EON LABS INC
Form 10-K
March 16, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004 **Commission File No. 001-31333**

EON LABS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**13-3653818**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1999 Marcus Avenue	
Lake Success, New York	**11042**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(516) 478-9700**
Securities registered pursuant to Section 12(b) of the Act: **None**
(Title of Class)
Securities registered pursuant to Section 12(g) of the Act: **Common Stock, par value $.01**
(Title of Class)

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 x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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. o

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

The aggregate market value of common stock held by non-affiliates of the registrant as of June 30, 2004 was $1,169,777,026, based upon the closing price of the Common Stock on that date, as reported by The NASDAQ National Market. 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.

Common Stock, $.01 par value	**88,850,364 shares**

Class	Outstanding at March 11, 2005

EON LABS, INC.

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FOR THE YEAR ENDED DECEMBER 31, 2004

PART I

Item 1. Business.

Overview

Eon Labs, Inc. (the Company) is a generic pharmaceutical company engaged in developing, licensing, manufacturing, selling and distributing a broad range of prescription pharmaceutical products primarily in the United States. The Company focuses primarily on drugs in a broad range of solid oral dosage forms, utilizing both immediate and sustained release delivery, in tablet, multiple layer tablet, film-coated tablet and capsule forms. The Company does not depend on any single drug or therapeutic category for a majority of its sales. For the year ended December 31, 2004, the Company generated sales and operating income of approximately $431.0 million and $172.6 million, respectively, and had total assets of approximately $545.2 million.

On June 11, 2002, the Company completed its initial public offering of common stock, which resulted in net proceeds of $139.2 million and the issuance of 20,401,626 shares of common stock. Upon the consummation of the Company s initial public offering, all of the previously outstanding shares of the Company s preferred stock were converted into 60,000,000 shares of common stock, par value $0.01 per share (Common Stock) of the Company. (The foregoing share amounts have been adjusted to reflect a 2-for-1 stock split effected by the Company on June 1, 2004.)

On February 20, 2005, the Company entered into an Agreement and Plan of Merger (the Merger Agreement) with Novartis Corporation, a New York corporation (Novartis), Zodnas Acquisition Corp., a Delaware corporation and wholly owned subsidiary of Novartis (Merger Sub), and, solely with respect to its guarantee of Novartis s and Merger Sub s obligations thereunder, Novartis AG (Parent). Pursuant to the Merger Agreement, Merger Sub will commence a tender offer (the Offer) to purchase all of the issued and outstanding shares of the Company s Common Stock, (other than those shares owned by Santo Holding (Deutschland) GmbH (Santo)), at a purchase price of $31.00 per share (the Offer Price).

In connection with the execution of the Merger Agreement, Novartis, Santo and Parent entered into an Agreement for Purchase and Sale of Stock (the Santo Agreement), pursuant to which Novartis agreed to purchase, and Santo agreed to sell, all of the shares of Common Stock held by Santo (the Santo Shares, such transaction, the Santo Purchase), representing approximately 67.5% of the outstanding shares of Common Stock, for 1.3 billion in cash on the terms and subject to the conditions set forth therein.

The Offer is not conditioned upon any minimum number of shares being tendered, but is contingent upon the contemporaneous (or immediately subsequent) closing of the Santo Purchase pursuant to the Santo Agreement. In addition to certain customary conditions, the closing of the Santo Purchase is conditioned on the acquisition by Novartis (Deutschland) GmbH of all of the outstanding shares and partnership interests of Hexal AG (Hexal), including shares held directly and indirectly by Dr. Thomas Strüngmann, the Chairman of the Board of Directors of the Company and an indirect significant stockholder of Santo, and Dr. Andreas Strüngmann, an indirect significant stockholder of Santo. Additionally, the Santo Purchase is subject to customary regulatory approvals, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Following the completion of the Offer and the purchase of the Santo Shares, if a majority of the outstanding shares of Common Stock other than the Santo Shares are purchased in the Offer, in accordance with Delaware General Corporation Law (the DGCL), Merger Sub will be merged with and into the Company and any remaining shares of Common Stock will be acquired by Merger Sub.

