes a recall as a result of the threat of judicially imposed seizure, injunction and/or criminal penalties.

ANDA Process

Although many of the products we currently manufacture and market do not require prior specific approval of the FDA, certain products which we currently market and intend to market under our product development program require prior FDA approval using the ANDA procedure prior to being marketed. We currently have 29 approved products, 6 products pending FDA approval, and 20 products in active development, of which the majority will require ANDA submissions.

The ANDA approval process is generally less time-consuming and complex than the NDA approval process. It generally does not require new preclincal and clinical studies because it relies on the studies establishing safety and efficacy conducted for the drug previously approved through the NDA process. The ANDA process does, however, occasionally, require one or more bioequivalency studies to show that the ANDA drug is bioequivalent to the previously approved drug. Bioequivalence compares the bioavailability of one drug product with that of referenced brand formulation containing the same active ingredient. When established, bioequivalency confirms that the rate of absorption and levels of concentration in the bloodstream of a formulation of the previously approved drug and the generic drug are equivalent. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product in the bloodstream needed to produce the same therapeutic effect. Such studies are not generally required to be performed for solutions (oral, ophthalmic, or solutions for inhalation). Suspensions and certain types of topical products do require bioequiovalency testing. In certain cases, such as nasal spray suspensions, clinical studies are required in addition to bioequivalency studies to show efficacy compared to the branded product. Such studies, though not as extensive as corresponding studies conducted by innovator companies as part of their NDA process, could require substantial funding.

The completion of a prospective product's formulation, testing and FDA approval generally takes several years. Development activities could begin several years in advance of the patent expiration date, and may include bioequivalency and clinical studies. Consequently, we are presently selecting and will continue to select and develop drugs we expect to market several years in the future.

The timing of final FDA approval of ANDA applications depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and/or its use and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods. Pending the resolution of any such issues the FDA is prohibited from granting final approval to generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children ("pediatric extension"). See "Patent Challenge Process."

Before approving a product, the FDA also requires that a company's procedures and operations conform to cGMP regulations, as defined in the U.S. Code of Federal Regulations. The Company must follow the cGMP regulations at all times during the manufacture of its products.

If the FDA concludes that all substantive ANDA requirements (chemistry, bioequivalency, labeling and manufacturing) have been satisfied, but a final ANDA approval cannot be granted because of patent or exclusivity-related considerations, the FDA may issue a tentative approval.

Patent Challenge Process

The Hatch-Waxman Act provides incentives for generic pharmaceutical manufacturers to challenge patents on branded pharmaceutical products, their methods of use, specific formulations, as well as to develop non-infringing forms of the patented subject matter. The purpose of the Hatch-Waxman Act is to stimulate competition by providing incentives to generic companies to introduce their products early, and at the same time to ensure that such suits are not frivolous.

If there is a patent listed in the FDA's Orange Book at the time of filing an ANDA with the FDA and the generic drug company intends to market the generic equivalent prior to the expiration of that patent, the generic company files with its ANDA a certification asserting that the patent is invalid, unenforceable and/or not infringed ("Paragraph IV certification"). After receiving notice from the FDA that its application is acceptable for filing, the generic company sends the patent holder and the holder of the New Drug Application ("NDA") for the brand-name drug a notice explaining why it believes that the patents in question are invalid, unenforceable or not infringed. Upon receipt of the notice from the generic company, the patent holder has 45 days during which to bring a patent infringement suit in federal district court against the generic company. The discovery, trial and appeals process in such suits can take several years and have high legal costs.

If a suit is commenced by the patent holder, the Hatch-Waxman Act provides for an automatic stay on the FDA's ability to grant final approval of the ANDA for the generic product. The period during which the FDA may not approve the ANDA and the patent challenger therefore may not market the generic product is 30 months, or such shorter or longer period as may be ordered by the court. The 30-month period may or may not, and often does not, coincide with the timing of the resolution of the lawsuit or the expiration of a patent, but if the patent challenge is successful or the challenged patent expires during the 30-month period, the FDA may approve the generic drug for marketing, assuming there are no other obstacles to approval such as exclusivities given to the NDA holder.

Under the Hatch-Waxman Act, the developer of a proposed generic drug which is the first to have its ANDA accepted for filing by the FDA, and whose filing includes a Paragraph IV certification, may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs and to build its market share before competitors can enter the market.

Medicaid and Medicare

Medicaid, Medicare and other reimbursement legislation or programs govern reimbursement levels and require all pharmaceutical manufacturers to rebate a percentage of their revenues arising from Medicaid-reimbursed drug sales to individual states. The required rebate is currently 11% of the average manufacturer's price for sales of Medicaid-reimbursed products marketed under ANDAs. We believe that federal or state governments may continue to enact measures aimed at reducing the cost of drugs to the public. For example, the extension of prescription drug coverage to all Medicare recipients has gained significant political support.

DEA

Because the Company sells and develops products containing controlled substances, it must meet the requirements and regulations of the Controlled Substances Act which are administered by the Drug Enforcement Agency ("DEA"). These regulations include stringent requirements for manufacturing controls and security to prevent diversion of or unauthorized access to the drugs in each stage of the production and distribution process. We have the approval of the DEA to sell certain generic pharmaceutical products containing narcotics. We are currently manufacturing 7 preparations containing narcotics and are developing other products that contain narcotics.

In order to manufacture and sell products containing narcotics, we have implemented stringent security precautions to insure that the narcotics are accounted for and properly stored. We believe that the Company is currently in compliance with all applicable DEA requirements.

Critical Accounting Policies

In preparing financial statements in conformity with generally accepted accounting principles in the United States of America, we are required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and revenues and expenses for the reporting period covered thereby. Actual results could differ from those estimates. Our estimates for sales returns and allowances, the useful lives of property and equipment, determination of impairment of long-lived assets, impact of legal matters and the realization of deferred tax assets represent a significant portion of the estimates made by management.

Revenue is recognized for product sales upon shipment and passing of risk to the customer and when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured and the Company has no further performance obligations. These estimates are presented in the financial statements as reductions to net revenues and accounts receivable. Estimated sales returns, allowances and discounts are provided for. Contract research income is recognized as work is completed and billable costs are incurred. In certain cases, contract research income is based on attainment of designated milestones.

Returns – Consistent with industry practice, the Company maintains a return policy that allows its customers to return product within a specified period. The Company's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. The Company continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

Chargebacks – The Company markets products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies and group purchasing organizations. The Company also markets products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as "indirect customers." The Company enters into agreements with its indirect customers and enters into agreements with its wholesalers to establish contract pricing for certain products. Indirect customers then independently select a wholesaler from which to actually purchase the products at these contracted prices. The Company will provide credit to the wholesaler for any difference

between the contracted price and the wholesaler's invoice price. Such credit is called a chargeback. The estimate for chargebacks is based on expected and historical sell-through levels by its wholesaler customers to contracted customers. The Company continually monitors its provision for chargebacks and makes adjustments when it believes that actual chargebacks may differ from established estimates.

Environment

We believe that our operations comply in all material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position.

Product Liability

The sale of pharmaceutical products can expose the manufacturer of such products to product liability claims by consumers. A product liability claim, if successful and in excess of our insurance coverage, could have a material adverse effect on our financial condition. We are currently a defendant in one product liability action. See Item 3. "Legal Proceedings" for a complete description of such actions. We maintain a product liability insurance policy which provides coverage in the amount $10,000,000 per claim and in the aggregate.

Employees

As of April 30, 2004, we employed 181 full-time persons and 19 part-time persons, of whom 23 were engaged in executive, financial and administrative capacities; 13 in marketing, sales and service; 91 full-time employees and 19 part-time employees in production, warehousing and distribution; and 54 in research and development and quality control functions. We are not a party to a collective bargaining agreement. The management of the Company considers its relations with its employees to be satisfactory.

Risk Factors

The following risk factors could have a material adverse effect on the Company's business, financial position or results of operations. These risk factors may not include all of the important factors that could affect our business or our industry or that could cause our future financial results to differ materially from historic or expected results or cause the market price of our common stock to fluctuate or decline.

Risk of New Product Introductions

Our future revenue growth and profitability are dependent in part, upon our ability to develop and introduce new products on a timely basis in relation to our competitors' product introductions. Our failure to do so successfully could have a material adverse effect on our financial position and results of operations.

Many products require FDA approval prior to being marketed. The process of obtaining FDA approval to manufacture and market new and generic pharmaceutical products is rigorous, time-consuming, costly and largely unpredictable. We may be unable to obtain requisite FDA approvals on a timely basis for new generic products that we may develop. The timing and cost of obtaining FDA approvals could adversely affect our product introduction plans, financial position and results of operations.

The ANDA process often results in the FDA granting final approval to a number of ANDAs for a given product. We may face immediate competition when we introduce a generic product into the market. These circumstances could result in significantly lower prices, as well as reduced margins, for generic products compared to brand products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

Risk that Approved Products May Not Achieve Expected Levels of Market Acceptance

Our approved products may not achieve expected levels of market acceptance, which could have a material adverse effect on our profitability, financial position and results of operations.

Even if we were able to obtain regulatory approvals of our new pharmaceutical products, generic or brand, the success of those products is dependent upon market acceptance. Levels of market acceptance for new products could be impacted by several factors, including:

- the availability of alternative products from our competitors
- the price of our products relative to that of our competitors
- the timing of our market entry
- the ability of our customers to market our products effectively to the retail level
- the acceptance of our products by government and private formularies

Some of these factors are not within our control. New products may not achieve expected levels of market acceptance. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, these studies have resulted, and may in the future result, in the discontinuance of product marketing. These situations, should they occur, could have a material adverse effect on our profitability, financial position and results of operations.

Industry is Highly Competitive

We face competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products, which could have a material adverse effect on our business, financial position and results of operations.

Our competitors may be able to develop products and processes competitive with or superior to our own for many reasons, including that they may have:

- proprietary processes or delivery systems

- larger research and development and marketing staffs
- larger production capabilities, in a particular, therapeutic areas
- more experience in testing and clinical trials
- more products
- more experience in developing new drugs and greater financial resources

Each of these factors and others could have a material adverse effect on our business, financial position and results of operations.

Government Regulation

Because the pharmaceutical industry is heavily regulated, we face significant costs and uncertainties associated with our efforts to comply with applicable regulations. Should we fail to comply, we could experience material adverse effects on our business, financial position and results of operations.

The pharmaceutical industry is subject to regulation by various federal and state governmental authorities. For instance, we must comply with FDA requirements with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. Failure to comply with FDA and other governmental regulations can result in fines, disgorgement, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of FDA's review of ANDAs, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal regulatory compliance programs and policies and have had a favorable compliance history, there is no guarantee that we may not be deemed to be deficient in some manner in the future. If we were deemed to be deficient in any significant way, it could have a material adverse effect on our business, financial position and results of operations.

In addition to the new drug approval process, the FDA also regulates the facilities and operational procedures that we use to manufacture our products. We must register our facilities with the FDA. All products manufactured in those facilities must be made in a manner consistent with current Good Manufacturing Practices ("cGMP"). Compliance with cGMP regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full technical compliance. Failure to comply with cGMP regulations could result in an enforcement action brought by the FDA, which periodically inspects our manufacturing facilities for compliance, which could include withholding the approval of ANDAs or other product applications of a facility if deficiencies are found at that facility. FDA approval to manufacture a drug is site-specific. If the FDA would cause our manufacturing facilities to cease or limit production, our business could be adversely affected. Delay and cost in obtaining FDA approval to manufacture at a different facility also could have a material adverse effect on our business, financial position and results of operations.

We are subject, as are generally all manufacturers, to various federal, state and local laws of general applicability, such as laws regulating working conditions, as well as environmental protection laws and regulations, including those governing the discharge of materials into the environment. Although we have not incurred significant costs associated with complying with such environmental provisions in the past, if changes to such environmental provisions are made in the future that require significant changes in our operations or if we engage in the development and manufacturing of new products requiring new or different environmental controls, we may be required to expend significant funds. Such changes could have a material adverse effect on our business, financial position and results of operations.

Limited Number of Major Customers

Our top 5 customers accounted for 47% of our total sales for fiscal 2004. Any significant reduction of business with any of our top 5 customers could have a material adverse effect on our business, financial position and results of operations.

Third Party Suppliers

Active pharmaceutical ingredients, packaging components, and other materials and supplies that we use in our pharmaceutical manufacturing operations, as well as certain finished products, are generally available and purchased from many different foreign and domestic suppliers. Additionally, we maintain sufficient raw materials inventory, and in certain cases where we have listed only one supplier in our applications with the FDA, we have received FDA approval to use alternative suppliers should the need arise. However, there is no guarantee that we will always have timely and sufficient access to a critical raw material or finished product. A prolonged interruption in the supply of a single-sourced active ingredient or finished product could cause our financial position and results of operations to be materially adversely affected.

Limited Number of Manufacturing Facilities

Our generic products are produced at our two manufacturing facilities located at one site. A significant disruption at these facilities, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis, which could have a material adverse effect on our business, financial position and results of operations.

Consolidation of Customers

A significant amount of our sales are made to a relatively small number of drug wholesalers, retail drug chains, managed care purchasing organizations, mail order and hospitals. These customers represent an essential part of the distribution chain of generic pharmaceutical products. These customers have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to attempt to extract price discounts on our products. The result of these developments may have a material adverse effect on our business, financial position and results of operations.