The Merger Agreement provides that upon consummation of the Offer, the Confidentiality Agreement, dated February 11, 2005, between the Company and Novartis (which currently restricts the ability of Novartis and its affiliates to acquire shares of Common Stock other than the Santo Shares (the

Public Shares) without approval of a majority of the special committee of independent board members, which was appointed to review the Offer and the Merger, and of the Company s Board of Directors) will be amended to provide that Novartis and its affiliates will be permitted to make acquisitions of Public Shares that are voluntary to the holders of Public Shares (such as by means of legally permissible open market purchases or tender offers), but, prior to February 11, 2006, Novartis and Merger Sub will not be permitted to cause a merger transaction (or other business combination) to be effected which would cancel Public Shares unless (i) a majority of the outstanding Public Shares vote in favor of such a transaction or (ii) Novartis and its subsidiaries, at that time, own at least 90% of the outstanding Common Stock; provided, that the consideration to be received by the holders of Public Shares in any such transaction described in (ii) above must be at least equal to $31.00 per Public Share. Following the completion of the Offer and until the earlier of the consummation of the Merger and February 11, 2006, Novartis and Merger Sub are required to use their reasonable best efforts to keep the Common Stock quoted for trading on the NASDAQ National Market unless the Company is no longer required to be registered under the Securities Exchange Act of 1934, as amended (the Exchange Act), or no longer satisfies NASDAQ s listing standards (other than standards entirely within the Company s control).

At the effective time of the Merger, each issued and outstanding share of Common Stock (other than shares owned by Novartis, any of its subsidiaries (including Merger Sub) or any of its affiliates, any shares held in the treasury of the Company and shares held by stockholders who properly demand appraisal and comply with the provisions of Section 262 of the DGCL, relating to dissenters rights of appraisal) will be converted into the right to receive an amount equal to the Offer Price. Following the consummation of the Merger, the Company will continue as the surviving corporation and will be a wholly owned subsidiary of Novartis.

The Company was incorporated under the laws of Delaware in 1992. Its principal executive offices are located at 1999 Marcus Avenue, Lake Success, New York 11042, and its telephone number is (516) 478-9700. The Company s website is *www.eonlabs.com.* The Company s annual reports on Form 10-K, along with all other reports and amendments filed with or furnished to the Securities and Exchange Commission (the SEC) are publicly available free of charge on the investor relations section of the Company s website as soon as reasonably practicable after the Company files such materials with, or furnishes them to, the SEC. The information on the Company s website is not part of this or any other report the Company files with, or furnishes to, the SEC. The SEC maintains an Internet site (*http://www.sec.gov*) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Generic Pharmaceutical Industry

Overview And Demand For Generic Pharmaceuticals

In recent years, the market for generic pharmaceuticals has grown dramatically. The Company believes this growth has been driven by several factors, including:

- The aging of the U.S. population and the resulting greater utilization of prescription pharmaceutical products at affordable prices;

- Efforts by the 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; and

- The increasing number of pharmaceutical products whose patents have expired or will expire over the next several years and are or will be subject to competition from generic equivalents.

The Company believes these factors will continue to increase demand for generic pharmaceuticals and accelerate the growth of the generic pharmaceutical industry in future years. Due to the pricing dynamics of the generic pharmaceutical industry described below, the expected annual sales for any particular pharmaceutical product decreases significantly following the introduction of competition from generic pharmaceuticals.

ANDA Approval Process

Generic pharmaceutical products are the chemical and therapeutic equivalent of a reference brand drug. Food and Drug Administration (FDA) approval of an Abbreviated New Drug Application (ANDA) for a generic product is required before a generic equivalent of an existing brand-name drug can be marketed. In order to be approved by the FDA, generic pharmaceutical products generally must undergo testing that shows that they are bioequivalent to their branded counterparts and are manufactured to the same quality standards. Demonstrating bioequivalence requires data showing that the generic formulation results in a product whose rate and extent of absorption are within an acceptable range of the results achieved by the brand-name reference drug, which is typically determined by a blood level comparison of healthy volunteers.

The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and whether the brand-name manufacturer is entitled to one or more statutory exclusivity periods. Pending the resolution of any such issues, the FDA final approval of the ANDAs for these generic products may be delayed. According to the FDA, as of January 2005, the industry average for the length of time to secure FDA approval of an ANDA was approximately 16 months from the date of filing.

Generic pharmaceutical products are typically launched upon expiration of a branded product s patent. 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 its product in children (a so-called pediatric extension).

If there is a patent listed in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluation Book, which identifies drug products approved on the basis of safety and effectiveness by the FDA (commonly referred to as the Orange Book), at the time of filing an ANDA with the FDA and the generic drug company indicates that it 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 (a so-called Paragraph IV certification). A generic drug company that is the first to submit an ANDA with a Paragraph IV certification to an Orange Book patent may be eligible to receive a 180-day period of market exclusivity in connection with that patent, providing an opportunity for the company to increase its market share before competitors enter the market. See Government Regulation Patent Challenge Process.

Generic Pharmaceutical Pricing Dynamics

Although generic pharmaceuticals must meet the same quality standards as branded pharmaceuticals, they are sold at prices that are typically 20% to 80% below those of their branded counterparts. This discount tends to increase, and margins consequently decrease, as the number of generic competitors rises for a given branded product. Because of this pricing dynamic, companies that are first to market for a generic pharmaceutical tend to earn higher margins than companies that subsequently enter the market for that product. Furthermore, the developer of a generic product that is the first to submit an ANDA with a Paragraph IV certification that a patent on the brand-name drug is invalid, unenforceable and/or not infringed may be eligible to receive a 180-day period of generic market exclusivity. During that 180-day

period, the exclusive generic product would tend to earn higher margins on a higher volume of sales than in a market in which other generic competition was also present. Products that are difficult to develop requiring difficult-to-source raw materials or representing smaller therapeutic niche markets, are generally marketed by fewer companies and may also offer margins that are higher than those where barriers to entry do not exist. See Government Regulation Patent Challenge Process.

Product Development

The Company obtains new generic pharmaceutical products primarily through internal product development and from strategic licensing or co-development arrangements with Hexal, as well as with other companies.

Timely Execution Of The Product Development Process

The Company focuses on the timely execution of the product development process as it strives to be first to market with a generic product. Being first to market on a number of products has enabled the Company to gain and maintain favorable market share for those products.

The Company s management approach, particularly its emphasis on cross-functional responsibilities and teamwork, enables it to integrate the various steps of the product development process. As a result of the success of the Company s integrated approach to product development, it is able to commence the manufacture and marketing of commercial batches of its products in a timely manner. This allows the Company at times to be first to market with a generic product. The product development process consists of multiple steps involved in identifying and commercializing new generic products, including:

- *Product Selection, Including Raw Materials Procurement*. The first step in the process includes selecting a possible product and determining whether the Company can successfully develop and eventually manufacture that product. The Company must review the quality, availability and pricing of the active pharmaceutical ingredient. The Company s experience in the generic pharmaceutical industry, particularly its knowledge of the raw materials market, facilitates the development process and enables it to produce high-quality finished products in a timely manner. In the early stages of development, the Company concentrates on creating a durable formulation that can eventually be manufactured in large quantities in order to avoid costly and time-consuming pilot plant activities.

- *Patent Infringement Determination.* Once the Company has procured sufficient raw materials, it must determine whether it can formulate the product without infringing on any applicable patent(s) or whether it has a viable challenge to the validity or enforceability of any applicable patent(s).