Indemnification Obligations

In the normal course of business, we periodically enter into employment, legal settlements, and other agreements which incorporate indemnification provisions. We maintain insurance coverage which we believe will effectively mitigate our obligations under these indemnification provisions. However, should our obligation under an indemnification provision exceed our coverage or should coverage be denied, it could have a material adverse effect on our business, financial position and results of operations.

Uncertainties of Estimates and Assumptions

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and results of operations.

The financial statements included in the periodic reports we file with the Securities and Exchange Commission ("SEC") are prepared in accordance with GAAP. The preparation of financial statements in accordance with GAAP involves making estimates of expenses and income. This includes, but is not limited to, estimates, judgments and assumptions used in the adoption of the provisions of SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets and SFAS No. 148, Accounting for Stock-Based Compensation - Transaction and Disclosure. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our business, financial position and results of operations.

Website Access to Filings with the Securities and Exchange Commission

Additional information about the Company is available on our website at www.hitechpharm.com. All of our electronic filings with the SEC including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available on our website free of charge as soon as reasonably practicable after they are electronically filed with and furnished to the SEC. Our SEC filings are also available through the SEC's website at www.sec.gov. Information contained on our website is not incorporated by reference in the Annual Report on Form 10-K and shall not be deemed "filed" under the Securities Exchange Act of 1934.

ITEM 2. PROPERTIES.

Our executive offices and manufacturing facilities are owned by the Company and located in Amityville, New York. They are comprised of five buildings with approximately 153,500 square feet, and include:

- A 40,000 square feet facility dedicated to liquid and semi-solid production
- A 21,500 square feet facility housing a sterile manufacturing facility, chemistry and microbiology laboratories
- A 62,500 square feet facility used for the warehousing of finished goods which also houses our Health Care Products Division
- A 21,500 square feet facility with 3,500 square feet of research and development space and 18,000 square feet of warehouse space

- An 8,000 square foot office building which is utilized for administrative offices

We believe that our properties are adequately covered by insurance and are suitable and adequate for our needs for several years.

ITEM 3. LEGAL PROCEEDINGS.

On December 18, 2003, Daiichi Pharmaceutical Co., Ltd. filed a complaint against the Company in the United States District Court for the District of New Jersey alleging infringement of its patent for a drug known as Levofloxacin, which it has sublicensed exclusively to Santen Inc. for use in certain ophthalmic pharmaceutical preparations. The plaintiff seeks a permanent injunction against the Company from engaging in the marketing within the United States of Levofloxacin Opthalmic Solution, described in the Company's new drug application with the United States Food and Drug Administration. On February 17, 2004, the Company filed an Answer and Counterclaim to the Complaint denying infringement of any valid claim in the patent suit, seeking a judicial declaration that the patent is invalid and not infringed. The Company believes it has meritorious defenses to the allegations in the Complaint. Legal costs in connection with this complaint are being paid for by a business partner.

On or about November 24, 2003 MedPointe Healthcare, Inc. ("MedPointe") filed a Verified Complaint and Application for Order to Show Cause with Temporary Restraints against the Company in the United States District Court for the District of New Jersey, Trenton vicinage. The suit alleges willful infringement by the Company of MedPointe's patent No. 6,417,206 as a result of the Company's offering to sell its Tannate 12-D S product, as a generic equivalent to MedPointe's Tussi-12®D S. On December 1, 2003 the Court entered Temporary Restraints against the Company pending the return date of the Order to Show Cause. On March 1, 2004 the Court issued a preliminary injunction enjoining the Company from marketing its Tannate 12-D S product. The Company will therefore not commence shipment of the Tannate 12-D S product until a final decision of the Court on the patent infringement claim has been reached. The Company has filed an appeal of this ruling. It is impossible to predict with certainty the outcome of this litigation.

On or about October 28, 2002 an action was commenced in the United States District Court for the Northern District of Texas, Dallas Division, against the Company, Wyeth, Wyeth Consumer Healthcare, Bayer Corporation, Bayer A.G., Novartis Consumer Health, Inc., Novartis Pharmaceuticals Corporation, Schering-Plough Corporation, The Delaco Company and Chattem, Inc. The complaint alleges claims for permanent and debilitating injuries as a result of exposure to phenylpropanolamine (hereinafter referred to as "PPA") through ingestion of PPA-containing products designed, formulated, marketed, distributed and/or sold by the Company and the other defendants. One plaintiff, Roger Grantham, claims he ingested a PPA-containing product manufactured by the Company. Mr. Grantham is a plaintiff in the Amanda Carrisalez case, which was originally filed in the United States District Court for the Northern District of Texas and was then transferred to the Multidistrict Litigation in Seattle. The plaintiffs, individually, seek compensatory damages in the amount of $15 million for actual damages, plus punitive damages. The Company filed an answer to this action and believes it has meritorious defenses. The Company's defense costs, after its deductible, are being covered under its product liability policy which has a $5 million limit for defense costs and liability ("Product Liability Policy"). The last date of sale of the limited number of products containing PPA by the Company was December 2000.

In March 2001, the Center for Environmental Health ("CEH") filed a lawsuit against several defendants alleging violations of California's Proposition 65 and Unfair Trade Practices Act for failure to provide clear and reasonable warnings regarding the carcinogenicity and reproductive toxicity of lead and the reproductive toxicity of cadmium to the users of FDA-approved anti-diarrheal medicines. In May 2004, the Company signed a settlement agreement, subject to Court approval. The settlement agreement provides that the Company may sell a reformulated product or the original formulated product with certain warnings. The Company believes that its liability in this matter will not exceed approximately $75,000.

The Company believes that these litigation matters will not have a material effect on the financial position of the Company.

From time to time, the Company becomes involved in various legal matters in addition to the above described matters that the Company considers to be in the ordinary course of business. While the Company is not presently able to determine the potential liability, if any, related to such matters, the Company believes none of such matters, individually or in the aggregate, will have a material adverse effect on its financial position.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of security holders during the quarter ended April 30, 2004.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

The Company's common stock is traded on the National Market System of the National Association of Securities Dealers Automated Quotation System ("NASDAQ") under the symbol HITK.

The following table sets forth the high and low closing sales prices per share of the Company's common stock for the periods indicated on the NASDAQ National Market System. The quotations are inter-dealer prices, without retail mark-up, mark-down or commissions paid, and may not necessarily reflect actual transactions.

Quarter Ended	High	Low
Fiscal 2003		
July 31, 2002	$ 7.60	$ 6.07
October 31, 2002	10.89	6.25
January 31, 2003	19.67	9.32
April 30, 2003	34.44	13.05
Fiscal 2004		
July 31, 2003	46.81	24.76
October 31, 2003	31.56	19.80
January 31, 2004	27.15	18.08
April 30, 2004	26.18	17.41

As of July 12, 2004 the closing price of the Common Stock on the Nasdaq National Market System was $16.93.

There were no purchases by the Company or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of the Company's Common Stock during the fourth quarter of the Company's fiscal year ended April 30, 2004.

Recent Sales of Unregistered Shares

On July 17, 2003, the Company recieved net proceeds of approximately $23.6 million through a private placement of 860,000 shares of our common stock at a purchase price of $29.21 per share. The proceeds will be used mainly for the funding of future acquisitions, research and development and for general corporate purposes. The private placement was made under an exemption from the registration requirements of the Securities Act of 1933, as amended, and purchasers may not offer or sell the securities sold in the offering in the absence of an effective registration statement or exemption from registration requirements. As part of the transaction, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission to register the resale of all of the common stock issued in the private placement.

The table below sets forth, as of the end of the fiscal year ended April 30, 2004, for the Hi-Tech Pharmacal Co., Inc. Employee Stock Option Plan and Director Stock Option Plan ("Plan") the number of securities to be issued upon the exercise of outstanding options, warrants and rights, the weighted average exercise price of the outstanding options, and other than securities to be issued upon the exercise of the outstanding options, the number of securities remaining for future issuance under the Plan:

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holder	1,622,000	$ 9.10	583,000
Equity compensation plans not approved by security holders	—	—	—
Total	1,662,000	$ 9.10	583,000

There are no Company equity compensation plans not approved by the Company's stockholders.

Common Stock Holders

The Company believes there are approximately 15,000 holders of Common Stock, not including shares held in street name by brokers and nominees.

Dividends

The Company has never declared or paid any cash dividends, and it does not anticipate that it will pay cash dividends in the foreseeable future. The declaration of dividends by the Company in the future is subject to the sole discretion of the Company's Board of Directors and will depend upon the operating results, capital requirements and financial position of the Company, general economic conditions and other pertinent conditions or restrictions relating to any financing. The Company's loan agreement prohibits the payment of cash dividends by the Company.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data presented below for the five years ended April 30, 2004 are derived from the audited financial statements of the Company. This data is qualified in its entirety by reference to, and should be read in conjunction with, Management's Discussion and Analysis of Financial Condition and Results of Operations and the Company's financial statements and related notes thereto included elsewhere herein.

YEAR ENDED APRIL 30	2004	2003	2002	2001	2000
Statement of operations data					
Net sales	$56,366,000	47,446,000	33,282,000	29,649,000	26,414,000
Costs and expenses:					
Costs of goods sold	26,207,000	23,508,000	17,507,000	15,315,000	14,979,000
Research and development	3,820,000	2,095,000	1,747,000	1,683,000	1,367,000
Selling, general and administrative	16,758,000	13,262,000	8,941,000	9,197,000	7,786,000
Contract research (income)	(504,000)	(216,000)	(368,000)	(250,000)	(279,000)
Interest expense	24,000	32,000	55,000	104,000	126,000
Interest (income) and other	(281,000)	(205,000)	(202,000)	(319,000)	(277,000)
Total	$46,024,000	38,476,000	27,680,000	25,730,000	23,702,000
Income before provision for income taxes	10,342,000	8,970,000	5,602,000	3,919,000	2,712,000
Provision for income taxes	3,750,000	3,243,000	2,089,000	1,528,000	1,020,000
Net income	$ 6,592,000	5,727,000	3,513,000	2,391,000	1,692,000
Basic earnings per share	$ 0.84	0.83	0.79	0.55	0.38
Diluted earnings per share	$ 0.74	0.74	0.71	0.54	0.38
Weighted average common shares outstanding:					
Basic earnings per share	7,873,000	6,893,000	4,460,000	4,357,000	4,401,000
Effect of potential common shares	985,000	811,000	457,000	57,000	57,000
Weighted average common shares outstanding:					
Diluted earnings per share	8,858,000	7,704,000	4,917,000	4,414,000	4,458,000

APRIL 30,	2004	2003	2002	2001	2000
Balance sheet data:					
Working capital	$55,772,000	24,085,000	17,937,000	13,095,000	10,676,000
Total assets	$75,552,000	43,828,000	33,072,000	27,510,000	25,829,000
Long-term debt	$ 0	0	62,000	217,000	556,000
Stockholders' equity	$66,788,000	35,040,000	26,111,000	20,980,000	18,739,000

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

GENERAL

The following discussion and analysis should be read in conjunction with the Financial Statements and Notes thereto appearing elsewhere in this Report.

The following table sets forth, for all periods indicated, the percentage relationship that items in the Company's Statements of Operations bear to net sales.

	YEAR ENDED APRIL 30,		
	2004	2003	2002
Net Sales	100.0%	100.0%	100.0%
Cost of Sales	46.5%	49.5%	52.6%
Gross profit	53.5%	50.5%	47.4%
Selling, general & administrative expense	29.7%	28.0%	26.9%
Research & development costs	6.8%	4.4%	5.2%
Contract research (income)	-0.9%	-0.5%	-1.1%
Interest expense	0.0%	0.1%	0.2%
Interest (income) and other	-0.5%	-0.4%	-0.6%
Total expenses	35.1%	31.6%	30.6%
Income before tax provision	18.4%	18.9%	16.8%
Income tax provision	6.7%	6.8%	6.3%
Net income	11.7%	12.1%	10.5%

RESULTS OF OPERATIONS FOR YEARS ENDED APRIL 30, 2004 AND 2003

For the fiscal year ended April 30, 2004 ("Fiscal 2004"), net sales increased by $8,920,000, or 19% to $56,366,000 from $47,446,000 for the fiscal year ended April 30, 2003 ("Fiscal 2003"). The increase was primarily the result of the successful introduction of five new generic products into the marketplace and increased shipments to the Company's existing customers. The Company's high level of customer service and the ability to produce high quality products have also contributed to our results. The Company's five leading products in Fiscal 2004 were Urea Cream and Lotion, Sulfamethoxazole and Trimethoprim, Promethazine with Codeine and Promethazine DM, Albuterol Sulfate Inhalation Solution and Syrup, and Lactulose Solution. Sales of Urea Cream and Lotion accounted for 13% of sales while sales of Sulfamethoxazole and Trimethoprim accounted for 11% of sales for Fiscal 2004.

Generic pharmaceutical products, which include private label contract manufacturing, had net sales for Fiscal 2004 of $50,307,000, an increase of $9,492,000, or 23%, compared to $40,815,000 in Fiscal 2003. The increase resulted from increased demand and the successful introduction of five new generic products into the marketplace in Fiscal 2004 which helped offset a significant decrease in sales of Tannate based products. Sales were particularly strong for Urea Cream and Lotion which recorded net sales of approximately $7,500,000 in its first year.

The Company's Tannate based products experienced lower sales as market demand shifted towards a new formulation, Tussi-12® D S marketed by MedPointe. The Company was not able to ship its version of Tussi 12® D S because of a suit brought against it by MedPointe, which resulted in a Temporary Restraining Order against the Company. The Company has filed an appeal of this ruling.

Health Care Products Division, which markets the Company's branded products, had net sales of $6,059,000 and $6,631,000 for Fiscal 2004 and 2003, respectively. Net sales decreased by $572,000, or 9%. This decrease is primarily the result of exported Health Care products which were improperly returned to the domestic market during the first half of the year. The Company has taken the necessary steps to minimize the impact of this diversion and believes that its consequences are limited.

Cost of sales, as a percentage of net sales, decreased from 50% for Fiscal 2003 to 47% for Fiscal 2004. The decrease in cost of sales as a percentage of sales was primarily driven by sales of certain new products, which have a higher gross margin than the average product in our portfolio. In the generic drug industry, certain products may contribute significantly to a company's gross profit. The gross profit on these products may change as market conditions change.

Selling, General and Administrative expenses, as a percentage of net sales, increased from 28% to 30%, an increase of $3,496,000. The increase from $13,262,000 for Fiscal 2003 to $16,758,000 for Fiscal 2004 resulted principally from increased sales commissions, freight expenditures, and professional fees related to patents and legal defenses. The Company incurred a non-cash pre-tax charge for options granted in 2000 and 2001 to a consultant who is a director of the Company in the amount of $258,000 for Fiscal 2004 compared to $451,000 in Fiscal 2003. This pre-tax charge was based, in part, on the market value of the Company's stock, which appreciated over the respective reporting periods.

Research and development costs increased to $3,820,000 or 82% for Fiscal 2004 from $2,095,000 for Fiscal 2003 as a result of, among other things, expenses associated with the filing of ANDAs with the FDA as well as development of non ANDA products for the Company. Expenses increased due to significant costs associated with developing a steroidal nasal spray which requires both bioequivalency studies and clinical studies. Expenses associated with developing steroidal nasal sprays will continue into fiscal year 2005. Additionally, the number of projects in development increased from 15 to 20.

Net income increased 15% or $865,000 to $6,592,000 for Fiscal 2004 from net income of $5,727,000 for Fiscal 2003, due to increased sales and gross margins, partially offset by higher research and development and selling, general, and administrative expenditures.

Diluted earnings per share for Fiscal 2004 were $0.74, unchanged from $0.74 for the prior year due to the factors mentioned above and increased shares outstanding, due to 860,000 shares issued in a private placement and the exercise of outstanding options.

RESULTS OF OPERATIONS FOR YEARS ENDED APRIL 30, 2003 AND 2002

For the fiscal year ended April 30, 2003 ("Fiscal 2003"), net sales increased by $14,164,000, or 43% to $47,446,000 from $33,282,000 for the fiscal year ended April 30, 2002 ("Fiscal 2002"). The increase was primarily the result of the successful introduction of 6 new generic products into the marketplace in Fiscal 2003 and increased shipments to the Company's existing customers as well as several new customers in Fiscal 2003. The Company's high levels of customer service and the ability to produce high quality products has also contributed to our results. Some of the leading products that were included in this mix for the past year were Albuterol Sulfate Inhalation Solution and Syrup,

Sulfamethoxazole and Trimethoprim, Lactulose Solution, Promethazine DM, as well as Promethazine with Codeine, Lidocaine and several other prescription products. No one product accounted for sales of 10% or more of total sales.

Generic pharmaceutical products, which include private label contract manufacturing, had net sales for Fiscal 2003 of $40,815,000, an increase of $13,583,000, or 50%, compared to the Fiscal 2002. The increase resulted from increased demand and the successful introduction of 6 new generic products into the marketplace in Fiscal 2003.

Health Care Products Division, which markets the Company's branded products, for Fiscal 2003 and 2002 had net sales of $6,631,000 and $6,050,000, respectively. Net sales increased by $581,000, or 10%.

Cost of sales, as a percentage of net sales, decreased from 53% for Fiscal 2002 to 50% for Fiscal 2003. Labor and overhead decreased approximately 17%. Units shipped increased 31% and the average unit selling price increased 8%. In the generic drug industry, certain products may contribute significantly to a company's gross profit. The gross profit on these products may change as market conditions change. If one or more other generic pharmaceutical manufacturers significantly reduce their prices in an effort to gain market share or the supplier of active ingredients increases its prices, the Company's profitability could be adversely affected.

Selling, General and Administrative expenses, as percentage of its sales, increased from 27% to 28%, an increase of $4,321,000. The increase from $8,941,000 for Fiscal 2002 to $13,262,000 for Fiscal 2003 resulted principally from increased sales commissions, freight expenditures, and professional fees. The Company incurred a non-cash pre-tax charge for options granted in 2000 and 2001 to a consultant who is a director of the Company in the amount of $451,000 for Fiscal 2003. This pre-tax charge was based, in part, on the market value of the Company's stock, which appreciated substantially over the respective reporting periods.

Research and development costs increased to $2,095,000 or 20% for Fiscal 2003 from $1,747,000 for Fiscal 2002 as a result of, among other things, expenses associated with the filing of Abbreviated New Drug Applications (ANDAs) with the FDA as well as development of non ANDA products for the Company.

Net income increased 63% or $2,214,000 to $5,727,000 for Fiscal 2003 from net income of $3,513,000 for Fiscal 2002, as a result of the factors noted above.

LIQUIDITY AND CAPITAL RESOURCES

The Company's operations are historically financed principally by cash flow from operations. At April 30, 2004 and April 30, 2003, working capital was approximately $55,772,000 and $24,085,000, respectively. The increase of $31,687,000 was primarily due to the private placement of 860,000 shares of common stock in July 2003 with net proceeds of $23,600,000, and cash flow from operations.

Cash flows from operating activities were approximately $5,573,000, which was the result principally of net income and depreciation of $8,067,000 partially offset by an increase in accounts receivable of $4,245,000. The increase in accounts receivable is due to slower payments from customers. The Company has taken measures to add staff and increase collection efforts to manage the increase in accounts receivable. The Company expects to continue increasing expenditures in research and development in the future. Cash flows used in investing activities were approximately $12,230,000 and were principally payments for fixed assets acquired and investments in marketable securities. Cash flows from financing activities were $23,700,000 and resulted principally from the private placement of 860,000 shares of common stock in July 2003 with net proceeds of $23,598,000 and $361,000 from the net proceeds exercise of incentive stock options.

On October 23, 2002 the Company replaced its existing credit facility with a new three year $8,000,000 revolving credit facility. The revolving credit facility bears interest at a rate elected by the Company equal to the Prime Rate or the LIBOR plus 1.50%. Loans are collateralized by inventory, accounts receivable and other assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants and prohibits the payment of cash dividends. At April 30, 2004 there were no borrowings under the credit facility.

On July 17, 2003 the Company entered into a definitive agreement with certain accredited investors with respect to the private placement of 860,000 shares of its common stock at a purchase price of $29.21 per share, for net proceeds after offering costs, of approximately $23.6 million. The net proceeds will be used mainly for the funding of future acquisitions, research and development and for general corporate purposes.

In June 2004, the Company acquired exclusive rights to market and distribute Naprelan® (naproxen sodium) controlled release tablets in the United States, its territories, and Puerto Rico. Elan Pharmaceuticals, Inc. had provided the underlying rights to Stat-Trade, Inc. ("STI") and STI simultaneously assigned its rights to the license to Hi-Tech. As consideration for the acquisition, Hi-Tech paid $3.6 million in cash for the license, inventory and related acquisition costs. Hi-Tech will pay STI consulting fees on an ongoing basis based on net profits on the sales generated by Naprelan®.

The Company believes that its financial resources consisting of current working capital, anticipated future operating revenue and its credit line will be sufficient to enable it to meet its working capital requirements for at least the next 12 months.

In May 1997, the Company announced a stock buy-back program under which the Board of Directors authorized the purchase of up to $1,000,000 of its common stock. In November 2003, the Company increased the stock buy-back program to an aggregate of $3,000,000. As of April 30, 2004, the Company had purchased 303,000 shares at a cost of $998,000.

NEW ACCOUNTING PRONOUNCEMENTS:

SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity," which was issued May 2003, will require redeemable preferred stock to be classified, in certain circumstances, as a liability, upon adoption by a public company at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 provides that mandatorily redeemable preferred stock should be classified as a liability if it embodies an unconditional obligation requiring the issuer to redeem the shares by transferring its assets at a specified or determinable date or upon an event certain to occur. The Company does not currently have any financial instruments with these characteristics. SFAS No. 150 had no effect on the Company's results of operations and financial position.

In May 2003, the FASB issued FAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ("FAS 149"). FAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under FAS No. 133. FAS 149 is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. The adoption of FAS 149 did not have any impact on the Company's financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for an entity that changes to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure provisions of SFAS 123 to require expanded and more prominent disclosures in annual financial statements about the method of accounting for stock based compensation and the proforma effect on reported results of applying the fair value method for

entities that use the intrinsic value method. The proforma disclosures are also required to be displayed prominently in interim financial statements. The Company does not intend to change to the fair value method of accounting and has included the disclosure requirements of SFAS 148 in the accompanying financial statements.

In January 2003, the FASB issued FASB Interpretation 46 ("FIN 46"), Consolidation of Variable Interest Entities which was revised in December 2003. FIN 46 clarifies the application of Accounting Research Bulletin 51, Consolidated Financial Statements, for certain entities that do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties or in which equity investors do not have the characteristics of a controlling financial interest ("variable interest entities"). Variable interest entities within the scope of FIN 46 will be required to be consolidated by their primary beneficiary. The primary beneficiary of a variable interest entity is determined to be the party that absorbs a majority of the entity's expected losses, receives a majority of its expected returns, or both. Entities that have interests in variable interest entities or special purpose entities, FIN 46 applies for periods ending after December 15, 2003. Application of this interpretation for all other public entities other than small business issuers is effective for periods ending after March 15, 2004. The adoption of FIN 46 had no impact upon the financial condition or results of operations of the Company.

REVENUE RECOGNITION

Revenue is recognized for product sales upon shipment and passing of risk to the customer and when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured and the Company has no further performance obligations. These estimates are presented in the financial statements as reductions to net revenues and accounts receivable. Estimated sales returns, allowances and discounts are provided for. Contract research income is recognized as work is completed and billable costs are incurred. In certain cases, contract research income is based on attainment of designated milestones.

Returns – Consistent with industry practice, the Company maintains a return policy that allows its customers to return product within a specified period. The Company's estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

Chargebacks – The Company markets products directly to wholesalers, distributors, retail pharmacy chains, mail order pharmacies and group purchasing organizations. The Company also markets products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as "indirect customers." The Company enters into agreements with its indirect customers and enters into agreements with its wholesalers to establish contract pricing for certain products. Indirect customers then independently select a wholesaler from which to actually purchase the products at these contracted prices. The Company will provide credit to the wholesaler for any difference between the contracted price and the wholesaler's invoice price. Such credit is called a chargeback. The estimate for chargebacks is based on expected and historical sell-through levels by its wholesaler customers to contracted customers. The Company continually monitors its provision for chargebacks and makes adjustments when it believes that actual chargebacks may differ from established estimates.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

The Company has entered into agreements for two studies on a product Hi-Tech has under current development. The total commitment under the agreements is $2.1 million which is expected to be paid by April 30, 2005.

As part of our ongoing business, we do not participate in transactions that generate relationships with unconsolidated entities or financial partnerships which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As of April 30, 2004 we are not involved in any material unconsolidated transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company's existing credit facility bears interest at a rate selected by the Company equal to the Prime Rate or LIBOR plus 1.50%. This facility is exposed to market rate fluctuations and may impact the interest paid on any borrowings under the credit facility. Currently, the Company has no borrowings under this facility; however, an increase in interest rates would impact interest expense on future borrowings.

The Company invests in U.S. treasury notes, government asset backed securities and corporate bonds, all of which are exposed to interest rate fluctuations. The interest earned on these investments may vary based on fluctuations in the interest rate.

In June 2004, the Company acquired rights to market and distribute Naprelan® (naproxen sodium) controlled release tablets in the United States, its territories, and Puerto Rico, from Elan Pharmaceuticals, Inc. ("Elan"), a company based in Ireland. Elan had provided the underlying rights to Stat-Trade, Inc. ("STI") and STI simultaneously assigned its rights to the license to Hi-Tech. Future purchases of the product from Elan are locked in at a predetermined price in US dollars and are not subject to fluctuations in foreign currency exchange rates for a period of five years.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Hi-Tech Pharmacal Co., Inc.
Amityville, New York

We have audited the accompanying balance sheets of Hi-Tech Pharmacal Company, Inc. (the "Company") as of April 30, 2004 and 2003, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended April 30, 2004. 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 the standards of the Public Company Accounting 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 financial statements referred to above present fairly, in all material respects, the financial position of the Company as of April 30, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended April 30, 2004, in conformity with U.S. generally accepted accounting principles.

EISNER LLP

New York, New York
June 17, 2004

HI-TECH PHARMACAL CO., INC.

BALANCE SHEETS

	April 30,	
	2004	**2003**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$32,627,000	$15,584,000
Investments in marketable securities – available for sale	10,005,000	—
Accounts receivable (less allowances for doubtful accounts of $275,000 and $270,000 at April 30, 2004 and 2003)	9,849,000	5,609,000
Inventory	7,104,000	6,824,000
Prepaid taxes	1,039,000	1,881,000
Deferred taxes	1,077,000	718,000
Other current assets	1,277,000	947,000
TOTAL CURRENT ASSETS	**$62,978,000**	**$31,563,000**
Property and equipment, net	12,321,000	11,571,000
Other assets	253,000	694,000
TOTAL	**$75,552,000**	**$43,828,000**

HI-TECH PHARMACAL CO., INC.