- *Formulation and Testing.* Thereafter, the Company formulates and subsequently tests the product to confirm that all applicable FDA quality requirements, including stability, have been met. The Company performs biostudies to determine whether the product is bioequivalent to the reference brand drug.

- *Filing and Approval.* Once a bioequivalent product has been successfully developed, the Company files an ANDA with the FDA seeking approval of the product. The Company s ANDAs are structured to meet all FDA requirements in the first cycle of FDA review, which helps to facilitate the review process with the FDA and to minimize the amount of time it takes to receive final FDA approval.

- *Validation.* After approval is received, the Company is required to show that the product can be produced in the same quality by validating the manufacturing processes of three subsequent batches.

Product Development Strategy

The Company s product development strategy focuses on products in both of the following areas:

- drugs with significant volume and high annual sales (including blockbuster drugs); and
- drugs in smaller volume or therapeutic niche markets.

Products that are difficult to bring to market are more likely to face limited competition, which should enable the Company to earn higher margins for a longer period of time.

The Company has been successful in overcoming:

- developmental, manufacturing or technological challenges, including difficult to source raw materials; and/or
- patents which have not yet expired and which could be challenged by including a Paragraph IV certification in the Company s ANDA that the patent is invalid, unenforceable or not infringed.

Patent Challenges

The Company actively challenges the patents protecting branded pharmaceutical products (and/or their use) where it believes such patents are invalid, unenforceable or not infringed by its products (and/or their use). Under the generic drug approval provisions of the Federal Food, Drug and Cosmetic Act (often known as the Hatch-Waxman Act), the developer of a bioequivalent drug which is the first to submit an ANDA with a Paragraph IV certification that the patent is invalid, unenforceable or not infringed, may be eligible to receive a 180-day period of generic market exclusivity in connection with that patent. Under some circumstances, the 180-day exclusivity period may have to be shared by two or more applicants. This period of market exclusivity provides the patent challenger with the opportunity to earn a return on the risks taken and legal and development costs incurred, and to build its market share. In addition, subsequent generic entrants pursuant to successful Paragraph IV challenges following the 180-day exclusivity period may benefit from continuing barriers to entry of other competitors, including ongoing litigation or technological hurdles. Due to the pricing dynamics of the generic pharmaceutical industry, the expected annual sales for any particular pharmaceutical product decreases significantly following the introduction of competition from generic pharmaceuticals. See Government Regulation Patent Challenge Process.

As of March 8, 2005, the Company was involved in patent litigation in connection with its Paragraph IV certifications for the following six products: Gabapentin capsules and tablets; Itraconazole capsules; Metaxalone tablets; Omeprazole capsules; Albuterol and Ipratropium Inhalation Solution; and Metoprolol Succinate tablets.

While it is not possible to determine with any degree of certainty the ultimate outcome of the following legal proceedings, the Company believes that it has meritorious defenses with respect to the claims asserted against the Company, and it intends to defend vigorously its position. An adverse outcome in any one of these proceedings could have a material adverse affect on the Company s future financial position and results of operations.

Gabapentin

In March 2001, Pfizer Inc. (Pfizer) filed suit against the Company in the U.S. District Court for the District of New Jersey alleging that the Company infringed a patent held by Pfizer by filing an ANDA to market the generic drug Gabapentin in capsule form. Fact and expert discovery have concluded and several dispositive motions have been filed by both parties and are pending.

In February 2004, Pfizer filed suit in the U.S. District Court for the Eastern District of New York alleging that the Company infringed a patent held by Pfizer by filing an ANDA to market the generic drug Gabapentin in tablet form. This case has been consolidated with other related cases now pending in the U.S. District Court for the District of New Jersey.