LIABILITIES		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ —	$ 62,000
Accounts payable	4,530,000	5,237,000
Accrued expenses	2,676,000	2,179,000
TOTAL CURRENT LIABILITIES	**$ 7,206,000**	**$ 7,478,000**
Deferred taxes	1,558,000	1,310,000
TOTAL LIABILITIES	**$ 8,764,000**	**$ 8,788,000**
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.01 per share; authorized 3,000,000 shares, none issued		
Common stock, par value $.01; authorized 50,000,000 shares; 8,386,000 and 7,438,000 shares issued at April 30, 2004 and 2003, respectively	84,000	74,000
Additional paid-in capital	38,822,000	13,479,000
Retained earnings	28,880,000	22,288,000
Treasury stock, 303,250 and 292,050 shares of common stock, at cost April 30, 2004 and 2003.	(998,000)	(801,000)
TOTAL STOCKHOLDERS' EQUITY	**$66,788,000**	**$35,040,000**
TOTAL	**$75,552,000**	**$43,828,000**

See notes to Financial Statements

HI-TECH PHARMACAL CO., INC.

STATEMENTS OF OPERATIONS

	2004	2003	2002
NET SALES	$56,366,000	$47,446,000	$33,282,000
Cost of goods sold	26,207,000	23,508,000	17,507,000
GROSS PROFIT	30,159,000	23,938,000	15,775,000
COST AND EXPENSES:			
Selling, general and administrative expense	16,758,000	13,262,000	8,941,000
Research and product development costs	3,820,000	2,095,000	1,747,000
Contract research (income)	(504,000)	(216,000)	(368,000)
Interest expense	24,000	32,000	55,000
Interest (income) and other	(281,000)	(205,000)	(202,000)
TOTAL	$19,817,000	$14,968,000	$10,173,000
Income before provision for income taxes	10,342,000	8,970,000	5,602,000
Provision for income taxes	3,750,000	3,243,000	2,089,000
NET INCOME	$ 6,592,000	$ 5,727,000	$ 3,513,000
BASIC EARNINGS PER SHARE	$ 0.84	$ 0.83	$ 0.53
DILUTED EARNINGS PER SHARE	$ 0.74	$ 0.74	$ 0.48
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING BASIC	7,873,000	6,893,000	6,690,000
EFFECT OF POTENTIAL COMMON SHARES	985,000	811,000	687,000
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING DILUTED	8,858,000	7,704,000	7,377,000

See notes to Financial Statements

HI-TECH PHARMACAL CO., INC.

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid in Capital	Retained Earnings	Treasury Stock at Cost	Total Stockholders' Equity
	Shares	Amount				
BALANCE—APRIL 30, 2001	**6,791,000**	**$68,000**	**$ 8,665,000**	**$13,048,000**	**$(801,000)**	**$20,980,000**
Net income				3,513,000		3,513,000
Issuance of options for consulting			106,000			106,000
Exercise of options	303,000	3,000	914,000			917,000
Tax benefit from exercise of options			595,000			595,000
BALANCE—APRIL 30, 2002	**7,094,000**	**71,000**	**10,280,000**	**16,561,000**	**(801,000)**	**26,111,000**
Net income				5,727,000		5,727,000
Issuance of options for consulting			41,000			41,000
Exercise of options and warrants	344,000	3,000	1,242,000			1,245,000
Tax benefit from exercise of options			1,916,000			1,916,000
BALANCE—APRIL 30, 2003	**7,438,000**	**74,000**	**13,479,000**	**22,288,000**	**(801,000)**	**35,040,000**
Net income				6,592,000		6,592,000
Exercise of options	88,000	1,000	360,000			361,000
Issuance of stock	860,000	9,000	23,589,000			23,598,000
Purchase of treasury stock					(197,000)	(197,000)
Issuance of options for consulting			443,000			443,000
Tax benefit from exercise of options			951,000			951,000
BALANCE—APRIL 30, 2004	**8,386,000**	**$84,000**	**$38,822,000**	**$28,880,000**	**$(998,000)**	**$66,788,000**

See notes to Financial Statements

HI-TECH PHARMACAL CO., INC.

STATEMENTS OF CASH FLOWS

	Year Ended April 30,		
	2004	**2003**	**2002**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	$ 6,592,000	$ 5,727,000	$ 3,513,000
Adjustments to reconcile net income to net cash provided by operating Activities:			
Depreciation and amortization	1,475,000	1,331,000	1,225,000
Loss on sale of equipment			10,000
Valuation of options and warrants for consulting expense	258,000	451,000	106,000
Deferred income taxes	(111,000)	(47,000)	(121,000)
Tax benefit from exercise of options	951,000	1,916,000	595,000
Provision for doubtful accounts	5,000		30,000
CHANGES IN OPERATING ASSETS AND LIABILITIES:			
Accounts receivable	(4,245,000)	(59,000)	(1,145,000)
Inventory	(280,000)	(804,000)	(533,000)
Prepaid taxes / Taxes payable	842,000	(1,417,000)	(717,000)
Other current assets	(330,000)	(161,000)	60,000
Other assets	441,000	26,000	19,000
Accounts payable	(707,000)	730,000	1,225,000
Accrued expenses	682,000	(274,000)	(157,000)
NET CASH PROVIDED BY OPERATING ACTIVITIES	**$ 5,573,000**	**$ 7,419,000**	**$ 4,110,000**
CASH FLOWS FROM INVESTING ACTIVITIES:			
Investment in marketable securities	(10,005,000)	—	—
Purchase of fixed assets	(2,225,000)	(3,412,000)	(1,329,000)
Proceeds from sale of equipment	—	—	50,000
Deposit for purchase of building			(65,000)
NET CASH (USED IN) INVESTING ACTIVITIES	**$(12,230,000)**	**$(3,412,000)**	**$(1,344,000)**

CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments—long-term debt	(62,000)	(155,000)	(340,000)
Issuance of common stock and exercise of options	23,959,000	1,245,000	917,000
Purchase of treasury stock	(197,000)		
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	**23,700,000**	**1,090,000**	**$ 577,000**
NET INCREASE IN CASH AND CASH EQUIVALENTS	**17,043,000**	**5,097,000**	**3,343,000**
Cash and cash equivalents at beginning of year	15,584,000	10,487,000	7,144,000
CASH AND CASH EQUIVALENTS AT END OF YEAR	**$32,627,000**	**$15,584,000**	**$10,487,000**
Supplemental disclosure of cash flow information			
Cash paid for: Interest	$ 24,000	$ 32,000	$ 57,000
Income taxes	$ 1,900,000	$ 2,960,000	$ 2,317,000

See notes to Financial Statements

(NOTE A) The Company and Summary of Significant Accounting Policies:

[1] Business:

Hi-Tech Pharmacal Co., Inc. (the "Company" or "Hi-Tech") manufactures and sells prescription and over-the-counter generic drugs, in liquid and semi-solid dosage forms including higher margin prescription products. In the generic drug industry, certain products may contribute significantly to a Company's gross profit. The gross profit on these products may change as market conditions change. The Company markets its products in the United States through distributors, retail drug and mass-merchandise chains and mail order companies. Sales of the Company are seasonal and usually peak between September and March of each year. This seasonality is caused by the fact that a significant portion of the Company's products are pharmaceutical preparations acting on the human respiratory system.

Generic pharmaceutical products, which include private label contract manufacturing, had net sales of $50,307,000, $40,815,000, and $27,232,000 for years ended April 30, 2004, 2003 and 2002, respectively.

Health Care Products Division, which markets the Company's branded products, had net sales of $6,059,000, $6,631,000 and $6,050,000, for the years ended April 30, 2004, 2003 and 2002, respectively.

[2] Inventory:

Inventories are valued at the lower of cost (first-in first-out or average cost) or market.

[3] Property and equipment:

Property and equipment is stated at cost less accumulated depreciation and amortization. Estimated accumulated depreciation and amortization of the respective assets is computed using the straight line method over their estimated useful lives.

[4] Income taxes:

The Company uses the liability method to account for deferred income taxes in accordance with statement of financial accounting standards ("SFAS") No. 109. 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 asset or liability is adjusted to reflect changes in the tax law as they occur.

[5] Revenue recognition:

Revenue is recognized for product sales upon shipment and passing of risk to the customer and when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured and the Company has no further performance obligations. These estimates are presented in the financial statements as reductions to net revenues and accounts receivable. The Company has estimated sales returns, allowances and discounts. Contract research income is recognized as work is completed and as billable costs are incurred. In certain cases, contract research income is based on attainment of designated milestones.

[6] Advertising Expense:

Advertising costs are expensed when first shown. Advertising expense for the years ended April 30, 2004, 2003 and 2002 amounted to $2,446,000, $1,969,000 and $1,682,000, respectively.

[7] Freight Expense:

Freight costs are included in selling, general, and administrative expense.

[8] Research and Development Costs:

Research and product development costs are charged to expense as incurred.

[9] Cash and cash equivalents:

The Company considers U.S. Treasury bills and government agency obligations with a maturity of three months or less when purchased to be cash equivalents.

[10] Earnings per share:

Basic earnings per common share is computed based on the weighted average number of common shares outstanding. Diluted income per common share gives effect to all dilutive potential common shares outstanding during the year. The dilutive effect of the outstanding options and warrants was computed using the treasury stock method. The number of potentially dilutive securities excluded from the computation of diluted income per share was approximately 244,000 at April 30, 2004.

[11] Long-lived assets:

The Company has adopted SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", which supersedes SFAS No. 121, and accounting and reporting provisions of Accounting Principles Board Opinion No. 30 ("APB30") for the disposal of a segment of a business. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long lived assets and discontinued operations. The Company records impairment losses on long-lived assets used in operations, including intangible assets, when events and circumstances indicate that the assets might be impaired and the un-discounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. No such losses have been incurred.

[12] Use of estimates:

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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. Such estimates by management include sales returns, chargebacks, allowances and discounts, inventory obsolescence, the useful lives of property and equipment and its impairment, impact of legal matters and the realization of deferred tax assets represent a significant portion of the estimates made by management.

[13] Stock-based compensation:

At April 30, 2004, the Company had various stock option plans, which are described more fully in Note M. As permitted under SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure," which amended SFAS No. 123, "Accounting for Stock-Based Compensation," the Company has elected to continue to follow the intrinsic value method in accounting for its stock-based employee compensation arrangements as defined by Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and related interpretations including Financial Accounting Standards Board Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation," an interpretation of APB No. 25. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation.

	Year Ended April 30,		
	2004	2003	2002
Reported net income	$6,592,000	$5,727,000	$3,513,000
Stock-based employee compensation determined under the fair value based method, net of tax	$ (672,000)	$ (273,000)	$ (170,000)
Pro forma net income	$5,920,000	$5,454,000	$3,343,000
Basic earnings per share:			
As reported	$ 0.84	$ 0.83	$ 0.53
Pro forma	$ 0.75	$ 0.79	$ 0.50
Diluted earnings per share:			
As reported	$ 0.74	$ 0.74	$ 0.48
Pro forma	$ 0.67	$ 0.71	$ 0.45

The fair value of each option is estimated on the date of grant, using the Black-Scholes option-pricing model with the following assumptions:

	2004	2003	2002
Risk-free interest rate	3.28% – 3.74%	2.75% – 3.13%	4.24% – 4.53%
Expected life of options	5	5	5
Expected stock price volatility	63.00%	61.00%	61.00%
Expected dividend rate	0.00%	0.00%	0.00%

The Black Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options. The pro-forma effect on net income in fiscal 2004, 2003 and 2002 is not necessarily representative of the pro-forma effect on net income in future years because it does not take into consideration pro-forma compensation expense related to grants made prior to fiscal 1998. The weighted average fair value of options granted is $12.67 in fiscal 2004, $8.29 in fiscal 2003 and $4.83 in fiscal 2002.

[12] New Accounting pronouncements:

SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity," which was issued May 2003, will require redeemable preferred stock to be classified, in certain circumstances, as a liability, upon adoption by a public company at the beginning of the first interim period beginning after June 15, 2003. SFAS No. 150 provides that mandatorily redeemable preferred stock should be classified as a liability if it embodies an unconditional obligation requiring the issuer to redeem the shares by transferring its assets at a specified or determinable date or upon an event certain to occur. The Company does not currently have any financial instruments with these characteristics. SFAS No. 150 had no effect on the Company's results of operations and financial position.

In May 2003, the FASB issued FAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ("FAS 149"). FAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under FAS No. 133. FAS 149 is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. The adoption of FAS 149 did not have any impact on the Company's financial position or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for an entity that changes to the fair value method of accounting for stock-based employee compensation. In addition, SFAS 148 amends the disclosure provisions of SFAS 123 to require expanded and more prominent disclosures in annual financial statements about the method of accounting for stock based compensation and the proforma effect on reported results of applying the fair value method for entities that use the intrinsic value method. The proforma disclosures are also required to be displayed prominently in interim financial statements. The Company does not intend to change to the fair value method of accounting and has included the disclosure requirements of SFAS 148 in the accompanying financial statements.

In January 2003, the FASB issued FASB Interpretation 46 ("FIN 46"), Consolidation of Variable Interest Entities which was revised December 2003. FIN 46 clarifies the application of Accounting Research Bulletin 51, Consolidated Financial Statements, for certain entities that do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties or in which equity investors do not have the characteristics of a controlling financial interest ("variable interest entities"). Variable interest entities within the scope of FIN 46 will be required to be consolidated by their primary beneficiary. The primary beneficiary of a variable interest entity is determined to be the party that absorbs a majority of the entity's expected losses, receives a majority of its expected returns, or both. Entities that have interests in variable interest entities or special purpose entities, FIN 46 applies for periods ending after December 15, 2003. Application of this interpretation for all public entities, other than small business issuers, is effective for periods ending after March 15, 2004. The adoption of FIN46 had no impact on the financial condition or results of operations of the Company.

(NOTE B) Marketable Securities:

Marketable securities consist primarily of corporate bonds and government asset-backed securities with maturities greater than three months at the time of purchase and are classified as available for sale. These securities, which are classified as available for sale, are carried at fair value, which approximated cost at April 30, 2004, and are held at an investment bank. The schedule of maturities as follows:

	April 30, 2004	Maturity Date
Schedule of maturities		
Corporate bond	$ 5,005,000	2029
Government asset-backed securities	5,000,000	2038
Total	$ 10,005,000	

(NOTE C) Inventory:

The components of inventory consist of the following:

	April 30,	
	2004	2003
Finished goods and work in process	$ 2,243,000	$2,869,000
Raw materials	4,861,000	3,955,000
Total	$ 7,104,000	$6,824,000

(NOTE D) Property and Equipment:

The components of net property and equipment consist of the following:

	April 30,	
	2004	2003
Land and building and improvements	$ 7,819,000	$ 7,037,000
Machinery and equipment	15,393,000	14,239,000
Transportation equipment	29,000	29,000
Computer equipment	1,171,000	990,000
Furniture and fixtures	759,000	651,000
	$25,171,000	$22,946,000
Accumulated depreciation and amortization	12,850,000	11,375,000
Total property and equipment—net	$12,321,000	$11,571,000

(NOTE E) Other Assets:

Included in other assets is the Company's investment in a joint venture for the marketing and development of a nutritional supplement. The net investment is approximately $182,000 and $172,000 at April 30, 2004 and 2003, respectively, on a cost basis. Mr. Reuben Seltzer, a director of the Company, has an ownership interest in the joint venture and is the son of Mr. Bernard Seltzer, Chairman of the Board of the Company.

(NOTE F) Customer Deposits and Contract Research Income:

Contract research income is recognized as work is completed and as billable costs are incurred. In certain cases, contract research income is based on attainment of designated milestones. Advance payments may be received to fund certain development costs.

(NOTE G) Credit Facility:

In October, 2002 the Company obtained a three year $8,000,000 revolving credit facility. The revolving credit facility bears interest at a rate selected by the Company equal to the Prime Rate or LIBOR plus 1.50%. Loans are collateralized by inventory, accounts receivable and other assets. The agreement contains covenants with respect to working capital, net worth and certain ratios, as well as other covenants and prohibits the payment of cash dividends. At April 30, 2004 and April 30, 2003 there were no borrowings under the credit facility.

(NOTE H) Long Term Debt:

Long-term debt consists of the following:

	April 30, 2003
Mortgage payable (1)	$ 31,000
Mortgage payable (2)	31,000
Total	$ 62,000
Less current portion	62,000
Long-term debt	$ 0

[1] The mortgage was payable in monthly installments of approximately $8,000 and interest at a varying rate of 1/2% above the bank's prime rate, 4.75% at April 30, 2003.

[2] The mortgage was payable in monthly installments of $3,125 plus interest at the rate of 1/2% over the bank's prime rate, 4.75% at April 30, 2003.

(NOTE I) Related Party Transactions:

The Company had an employment agreement with the Chairman of the Board which expired April 30, 2004. Compensation under the agreement for the years ended April 30, 2004, 2003 and 2002 was $266,000, $254,000, and $242,000, respectively. The agreement also provided for a bonus equal to 1% of the annual increase of net sales of the Company. Annual bonuses under the agreement were $89,000, $142,000 and $30,000 for the years ended April 30, 2004, 2003 and 2002, respectively. The Company and the Chairman are in the process of negotiating the terms of a new employment agreement. The Company continues to pay the annual salary under the expired employment agreement.

The Company has an employment agreement with the President and Chief Executive Officer which was amended effective May 1, 2004 through April 30, 2007. Compensation under the agreement for the years ended April 30, 2004, 2003, and 2002 was $365,000, $364,000, and $347,000, respectively. The agreement provides for a base salary of $364,000 for the fiscal year ended April 30, 2005 with 5% increases for each following year. The agreement also provides for an annual bonus based on the income of the Company. Annual bonuses under the agreement were $323,000, $233,000 and $154,000 for the years ended April 30, 2004, 2003 and 2002, respectively.

The Company utilizes the services of Mr. Reuben Seltzer, an attorney and a director, and the son of the Company's Chairman of the Board. He provided legal and new business development services throughout the year. For each of the fiscal years 2004, 2003 and 2002 he received fees and expense reimbursements of $155,000, $140,000, and $128,000 respectively.

In addition, in each of fiscal years 2002 and 2001 the Company granted Mr. Reuben Seltzer an option to purchase 37,500 shares of the Company's common stock at an exercise price of $5.76 and $2.67, respectively, which vests at 25% per annum and are exercisable through 2005 and 2006, respectively. During the years ended April 30, 2004, 2003 and 2002, the Company valued this option using the Black Scholes option pricing model at $258,000, $451,000, and $93,000, respectively, which was charged to operations. Corresponding liabilities of $225,000 and $410,000 have been included in accrued expenses at April, 2004 and April 2003, respectively.

The Company valued this option using the Black Scholes option pricing model assuming risk free rate of 2.31%-4.40%, volatility of 61%-63%, dividend yield of 0%, 5 year term and a stock price of $19.58 to $34.00 and an exercise price of $2.67 to $5.76 for the year ended April 30, 2004, risk free rate of 2.85%-4.40%, volatility of 58%-61%, dividend yield of 0%, 5 year term and a stock price of $6.67 to $33.90 and an exercise price of $2.67 to $5.76 for the year ended April 30, 2003 and a risk free rate of 3.66%-4.53%, volatility of 42%-58%, dividend yield of 0%, 5 year term, stock price of $7.53 to $7.73 and an exercise price of $2.67 to $5.76 for the year ended April 30, 2002.

The Company may record additional expenses relating to these options until they are fully vested at the then market price, at which time a corresponding adjustment will be made to stockholders equity.

Tashlik, Kreutzer, Goldwyn and Crandell P.C. received $283,000, $252,000, and $105,000 in legal fees and disbursements in each of the years ended April 30, 2004, 2003 and 2002, respectively, for services performed for the Company. Mr. Martin M. Goldwyn, a member of such firm, is a director of the Company.

(NOTE J) Commitments and Contingencies:

[1] Government regulation:

The Company's products and facilities are subject to regulation by a number of Federal and State governmental agencies. The Food and Drug Administration ("FDA"), in particular, maintains oversight of the formulation, manufacture, distribution, packaging and labeling of all of the Company's products. The Company believes that it is substantially in compliance with the FDA's Good Manufacturing Practices.

[2] Employment agreements:

The Company has an employment agreement with the Vice President and Chief Financial Officer which expires July 31, 2005. The agreement automatically renews for successive one-year terms. Annual base salary through July 31, 2004 is $175,000 and $200,000 through July 31, 2005. The agreement provides for annual bonuses of not less than $25,000.

[3] Contractual Obligations:

The Company has entered into agreements for two studies on a product Hi-Tech has under current development. The total commitment under the agreements is $2.1 million which is expected to be paid by April 30, 2005.

[4] Legal Proceedings:

On December 18, 2003, Daiichi Pharmaceutical Co., Ltd. filed a complaint against the Company in the United States District Court for the District of New Jersey alleging infringement of its patent for a drug known as Levofloxacin, which it has sublicensed exclusively to Santen Inc. for use in certain ophthalmic pharmaceutical preparations. The plaintiff seeks a permanent injunction against the Company from engaging in the marketing within the United States of Levofloxacin Opthalmic Solution, described in the Company's new drug application with the United States Food and Drug Administration. On February 17, 2004, the Company filed an Answer and Counterclaim to the Complaint denying infringement of any valid claim in the patent suit, seeking a judicial declaration that the patent is invalid and not infringed. The Company believes it has meritorious defenses to the allegations in the Complaint. Legal costs in connection with this complaint are being paid for by a business partner.

On or about November 24, 2003 MedPointe Healthcare, Inc. ("MedPointe") filed a Verified Complaint and Application for Order to Show Cause with Temporary Restraints against the Company in the United States District Court for the District of New Jersey, Trenton vicinage. The suit alleges willful infringement by the Company of MedPointe's patent No. 6,417,206 as a result of the Company's offering to sell its Tannate 12-D S product, as a generic equivalent to MedPointe's Tussi-12®D S. On December 1, 2003 the Court entered Temporary Restraints against the Company pending the return date of the Order to Show Cause. On March 1, 2004 the Court issued a preliminary injunction enjoining the Company from marketing its Tannate 12-D S product. The Company will therefore not commence shipment of the Tannate 12-D S product until a final decision of the Court on the patent infringement claim has been reached. The Company has filed an appeal of this ruling. It is impossible to predict with certainty the outcome of this litigation.

On or about October 28, 2002 an action was commenced in the United States District Court for the Northern District of Texas, Dallas Division, against the Company, Wyeth, Wyeth Consumer Healthcare, Bayer Corporation, Bayer A.G., Novartis Consumer Health, Inc., Novartis Pharmaceuticals Corporation, Schering-Plough Corporation, The Delaco Company and Chattem, Inc. The complaint alleges claims for permanent and debilitating injuries as a result of exposure to phenylpropanolamine (hereinafter referred to as "PPA") through ingestion of PPA-containing products designed, formulated, marketed, distributed and/or sold by the Company and the other defendants. One plaintiff, Roger Grantham, claims he ingested a PPA-containing product manufactured by the Company. Mr. Grantham is a plaintiff in the Amanda Carrisalez case, which was originally filed in the United States District Court for the Northern District of Texas and was then transferred to the Multidistrict Litigation in Seattle. The plaintiffs, individually, seek compensatory damages in the amount of $15 million for actual damages, plus punitive damages. The Company filed an answer to this action and believes it has meritorious defenses. The Company's defense costs, after its deductible, are being covered under its product liability policy which has a $5 million limit for defense costs and liability ("Product Liability Policy"). The last date of sale of the limited number of products containing PPA by the Company was December 2000.

In March 2001, the Center for Environmental Health ("CEH") filed a lawsuit against several defendants alleging violations of California's Proposition 65 and Unfair Trade Practices Act for failure to provide clear and reasonable warnings regarding the carcinogenicity and reproductive toxicity of lead and the reproductive toxicity of cadmium to the users of FDA-approved anti-diarrheal medicines. In May 2004, the Company signed a settlement agreement, subject to Court approval. The settlement agreement provides that the Company may sell a reformulated product or the original formulated product with certain warnings. The Company believes that its liability in this matter will not exceed approximately $75,000.

The Company believes that these litigation matters will not have a material effect on the financial position of the Company.

From time to time, the Company becomes involved in various legal matters in addition to the above described matters that the

Company considers to be in the ordinary course of business. While the Company is not presently able to determine the potential liability, if any, related to such matters, the Company believes none of such matters, individually or in the aggregate, will have a material adverse effect on its financial position.

(NOTE K) Fair Value of Financial Instruments:

The carrying amounts of certain financial instruments such as cash and cash equivalents, investments, accounts receivable, accounts payable, short-term borrowings and long-term debt approximate their fair values. The fair values of the financial instruments are determined by reference to market data and other valuation techniques, as appropriate.

(NOTE L) Income Taxes:

[1] The provision for income taxes is comprised of the following:

	Year Ended April 30,		
	2004	2003	2002
Current:			
Federal	$3,697,000	$3,137,000	$1,948,000
State	164,000	153,000	262,000
Deferred:			
Federal	(99,000)	(40,000)	(103,000)
State	(12,000)	(7,000)	(18,000)
Total	$3,750,000	$3,243,000	$2,089,000

[2] Expected tax expense based on the statutory rate is reconciled with actual tax expense as follows:

	Year Ended April 30		
	2004	2003	2002
Statutory rate	34.0%	34.0%	34.0%
State income tax, net of federal income tax benefit	1.8%	1.7%	3.3%
Other	0.5%	0.5%	0.0%
Effective tax rate	36.3%	36.2%	37.3%

For the periods ended April 30, 2004, April 30, 2003, and April 30, 2002 the Company's state effective tax rate was reduced due to the utilization of state investment tax credits. Future state income tax rates may be affected by the availability of state investment tax credits.

[3] Deferred tax assets and liabilities are composed of the following:

	April 30, 2004	April 30, 2003
Current deferred tax assets:		
Allowances and write-offs not currently deductible for accounts recievable and doubtful accounts	510,000	222,000
Expenses not currently deductible	567,000	496,000
	1,077,000	718,000
Non-current deferred tax liability:		
Depreciation	(1,558,000)	(1,310,000)

(NOTE M) Common Stock:

[1] Stock Option Plans:

The Company's 1992 Stock Option Plan, as amended (the "Plan") provides for the issuance of either incentive stock options or non-qualified stock options. The maximum number of shares of common stock for which options may be granted is 2,738,000 shares. All stock options granted are exercisable at a price determined by the stock option committee of the Plan. However, Incentive Stock Options ("ISOs"), as defined by the Internal Revenue Code, must not be less than the fair market value of the stock, at the date of grant. All options are exercisable in installments commencing one year from date of grant and must be exercised within ten years of the date of grant, except for ISOs granted to persons owning more than 10% of the Company's common stock which must be exercised within five years of the date of the grant.