Itraconazole

Shortly after the Company filed an ANDA for Itraconazole capsules in January 2001, Janssen Pharmaceutica, Inc. (Janssen) filed suit against the Company in the U.S. District Court for the Eastern District of New York for patent infringement. In July 2004, the U.S. District Court for the Eastern District of New York ruled on the pending patent infringement case. The suit filed by Janssen in April 2001 claimed that the Company s filing of an ANDA for Itraconazole infringed its patent. The District Court found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. Janssen has appealed the District Court s decision of non-infringement. On February 9, 2005, the Company began shipping Itraconazole 100mg capsules.

Metaxalone

In January 2003, Elan Pharmaecuticals, Inc. filed suit against the Company in the U.S. District Court for the Eastern District of New York for patent infringement based on the Company s filing of an ANDA to market a generic Metaxalone tablet. The Company asserted affirmative defenses and counterclaims alleging that the patents are invalid and not infringed. No trial date has been set. The Company has amended its ANDA to include an 800mg tablet. In response, Elan has amended its prior complaint to add the 800mg tablet to its suit. The litigation for both the 400mg and 800mg tablets has been consolidated into a single case.

Omeprazole

In May 2000, AstraZeneca A.B. (AstraZeneca) filed suit against the Company in the U.S. District Court for the Southern District of New York alleging infringement of six patents based on the Company s filing of an ANDA to market generic Omeprazole capsules. The Company denied AstraZeneca s allegations and filed appropriate counterclaims. Subsequently, AstraZeneca has sought to withdraw its claims regarding four of these patents after three were held invalid and the other was found to be uninfringed in a related litigation against other generic drug companies. The discovery process is nearing completion, but a trial date has not yet been set.

Albuterol and Ipratropium

In March 2004, Dey, L.P. (Dey) commenced a patent infringement action against the Company in the U.S. District Court for the Central District of California. The complaint alleges that the Company infringed a patent owned by Dey covering Albuterol and Ipratropium Inhalation Solution, System, Kit and Methods for Relieving Symptoms of Chronic Obstructive Pulmonary Disease by filing an ANDA for a product that allegedly uses methods covered by the patent and by using the inventions claimed in the patent. Discovery in this case is ongoing.

Metoprolol Succinate

In April 2004, AstraZeneca filed suit against the Company in the U.S. District Court of Delaware, alleging that the Company infringed patents held by AstraZeneca by filing an ANDA to market the generic drug Metoprolol Succinate in tablet form. The case has been consolidated for discovery purposes in the Eastern District of Missouri (St. Louis). Discovery is ongoing. Motions for summary judgment of patent invalidity have been filed and are pending.

Steady Stream Of A Broad Range Of Generic Pharmaceutical Products

The Company has a higher likelihood of achieving favorable market share when it is able to offer its customers numerous products that respond to their market-driven need for a variety of generic alternatives. As of December 31, 2004, the Company marketed over 140 generic pharmaceutical products. The Company develops and manufactures generic prescription pharmaceutical products in solid oral dosage forms, with both immediate and sustained release delivery, and is also developing several generic products that utilize transdermal patch delivery technology with Hexal and is collaborating with third parties to develop injectables and opthalmics products. The Company does not depend on any single drug or therapeutic category for a majority of its sales.

The Company s integrated approach to product development has enabled it to be among the leaders in obtaining new product approvals. During 2004, the Company received 10 final ANDA approvals, including approval of three applications that already had tentative approvals at December 31, 2003.

The Company is currently involved in the development of approximately 40 pharmaceutical products, including products with applications pending with the FDA. As of December 31, 2004, there were 25 ANDAs pending approval at the FDA and an additional 2 tentative approvals that had been received. Other than the following products, no single product represented more than 10% of the Company s net sales during the past three years: Bupropion, which was launched in 2004, represented 17.8% of the Company s net sales in 2004 and Lovastatin, which represented 10.0%, 14.8% and 6.6% of the Company s net sales in 2004, 2003 and 2002, respectively.