In August 1994 the Company adopted the 1994 Directors Stock Option Plan (the "Directors Plan") and reserved 300,000 shares of common stock for issuance thereunder. The Directors Plan provides for the annual grant of options to purchase 7,500 shares of common stock (plus 750 additional shares for committee chairpersons) to non-employee directors at fair market value at the date of grant.

[2] Additional information with respect to the 1992 Stock Option Plan is as follows:

	Options		Exercisable Options	
	Number of Shares	Weighted Average Exercise Price Per Share	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at April 30, 2001	1,354,538	$ 3.193	967,257	$ 3.38
Cancelled	(6,825)	$ 2.937		
Exercised	(297,525)	3.060		
Granted	270,675	5.923		
Outstanding at April 30, 2002	1,320,863	$ 3.784	847,217	$ 3.40
Cancelled	(13,650)	4.819		
Exercised	(305,875)	3.974		
Granted	286,950	15.041		
Outstanding at April 30, 2003	1,288,288	$ 6.231	705,098	$ 3.26
Cancelled	(12,249)	7.28		
Exercised	(88,305)	4.19		
Granted	244,300	22.95		
Outstanding at April 30, 2004	1,432,034	$ 9.18	825,011	$ 4.40

(NOTE M) Common Stock (continued):

The following table summarizes information about the 1992 Stock Option Plan at April 30, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 2.45 to $ 2.75	451,018	4.7	$ 2.60	407,078	$ 2.59
$ 3.50 to $ 3.50	179,024	2.7	3.50	179,024	3.50
$ 4.00 to $ 4.42	59,250	1.8	4.42	59,250	4.42
$ 5.76 to $ 6.34	220,194	7.5	5.76	110,097	5.76
$ 12.47 to $ 13.05	128,248	8.6	12.53	32,062	12.53
$ 17.33 to $ 17.33	150,000	8.7	17.33	37,500	17.33
$ 22.49 to $ 29.93	244,300	9.6	22.95	—	
	1,432,034		$ 9.18	825,011	$ 4.40

At April 30, 2004, 488,938 shares were available for future grant under the Plan.

[3] Additional information with respect to the 1994 Directors Stock Option Plan is as follows:

	Options		Exercisable Options	
	Number of Shares	Weighted Average Exercise Price Per Share	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at April 30, 2001	103,500	$ 3.460	60,750	$ 3.83
Granted	23,250	$ 6.433		
Exercised	(5,250)	$ 3.083		
Outstanding at April 30, 2002	121,500	$ 4.049	70,125	$ 3.72
Granted	47,250	$10.964		
Exercised	(10,000)	$ 3.009		
Outstanding at April 30, 2003	158,750	$ 6.231	86,376	$ 4.11
Granted	31,500	$ 20.25		
Outstanding at April 30, 2004	190,250	$ 8.55	112,063	$ 4.86

The following table summarizes information about the 1994 Directors Stock Option Plan at April 30, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 2.75 to $ 3.50	46,250	5.0	$ 2.95	42,875	$ 2.96
$ 3.50 to $ 5.25	42,000	1.8	4.39	42,000	4.40
$ 5.25 to $ 6.50	23,250	7.5	6.43	11,625	6.43
$ 6.50 to $ 7.75	15,000	8.0	7.73	7,500	7.73
$ 12.00 to $ 12.50	32,250	8.6	12.47	8,063	12.47
$ 20.25	31,500	9.6	20.25	—	—
	190,250	6.5	$ 8.55	112,063	$ 4.86

At April 30, 2004, 94,500 shares were available for future grant under the Plan.

(NOTE M) Common Stock (continued):

[5] Stock buy-back program:

In May 1997, the Company announced a stock buy-back program under which the Board of Directors authorized the purchase of up to $1,000,000 of its common stock. In November 2003, the Company increased the stock buy-back program to an aggregate of $3,000,000. As of April 30, 2004 the Company had purchased 303,050 shares at a cost of $998,000.

[6] Warrants:

In November 2000, the Company granted 37,500 warrants to a consultant in return for financial advisory services and recorded a charge to operations of $38,000. In January 2003, the warrants were exercised using the cashless feature of the warrant.

(NOTE N) Significant Customers and Concentration of Credit Risk:

For the year ended April 30, 2004 two customers accounted for net sales of approximately 14 % and 11%, respectively. These customers represented approximately 31% of the accounts receivables at April 30, 2004. For the year ended April 30, 2003 two customers accounted for approximately 14 % and 11% of net sales and approximately 23% of accounts receivable at April 30, 2003. For the year ended April 30, 2004, two products accounted for approximately 13% and 11% of net sales.

Cash in excess of Federal Deposit Insurance Company limitations is held in certain banks.

(NOTE O) Savings Plan:

The Company has a defined contribution plan that qualifies under Section 401(k) of the Internal Revenue Code for the benefit of substantially all full time eligible employees. Employees may contribute between 1% and 15% of their salary up to the dollar maximum allowed by the Internal Revenue Service. Company contributions are voluntary and are made at the discretion of the Board of Directors. The Company contributed $155,000, $109,000, and $106,000, for fiscal years 2004, 2003 and 2002, respectively.

(Note P) Quarterly Financial Results (unaudited):

	Quarter				Year
	1	2	3	4	
Fiscal 2004					
Net Sales	$9,264,000	$15,653,000	$18,035,000	$13,414,000	$56,366,000
Gross profit	$4,748,000	$ 8,606,000	$ 9,628,000	$ 7,177,000	$30,159,000
Net income	$ 953,000	$ 2,402,000	$ 2,149,000	1,088,000	$ 6,592,000
Earnings per share—Basic	$ 0.13	$ 0.30	$ 0.27	$ 0.13	$ 0.84
Earnings per share—Diluted	$ 0.11	$ 0.27	$ 0.24	$ 0.12	$ 0.74
Fiscal 2003					
Net Sales	$8,829,000	$11,765,000	$15,913,000	$10,939,000	$47,446,000
Gross profit	$4,478,000	$ 6,214,000	$ 7,663,000	$ 5,583,000	$23,938,000
Net income	$ 944,000	$ 1,601,000	$ 1,911,000	1,271,000	$ 5,727,000
Earnings per share—Basic	$ 0.14	$ 0.23	$ 0.28	$ 0.18	$ 0.83
Earnings per share—Diluted	$ 0.13	$ 0.22	$ 0.24	$ 0.16	$ 0.74
Fiscal 2002					
Net Sales	$5,893,000	$ 8,454,000	9,341,000	9,594,000	33,282,000
Gross profit	$2,743,000	$ 3,833,000	4,774,000	4,425,000	15,775,000
Net income	$ 481,000	$ 878,000	1,009,000	1,145,000	3,513,000
Earnings per share—Basic	$ 0.07	$ 0.13	0.15	0.17	0.53
Earnings per share—Diluted	$ 0.07	$ 0.12	0.13	0.15	0.48

Per common share amounts for fiscal quarters have been calculated independently and may not in the aggregate equal the amount for the full year.

(Note Q) Subsequent Events:

In June 2004, the Company acquired exclusive rights to market and distribute Naprelan® (naproxen sodium) controlled release tablets in the United States, its territories, and Puerto Rico. Elan Pharmaceuticals, Inc. had provided the underlying rights to Stat-Trade, Inc. ("STI") and STI simultaneously assigned its rights to the license to Hi-Tech. As consideration for the acquisition, Hi-Tech paid $3.4 million in cash for the license and inventory, and approximately $170,000 for related acquisition costs. Hi-Tech will pay STI consulting fees on an ongoing basis based on net profits on the sales generated by Naprelan®.

HI-TECH PHARMACAL CO., INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON SCHEDULE II

To the Board of Directors and Stockholders
Hi-Tech Pharmacal Co., Inc.
Amityville, New York

Our audits were conducted for the purpose of forming an opinion on the basic financial statements of Hi-Tech Pharmacal Co., Inc. as of April 30, 2004 and 2003 and for each of the three years in the period ended April 30, 2004 taken as a whole. The information included on Schedule II is presented for purposes of additional analysis and is not a required part of the basic financial statements. Such information has been subjected to the auditing procedures applied in the audits of the basic financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

Eisner LLP

New York, New York
June 17, 2004

HI-TECH PHARMACAL CO., INC.

SCHEDULE II

HI-TECH PHARMACAL CO., INC.
VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at Beginning of Period	Charges in costs and expenses	Deductions	Balance at End of Period
Allowance for doubtful accounts				
Year ended April 30, 2004	$ 270,000	$ 5,000	(a)	$ 275,000
Year ended April 30, 2003	$ 270,000			$ 270,000
Year ended April 30, 2002	$ 240,000	$ 30,000	(a)	$ 270,000
Accumulated depreciation				
Year ended April 30, 2004	$11,375,000	$1,475,000		$12,850,000
Year ended April 30, 2003	$10,344,000	$1,331,000	$ 300,000(b)	$11,375,000
Year ended April 30, 2002	$ 9,377,000	$1,225,000	$ 258,000(b)	$10,334,000

(a) Change in reserve required
(b) Disposition of equipment or retirements

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

NONE

ITEM 9A. CONTROLS AND PROCEDURES.

Under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of the design and operation of its disclosure controls and procedures within 90 days of the filing date of this annual report, and, based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that these disclosure controls and procedures are effective. There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

HI-TECH PHARMACAL CO., INC.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The Board of Directors consists of six members. All Directors are elected at each Annual Meeting of Shareholders and hold office until the next Annual Meeting of Shareholders when their respective successors are duly elected and qualified.

Set forth below is the name and age of each Director, his position with the Company and his principal occupation during the past five years and the year in which each Director was first elected as a Director of the Company.

Name of Director	Principal Occupation and other Directorships	Age	Elected to the Board
Bernard Seltzer	Bernard Seltzer has been Chairman of the Company since January 1990. As of May 1, 1998 Mr. Seltzer resigned as President and Chief Executive Officer of the Company. From May 1983 to January 1990, Mr. Seltzer was Vice President of Sales of the Company. Prior thereto, Mr. Seltzer was the Vice President of Sales and Marketing of Ketchum Laboratories, Inc., a pharmaceutical manufacturer and the predecessor of the Company.	80	1983
David S. Seltzer	David S. Seltzer has been Chief Executive Officer and President of the Company since May 1, 1998 and a Director, Secretary and Treasurer since February 1992. From July 1992 to May 1, 1998 Mr. Seltzer was Executive Vice President - Administration and since July 1992, Vice President – Administration and Chief Operating Officer of the Company since March 1992. Mr. Seltzer received a B.A. in Economics from Queens College in 1984. David S. Seltzer is the son of Bernard Seltzer.	44	1992

Name of Director	Principal Occupation and other Directorships	Age	Elected to the Board
Reuben Seltzer	Reuben Seltzer has been a Director of the Company since April 1992. Mr. Seltzer is currently serving as a consultant to the Company on legal matters and special projects. Mr. Seltzer has been president of R.M. Realty Services Inc., a real estate investment and consulting company since May 1988. From May 1983 to May 1988 Mr. Seltzer was a vice president and attorney with Merrill Lynch Hubbard Inc., a real estate investment subsidiary of Merrill Lynch and Company. Mr. Seltzer received a B.A. in Economics from Queens College in 1978, a Juris Doctor from the Benjamin N. Cardozo School of Law in 1981 and a L.L.M. from the New York University School of Law in 1987. Reuben Seltzer is the son of Bernard Seltzer.	48	1992
Martin M. Goldwyn	Martin M. Goldwyn was elected a Director of the Company in May 1992. Mr. Goldwyn is a member in the law firm of Tashlik, Kreutzer, Goldwyn & Crandell P.C. Mr. Goldwyn received a B.A. in finance from New York University in 1974 and a Juris Doctor from New York Law School in 1977.	52	1992

Name of Director	Principal Occupation and other Directorships	Age	Elected to the Board
Yashar Hirshaut, M.D.	Yashar Hirshaut has been a Director of the Company since September 1992. Dr. Hirshaut is a practicing medical oncologist and is currently an Associate Clinical Professor of Medicine at Cornell University Medical College. Since July 1986, he has been a Research Professor of Biology at Yeshiva University. In addition, he has served as editor-in-chief of the Professional Journal of Cancer Investigation since July 1981. Dr. Hirshaut received a B.A. from Yeshiva University in 1959 and his medical degree from Albert Einstein College of Medicine in 1963.	65	1992
Robert M. Holster	Robert M. Holster was elected a Director of the Company in April, 2002. Mr. Holster is President and Chief Operating Officer of HMS Holding Corp. (NASD: HMSY), a company providing information based revenue enhancement services to healthcare providers and payors. From 1993 to 1998 Mr. Holster was President and Chief Executive Officer of HHL Financial Services Inc., a healthcare accounts receivable management company. Prior to that Mr. Holster served in a number of executive positions, including Chief Financial Officer of Macmillan, Inc. and Controller of Pfizer Laboratories, a division of Pfizer, Inc.	57	2002

Executive Officers

The executive officers of the Company are set forth in the table below. All executive officers are elected at the annual meeting or interim meetings of the Board of Directors. No arrangements or understanding exists between any executive officer and any other person pursuant to which he was elected as an executive officer.

Name	Age	Position and Period Served
Bernard Seltzer	80	Chairman of the Company since January 1990.
David S. Seltzer	44	Chief Executive Officer and President of the Company since May 1, 1998 and a Director, Secretary and Treasurer since February 1992. Mr. Seltzer served as Executive Vice President of Administration since February 1992.
Elan Bar-Giora	60	Executive Vice President-Operations of the Company since July 1992 and Vice President-Operations of the Company since August 1990.
William Peters	36	Vice President and Chief Financial Officer of the Company since May 2004.

Significant Employees

Name	Age	Position and Period Served
Tanya Akimova, Ph.D.	50	Director of New Business Development since October 2000.
Gary M. April	47	President of Health Care Products Division since May 1998 and Divisional Vice President of Sales since January 1993.
Edwin A. Berrios	51	Vice President of Sales since November 2000.

Name	Age	Position and Period Served
Joanne Curri	60	Director of Regulatory Affairs since January 1992.
Polireddy Dondeti, Ph.D.	39	Senior Director of Research and Development since October 2003.
Jesse Kirsh	43	Senior Director of Quality Assurance since March 1994.
Pudpong Poolsuk	60	Senior Director of Science since May 2000.
Margaret Santorufo	38	Vice President and Controller since May 2004.

Audit Committee

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The members of the Audit Committee are Robert M. Holster and Yashar Hirshaut M.D., and each member is independent as such term is defined under the rules promulgated by the National Association of Securities Dealers' listing standards. On March 16, 2004 we notified Nasdaq that effective January 1, 2004, due to the resignation of Martin M. Goldwyn from the Audit Committee, we would not be in compliance with the audit committee requirements set forth in Rule 4350A of the National Association of Securities Dealers. Nasdaq has granted us a cure period until the earlier of our next annual shareholders' meeting or January 1, 2005 to appoint a third member to the Audit Committee. Until such time, we are relying on an exemption from satisfying the audit committee requirements set forth in Rule 4350A, and we believe that the Audit Committee will not be materially adversely affected and will be able to act independently.

Audit Committee Financial Expert

The Board of Directors of the Company has determined that Robert M. Holster is an audit committee financial expert as defined by Item 401(h) of Regulation S-K of the Exchange Act and is independent within the meaning of Item 7(d)(3)(iv) of Schedule 14A of the Exchange Act.

Code of Ethics

We have adopted a code of ethics for directors, officers and employees. We will provide a copy of our Code of Ethics to any person, without charge, upon request to Hi-Tech Pharmacal Co., Inc., Attention: Investors Relations, 369 Bayview Avenue, Amityville, NY 11701, (631) 789-8228.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's Directors and Executive Officers and persons who own more than ten percent of a registered class of the

Company's equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, Directors and greater than ten percent shareholders are required by Securities and Exchange Commission regulation to furnish the Company with copies of all Section 16(a) forms they file. The Company believes that all Section 16(a) filing requirements were met during Fiscal 2004. In making this statement, the Company has relied on the written representations of its incumbent directors and officers and copies of the reports that they have filed with the Securities and Exchange Commission and Nasdaq.

ITEM 11. EXECUTIVE COMPENSATION.

The following table shows, for the fiscal years ended April 30, 2004, 2003, and 2002, the compensation paid or accrued by the Company to or for each of the executive officers of the Company.

I. SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation			Long Term Compensation Awards	
		Salary ($)	Bonus ($)	Other Annual Compensation (1) ($)	Securities Underlying Options/(#)(2)	All Other Compensation (3) ($)
Bernard Seltzer	2004	266,000	89,000	-0-	25,000	-0-
Chairman	2003	254,000	142,000	-0-	37,500	-0-
	2002	241,500	30,000	-0-	-0-	-0-
David S. Seltzer	2004	365,000	323,000	-0-	50,000	2,000
President, Chief	2003	364,000	233,000	-0-	75,000	7,100
Executive Officer,	2002	347,000	154,000	-0-	75,000	5,600
Secretary and Treasurer						
Elan Bar-Giora	2004	159,000	50,000	-0-	25,000	-0-
Executive Vice	2003	151,000	50,000	-0-	37,500	-0-
President- Operations	2002	140,000	44,000	-0-	15,000	-0-
Arthur S. Goldberg	2004	163,000	-0-	-0-	10,000	-0-
Vice President of Finance	2003	154,000	-0-	-0-	15,000	-0-
and Chief Financial Officer (4)	2002	138,000	15,000	-0-	11,250	-0-
William Peters	2004	112,000	-0-	-0-	15,000	900
Vice President of Corporate Development (4)						

(1) The named executive officers received various perquisites, the cost of which did not exceed the lesser of $50,000 or 10% of annual salary plus bonus.

(2) Adjusted to reflect a 3-for-2 stock split distributed January 2003.

(3) Represents the dollar value of the premium paid by the Company during the fiscal years ended April 30, 2004, 2003, and 2002 with respect to term life insurance for the benefit of the named executive officer.

(4) Subsequent to April 30, 2004, Arthur Goldberg retired and William Peters was appointed as Vice President and Chief Financial Officer. The Company will pay severence to Mr. Goldberg of approximately $55,000 pursuant to his employment agreement.

Stock Options

The following table contains information concerning the grant of stock options under the Company's Amended and Restated Stock Option Plan ("Plan") to the named executive officers of the Company during Fiscal Year 2004.

I. OPTION GRANTS IN LAST FISCAL YEAR

Individual Grants

Name	Number of Securities Underlying Options Granted (#)(1)	% of Total Options Granted to Employees in Fiscal Year	Exercise Price ($/Sh)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term 5%($)10%($)(2)
Bernard Seltzer	25,000	10%	$22.49	December 4, 2013	$ 354,000/$896,000
David S. Seltzer	50,000	20%	$22.49	December 4, 2013	$707,000/$1,792,000
Elan Bar-Giora	25,000	10%	$22.49	December 4, 2013	$ 354,000/$896,000
Arthur S. Goldberg	10,000	4%	$22.49	December 4, 2013	$ 141,000/$358,000
William Peters	15,000	6%	$29.93	September 9, 2013	$ 282,000/$716,000

(1) Options granted are scheduled to vest and become exercisable in yearly increments of 25% with full vesting occurring in four years. Options expire ten years after grant under the terms of the Company's Plan.

(2) Amount reflects the potential realizable value at assumed annual rate of appreciation for the option term based on a market value of underlying shares of common stock on the date of grant less the exercise price.

Option Exercises And Holdings

The following table sets forth information with respect to the named executives concerning the exercise of options during Fiscal Year 2004 and unexercised options held as of the end of Fiscal Year 2004.

III. AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

Name	Shares Acquired on Exercise (#)	Value Realized ($)	Number of Securities Underlying Unexercised Options at Fiscal Year-End (#) Exercisable/ Unexercisable	Value of Unexercised In-the-Money Options at Fiscal Year-End ($)(1) Exercisable/ Unexercisable
Bernard Seltzer	—	—	9,375/53,125	$ 32,000/$53,000
David S. Seltzer	—	—	450,000/162,500	$ 7,135,000/$1,006,000
Elan Bar-Giora	18,750	$ 603,713	65,625/64,375	$ 746,000/$281,000
Arthur S. Goldberg	12,063	$ 343,701	5,750/29,687	$ 44,000/$156,000

(1) Amounts reflect the market value of the underlying shares of Common Stock on April 30, 2004 less the exercise price.

Employment Contracts and Termination of Employment

Bernard Seltzer and David S. Seltzer serve as Chairman of the Board and as President and Chief Executive Officer, Chief Operating Officer, Secretary and Treasurer, respectively, of the Company. Bernard Seltzer resigned as President and Chief Executive Officer effective as of May 1, 1998. David Seltzer was elected to serve as President and Chief Executive Officer effective May 1, 1998. David Seltzer's employment agreement provides that his annual base salary is $382,884, for the fiscal year commencing May 1, 2004 through April 30, 2005. The increase in annual base salary for each fiscal year thereafter is determined by multiplying his annual base salary for the prior fiscal year by the greater of 5% or the increase in the Consumer Price Index as of May 1 of each such year over the index as of May 1 of the prior year. Bernard Seltzer's annual base salary for fiscal year May 1, 2003 through April 30, 2004 is approximately $266,000. Mr. Bernard Seltzer's employment agreement expired on April 30, 2004. The Company and Mr. Seltzer are in the process of negotiating the terms of a new employment agreement for him. The Company continues to pay Mr. Seltzer's annual salary under the expired employment agreement.

Mr. David Seltzer may receive a bonus during each year of his employment in accordance with the goals set by the Board of Directors. For the fiscal year ending April 30, 2005, the Board of Directors has set target performance goals so that if the Company's pre-tax net income exceeds 120% of the prior year's pre-tax net income, Mr. Seltzer's bonus shall equal a percentage of his base salary, which percentage shall be the product of

(i) the percentage increase of the Company's pre-tax net income from the pre-tax net income of the immediately preceding year and (ii) two and one-half (2 1/2). In the event the Company's pre-tax net income of any year exceeds the pre-tax net income of the immediately preceding year, the bonus shall accrue up to a maximum of 100% of the base salary. In the event the Company's pre-tax net income does not exceed the prior year's pre-tax net income, there will be no bonus to Mr. Seltzer. In addition to receiving his base salary and bonus, Mr. Seltzer may receive an additional bonus up to a maximum of 100% of his base salary during each year of his employment at the discretion of the Board of Directors, taking into account, among other things, progress toward strategic objectives not fully measured by pre-tax net income, including but not limited to the Company's acquisitions, strategic alliances and approvals of Abbreviated New Drug Applications by the Food and Drug Administration. The employment agreement also contains standard confidentiality provisions and a non-compete provision for a term of one year after the termination of his employment.

Under the employment agreement for David S. Seltzer, the Company will pay to his estate upon his death, his base salary for a period of twelve (12) months after the end of the month in which death occurred. In the event of total disability, he will continue to receive his base salary for the remaining term of his employment agreement. In addition to base salary, David S. Seltzer will be paid an amount equal to a percentage of the bonus, if any, based on the portion of such year in which death, total disability or termination of employment occurred. If termination is for cause or because he wrongfully leaves his employment, then, upon such occurrence, the employment agreement shall be deemed terminated and the Company shall be released from all obligations.

Arthur S. Goldberg retired from his service as Vice President-Finance and Chief Financial Officer of the Company effective June 5, 2004. Mr. Goldberg's annual base salary was approximately $162,000 for the period ending on July 31, 2005. Commencing August 1, 2003, his annual compensation was adjusted by the greater of (i) 5% or (ii) the percentage increase, if any, in the Consumer Price Index ("CPI") for the most recent calendar month for which the CPI has been published over the CPI for the same calendar month in the preceding year. The Company will pay Mr. Goldberg approximately $55,000 in severance pay. Such employment agreement contains standard confidentiality provisions.

The Company has an employment agreement with William Peters, the Vice President and Chief Financial Officer which expires on July 31, 2005. The agreement automatically renews for successive one-year terms. Annual base salary through July 31, 2004 is $175,000 and $200,000 through July 31, 2005. The agreement provides for annual bonuses of no less than $25,000. Mr. Peters received options to purchase 15,000 shares of the Company's Common Stock and on August 1, 2004, he will receive additional options to purchase 25,000 shares of the Company's Common Stock. The employment agreement provides for severance payments to Mr. Peters equal to (i) the sum of his salary for the greater of 6 months or the balance of the term of the agreement and (ii) the pro forma portion of his annual bonus which in no event will be less than the annual bonus for the second year of his employment in the event of termination. In the event of a termination upon total disability, the Company will pay to Mr. Peters the salary which would otherwise be payable to him during the continuance of such disability. Such employment agreement contains standard confidentiality provisions. In the event of a change in control and the Company terminates Mr. Peters' employment either 60 days prior to or following a change in control, other than for cause or his death or total disability ("Change in Control Termination"), the Company will pay or cause its successor to pay to Mr. Peters in a cash lump sum an amount equal to to 1.5 times his annual salary plus his annual bonus for the year immediately following the Change of Control Termination.

Director Compensation

For their service on the Board, the Company pays each director a fee of $500 per meeting. Each member of the Board is reimbursed for expenses incurred in connection with each Board or Committee meeting attended.

Stock Option Plans

The Amended and Restated Stock Option Plan (the "Plan")

The Company's Amended and Restated Stock Option Plan provides for a total of 2,738,000 shares of Common Stock authorized to be granted under such Plan. During Fiscal 2004, the Company granted options to purchase 229,300 shares of Common Stock at $22.49 per share and 15,000 shares at $29.93 per share. During Fiscal 2004, 12,249 options were cancelled or expired, and

488,938 shares are available for future grant under such Plan. The Company's Plan provides for the grant of options to its key employees and directors in order to give such employees a greater personal interest in the success of the Company and an added incentive to continue and advance in their employment. The Company's Plan provides for a fifteen year expiration period for non-statutory options and ten years for incentive stock options granted thereunder and allows for the exercise of options by delivery by the optionee of previously owned Common Stock of the Company having a fair market value equal to the option price, or by a combination of cash and Common Stock.

The Plan is administered by the Stock Option Committee of the Board of Directors. The Committee has broad discretion in determining the recipients of options and numerous other terms and conditions of the options.

The exercise price for shares purchased upon the exercise of non-statutory options granted under the Plan is determined by the Stock Option Committee as of the date of the grant.

The exercise price of an incentive stock option must be at least equal to the fair market value of the Common Stock on the date such option is granted (110% of the fair market value for shareholders who, at the time the option is granted, own more than 10% of the total combined classes of stock of the Company or any subsidiary). No employees may be granted incentive stock options in any year for shares having a fair market value, determined as of the date of grant, in excess of $100,000.