Strategic Relationships

The Company has a strategic relationship with the second largest generic pharmaceutical company in Germany, Hexal, a company that is under common control with Santo. Santo owns a majority of the Company s outstanding common stock. Hexal s line of generic products is represented in markets worldwide. In addition, Hexal owns patented technologies on a number of pharmaceutical products and processes.

While the Company develops most of its products internally using its team of scientists and formulators, it develops certain products in conjunction with Hexal and other companies. In March 2002, the Company entered into a technology agreement with Hexal that memorialized a prior relationship. Pursuant to that agreement, Hexal cooperates with the Company with respect to the development, manufacture and sale in the U.S. of, and the sharing of certain information relating to, certain generic pharmaceutical products that Hexal develops. At the Company s request, it has the right of first refusal to purchase or license from Hexal the U.S. sales and marketing rights with respect to all generic pharmaceutical products that Hexal develops. The Company also has entered into product-specific strategic alliances with Hexal with respect to several products, including four products which have received FDA approval Cyclosporine, Flutamide , Omeprazole and Citalopram Hydrobromide. The Company has an ANDA pending for a sustained release product which is based on technology and a formulation provided by Hexal.

The Company and Hexal collaborate on the development of products that use transdermal patch delivery technology. The Company has ANDAs pending for two products that utilize patch technology. The first product filed will be manufactured at the Company s facility in Wilson, North Carolina; the second product will be sourced from Hexal. The Company has expanded its patch manufacturing capacity located at its Wilson facility and now has sufficient manufacturing capacity to produce the product.

The Company also consults with Hexal regarding available sources of active pharmaceutical ingredients.

The Company s Cyclosporine, USP (Modified), Leuprolide Acetate, Flutamide, USP and Sucralfate USP products are manufactured by third-party producers.

Research and Development

In 2004, the Company spent $21.7 million for research and development compared to $22.5 million in 2003 and $13.2 million in 2002.

Active Pharmaceutical Ingredients

The active compounds for the Company s products, also called active pharmaceutical ingredients or APIs, are purchased from specialized manufacturers throughout the world and are essential to its business and success. 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.

When choosing a manufacturer for a specific API, the most important factors the Company considers are:

- high quality standards, including current Good Manufacturing Practices (cGMPs);
- cutting-edge chemical and process technologies;
- patent know-how; and
- flexible processes and capacities which enable it to offer competitive prices.

An in-depth knowledge of those factors and long-term experience and established relationships in this area by the Company s key personnel (including its purchasing department) enable it to make the right choices in selecting the best suitable suppliers very early in the product development process. The Company s skills in this area also help it to identify unique opportunities for difficult to source APIs. The Company is proactive in maintaining good relationships with its API suppliers because it believes that these relationships allow it to save crucial time and be cost competitive, to the mutual benefit of the Company and its suppliers.

Sales And Distribution

The Company s sales are generated primarily by its own sales force, which is supported by its customer service, sales and distribution employees. In 2004, the Company had over 100 customers in the United States. Except for AmerisourceBergen Corporation and McKesson Corporation, no other customers represented more than 10% of the Company s net sales during the past three years. AmerisourceBergen Corporation s net sales represented 12.2%, 28.3% and 32.2% of total sales for the years 2004, 2003, and 2002, respectively. McKesson Corporation s net sales represented 22.9%, 14.7% and 14.8% for the years 2004, 2003, and 2002, respectively. Sales to customers outside of the United States were less than 1% of the Company s aggregate net sales in each of the past three years.

Government Regulation

All pharmaceutical manufacturers, including the Company, are subject to extensive regulation by the federal government, principally by the FDA, and, to a lesser extent, by the U.S. Drug Enforcement Administration (the DEA), the U.S. Environmental Protection Agency and state governments. The Federal Food, Drug and Cosmetic Act, the Controlled Substances Act and other federal statutes and regulations govern or influence the testing, manufacturing, safety, labeling, storage, record-keeping, approval, pricing, advertising and promotion of the Company s products. Noncompliance with applicable requirements can result in fines, recalls and seizure of products. Additionally, the FDA has the authority to revoke drug approvals previously granted.