No incentive option may have a term of more than ten years (in the case of incentive stock options, five years for shareholders holding 10% or more of the Common Stock of the Company). Options generally may be exercised only if the option holder remains continuously associated with the Company or a subsidiary from the date of grant to the date of exercise. However, options may be exercised upon termination of employment or upon the death or disability of any employee within certain specified periods.

Directors Plan

The Company's 1994 Directors Stock Option Plan ("Directors Plan") provides for a total of 300,000 shares of Common Stock authorized to be granted under the Directors Plan.

The Directors Plan provides for the automatic annual grant of options to non-employee directors and is administered by the Board of Directors. Each non-employee director will be automatically granted 7,500 shares of Common Stock on the date of each annual meeting of the Company's shareholders. A non-employee director who chairs the audit or other committees of the Board of Directors will be automatically granted annually an option to purchase an additional 750 shares of Common Stock.

To remain eligible, a non-employee director must continue to be a member of the Board of Directors. Each option granted is exercisable in increments of 25% per year commencing on the first

anniversary date of the date of grant. The exercise price for all options may not be less than the fair market value of the Common Stock on the date of grant. Options under the Directors Plan have a term of 10 years and may be exercised for limited periods after a person ceases to serve as a director.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The following table identifies as of July 9, 2004 each person known to the Company to be the beneficial owner of more than five percent of the Company's Common Stock, each director of the Company, and all directors and officers of the Company as a group, and sets forth the number of shares of the outstanding Common Stock beneficially owned by each such person and such group and the percentage of the shares of the outstanding Common Stock owned by each such person and such group. Except as noted below, the named person has sole voting power and sole investment power over the securities.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership (1)	Percent of Common Stock
Bernard Seltzer c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	442,509(2)	5.3%
David S. Seltzer c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	1,438,231(3)	16.2%
Reuben Seltzer c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	889,486(4)	10.4%

Elan Bar-Giora c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	69,375(5)	*
Martin M. Goldwyn c/o Tashlik, Kreutzer, Goldwyn & Crandell P.C. 40 Cuttermill Road Great Neck, New York 11021	29,625(6)	*
Yashar Hirshaut, M.D. c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	41,750(7)	*
Robert M. Holster c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	9,563(8)	*
Arthur Goldberg c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	25,437(9)	*
William Peters c/o Hi-Tech Pharmacal Co., Inc. 369 Bayview Avenue Amityville, New York 11701	0	*
All Directors and Executive Officers as a group (8 persons)	2,945,976(10)	31.9%
Accipiter Capital MGMT LLC 717 Fifth Avenue New York, NY 10022	537,117	6.4%

* Amount represents less than 1% of Common Stock including shares issuable to such beneficial owner under options which are presently exercisable or will become exercisable within 60 days.

(1) Unless otherwise indicated, each person has sole voting and investment power with respect to the shares shown as beneficially owned by such person.

(2) Amount does not include 90,000 shares of Common Stock owned by Mr. Seltzer's wife, as to which Bernard Seltzer disclaims beneficial ownership.

(3) Amount includes options to purchase 468,750 shares of Common Stock exercisable within 60 days of July 9, 2004 and 282,211 shares of Common Stock owned by Mr. Seltzer's wife and children and a trust for the benefit of one of his children.

(4) Amount includes options to purchase 199,875 shares of Common Stock exercisable within 60 days of July 9, 2004 and 269,650 shares of Common Stock owned by Mr. Seltzer's wife and children.

(5) Amount includes options to purchase 69,375 shares of Common Stock exercisable within 60 days of July 9, 2004.
(6) Amount represents options to purchase 29,625 shares of Common Stock exercisable within 60 days of July 9, 2004.
(7) Amount represents options to purchase 41,750 shares of Common Stock exercisable within 60 days of July 9, 2004.
(8) Amount includes options to purchase 9,563 shares of Common Stock exercisable within 60 days of July 9, 2004.
(9) Amount includes options to purchase 25,437 shares of Common Stock exercisable within 60 days of July 9, 2004.
(10) Amount includes options to purchase 844,375 shares of Common Stock exercisable within 60 days of July 9, 2004.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

For the fiscal year ended April 30, 2004, Mr. Reuben Seltzer was engaged by the Company to provide new business development and legal services. For such services, Mr. Reuben Seltzer received $155,000. Mr. Reuben Seltzer is a director of the Company and the son of Mr. Bernard Seltzer, the Company's Chairman of the Board.

The Company and Reuben Seltzer each have an approximately 19.5% interest in Marco Hi-Tech JV Ltd., a New York corporation ("Marco Hi-Tech"), which markets raw materials for nutraceutical products and has licensed the patent rights to Huperzine and analogues from the Mayo Clinic. Marco Hi-Tech manufactures and distributes Huperzine as a dietary supplement under the Dietary Supplement Health and Education Act of 1994 and is developing analogues and derivatives to Huperzine. It is currently developing other products for the nutraceutical market.

The Company believes that material affiliated transactions between the Company and its directors, officers, principal stockholders or any affiliates thereof have been, and will be in the future, on terms no less favorable than could be obtained from unaffiliated third parties.

Tashlik, Kreutzer, Goldwyn & Crandell P.C. received $283,000 in legal fees and disbursements for services performed for the Company during the Company's fiscal year ended April 30, 2004. Mr. Martin M. Goldwyn, a member of such firm, is a director of the Company.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit and Audit-related Fees

Eisner LLP has served as the auditors for the Company for the fiscal year ended April 30, 2004. Eisner LLP billed us $158,000 and $164,000, in the aggregate, for professional services for the audit of our annual financial statements for fiscal 2004 and 2003, respectively, and for the review of our interim financial statements which are included in our quarterly reports on Form 10-Q for fiscal 2004.

Eisner LLP billed us $61,000 and $29,000 for other audit-related fees for fiscal 2004 and 2003, respectively. Other audit-related fees related primarily to services rendered in connection with our filing of registration statements with the SEC and due diligence in connection with potential acquisitions and accounting consultations.

Tax Fees

Eisner LLP billed us $24,000 and $46,000 for fiscal 2004 and 2003, respectively, for domestic tax preparation work.

All Other Fees

Eisner LLP has billed us $0 in the aggregate for professional services rendered for all services other than those services captioned "Audit Fees", "Tax Fees" and "Financial Information Systems Design and Implementation Fees" in fiscal 2004. These services included consulting and other services.

All non-audit services were reviewed with the Audit Committee, which concluded that the provision of such services by Eisner LLP was compatible with the maintenance of that firm's independence in the conduct of its auditing function.

Financial Information Systems Design and Implementation Fees

Eisner LLP did not provide and did not bill nor was paid any fees for financial information systems design and implementation services in fiscal 2004 and 2003 as described in paragraph (c)(4)(ii) of Rule 2-01 of Regulation S-X.

Policy on Audit Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditor

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of the independent auditor. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent auditor.

Prior to engagement of the independent auditor for the next year's audit, management will submit a list of services and related fees expected to be rendered during that year within each of four categories of services to the Audit Committee for approval.

1. *Audit* services include audit and review work performed on the financial statements, as well as work that generally only the independent auditor can reasonably be expected to provide, including comfort letters, statutory audits, and discussions surrounding the proper application of financial accounting and/or reporting standards.

2. *Audit-Related* services are for assurance and related services that are traditionally performed by the independent auditor, including due diligence related to mergers and acquisitions, employee benefit plan audits, and special procedures required to meet certain regulatory requirements.

3. *Tax* services include all services, except those services specifically related to the audit of the financial statements, performed by the independent auditor's tax personnel, including tax analysis; assisting with coordination of execution of tax related activities, primarily in the area of corporate development; supporting other tax related regulatory requirements; and tax compliance and reporting.

4. *Other Fees* are those associated with services not captured in the other categories. The Company generally does not request such services from the independent auditor.

Prior to engagement, the Audit Committee pre-approves independent auditor services within each category. The fees are budgeted and the Audit Committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent auditor for additional services not contemplated in the original pre-approval categories. In those instances, the Audit Committee requires specific pre-approval before engaging the independent auditor.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

(a) (1) Financial Statements filed as part of this Report are listed in Item 8 of this Report.

(2) No other financial schedules have been included because they are not applicable, not required or because required information is included in the consolidated financial statements or notes thereto.

(a) Exhibit Number	Description of Document	Page Number Foot- Notes
3.1	Certificate of Amendment to the Certificate of Incorporation	(1)
3.2	Restated Certificate of Incorporation and By-Laws	(2)
4.3	Copy of Hi-Tech Pharmacal Co., Inc. Stock Option Plan	(3)
4.4	Copy of Hi-Tech Pharmacal Co., Inc. Stock Option Agreement	(4)
4.5	Copy of 1994 Directors Stock Option Plan	(5)
*10.1	Amended and Restated Executive Employment Agreement with David S. Seltzer	
*10.2	Amendment No. 1 to Amended and Restated Executive Employment Agreement of David Seltzer	
10.3	Employment Agreement of William Peters	(6)
10.4	Revolving Credit and Term Loan Agreement, dated October 23, 2002. Confidential Treatment was granted for portions of this Agreement.	(7)
10.5	First Amendment to the Revolving Credit and Term Loan Agreement dated November 1, 2002. Confidential Treatment has been requested for portions of this agreement.	(8)
10.6	Second Amendment to the Revolving Credit and Term Loan Agreement dated November 15, 2002. Confidential Treatment was granted for portions of this agreement.	(9)
*23.1	Consent of Eisner LLP	
*31.1	Certification pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
*31.2	Certification pursuant to Rule 13a-14 or 15d-14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	
*32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	

* Filed herewith

(1) Filed as Exhibit 3.1 to Hi-Tech Pharmacal Co., Inc. Annual Report on Form 10-K for the fiscal year ended April 30, 2003 and incorporated herein by reference.

(2) Filed as Exhibit 3.0 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for the quarterly period ended October 31, 1994 and incorporated herein by reference.
(3) Filed as Exhibit 10.1 to Hi-Tech Pharmacal Co., Inc. Registration Statement on Form S-1 (No. 33-47860) and incorporated herein by reference.
(4) Filed as Exhibit 10.2 to Hi-Tech Pharmacal Co., Inc. Registration Statement on Form S-1 (No. 33-47860) and incorporated herein by reference.
(5) Filed as Exhibit 10.1 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for the quarterly period ended October 31, 1994 and incorporated herein by reference.
(6) Filed as Exhibit 10.3 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for the quarterly period ended July 31, 2003 and incorporated herein by reference.
(7) Filed as Exhibit 10.7 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for quarterly period ended October 31, 2002 and incorporated herein by reference.
(8) Filed as Exhibit 10.8 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for quarterly period ended October 31, 2002 and incorporated herein by reference.
(9) Filed as Exhibit 10.9 to Hi-Tech Pharmacal Co., Inc. Quarterly Report on Form 10-Q for quarterly period ended October 31, 2002 and incorporated herein by reference.

(b) A report on Form 8-K was filed on March 12, 2004.

HI-TECH PHARMACAL CO., INC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: July 14, 2004

HI-TECH PHARMACAL CO., INC.

By: /s/ David S. Seltzer

David S.Seltzer, Chief Executive Officer, President, Secretary & Treasurer

By: /s/ William Peters

William Peters
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

July 14, 2004

/s/ Bernard Seltzer

Bernard Seltzer, Chairman of the Board

/s/ David S. Seltzer — July 14, 2004

David S. Seltzer, Director,
Chief Executive Officer, President,
Treasurer, Secretary

July 14, 2004

/s/ Reuben Seltzer

Reuben Seltzer, Director

July 14, 2004

/s/ Martin M. Goldwyn

Martin M. Goldwyn, Director

July 14, 2004

/s/ Yashar Hirshaut, M.D.

Yashar Hirshaut, M.D., Director

July 14, 2004

/s/ Robert M. Holster

Robert M. Holster, Director

Corporate Information

Board of Directors

Bernard Seltzer
Chairman

David Seltzer
Chief Executive Officer and President

Reuben Seltzer
President of Marco - Hi-Tech, JV Ltd.

Martin M. Goldwyn (2)
Partner, Tashlik, Kreutzer, Goldwyn & Crandell PC

Yashar Hirshaut, M.D. (1)(2)(3)
Assoc. Clinical Professor of Medicine,
Cornell University Medical College
Research Professor of Biology Yeshiva University

Robert M. Holster (1)(2)(3)
President and Chief Executive Officer HMS Holdings Corp.

(1) Audit Committee Member
(2) Stock Option Committee Member
(3) Nominating Committee Member

Corporate Office

Hi-Tech Pharmacal Co., Inc.
369 Bayview Avenue, Amityville, NY 11701
(631) 789-8228

Counsel

Tashlik, Kreutzer, Goldwyn & Crandell PC
40 Cuttermill Road, Suite 200
Great Neck, NY 11021

Auditor

Eisner LLP
750 Third Avenue
New York, NY 10017-2703

Transfer Agent

Continental Stock Transfer & Trust Company
17 Battery Place, New York NY 10004

Form 10-K

A copy of the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, is available to shareholders on request. It may be obtained without charge by writing to:

Mr. David Seltzer, Secretary
Hi-Tech Pharmacal Co., Inc.
369 Bayview Avenue, Amityville, NY 11701

Executive Officers & Board of Directors

Bernard Seltzer
Chairman

David Seltzer
Chief Executive Officer and President

Elan Bar-Giora
Executive Vice President-Operations

William Peters
Vice President and Chief Financial Officer

Martin Goldwyn
Director

Reuben Seltzer
Director

Yashar Hirshaut, MD
Director

Robert Holster
Director

Hi·Tech® PHARMACAL Co, Inc.

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www.diabeticproducts.com