ANDA Process

FDA approval is required before a generic equivalent of an existing brand-name drug can be marketed. The Company seeks approval for such products by submitting an ANDA to the FDA. While an ANDA is not required to contain complete clinical studies, it normally must contain bioavailability and/or bioequivalence studies. Bioavailability indicates the rate and extent of absorption and levels of concentration of a drug product at the site of drug action needed to produce a therapeutic effect. Bioequivalence compares the bioavailability of one drug product with another and, when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body are the same as the previously approved brand-name drug. An ANDA may be submitted for a drug on the basis that it is the equivalent to a previously approved brand-name drug or, with FDA approval of a petition, a new dosage form, strength, or route of administration that is suitable for use for the indications specified.

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 FDA final approval of generic products may be delayed. 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 (a so-called pediatric extension). See Government Regulation Patent Challenge Process.

Before approving a product, the FDA also requires that the 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. The FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether the Company s systems and processes are in compliance with cGMP and other FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and Warning Letters that could cause the Company to modify certain activities identified during the inspection. A Form 483 notice may be issued at the conclusion of an FDA inspection and lists conditions the FDA inspectors believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter is issued only for violations of regulatory significance for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

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 and/or their methods of use, as well as to develop non-infringing forms of the patented subject matter. The Hatch-Waxman legislation places significant burdens on the challenger to ensure that such suits are not frivolous, but also offers the opportunity for significant financial reward if the challenge is successful.

If there is a patent listed in the FDA s Orange Book 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 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 patent in question is 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.

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 under some circumstances. If applicable, 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 submit an ANDA with a Paragraph IV certification to a patent listed in the Orange Book, may be eligible to receive a 180-day period of generic market exclusivity in connection with that patent. 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.

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 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. The DEA regulates allocation to the Company of raw materials used in the production of controlled substances based on historical sales data. The Company believes it is currently in compliance with all applicable DEA requirements.

Medicaid/Medicare

In November 1990, a law regarding reimbursement for prescribed Medicaid drugs was passed as part of the Congressional Omnibus Budget Reconciliation Act of 1990. The law requires drug manufacturers to enter into a rebate contract with the Federal Government. All generic pharmaceutical manufacturers whose products are covered by the Medicaid program are required to rebate to each state a percentage of their average manufacturer s price for the products in question. Many states also have implemented supplemental rebate programs that obligate manufacturers to pay rebates on average manufacturer s prices in excess of those required under federal law. The Company accounts for future estimated rebates in its consolidated financial statements.

In December 2003, the Attorneys General in at least six states sent letters to numerous pharmaceutical manufacturers instructing them to maintain all records relating to their reporting of pricing information under the Medicaid Drug Rebate Statute. The letters state that the document retention demand is in furtherance of an ongoing investigation of the manufacturers compliance with Medicaid drug rebate program requirements. The Company received letters from some, but not all, of the states believed to be involved. The Company believes these letters may have been motivated, at least in part, by a federal regulation published in August 2003 that, effective January 1, 2004, would have limited the document retention provisions under the federal Medicaid Drug Rebate Statute to three years unless the records are the subject of an audit or a government investigation of which the manufacturer is aware. That regulation was amended, effective January 6, 2004, to substitute a 10-year record retention requirement. The Company has not received any subpoenas, informal document requests, or any other communications from

federal or state enforcement authorities that suggest an investigation of its Medicaid drug rebate reporting practices is under way. The Company believes it operates in compliance with the requirements of the Medicaid Drug Rebate Statute.

In December 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was signed into law. It will make prescription drug coverage available on a voluntary basis to all Medicare beneficiaries beginning in 2006. Beneficiaries will elect coverage under managed care plans or prescription-drug-only plans that will negotiate discounted purchase arrangements with manufacturers. Because individuals eligible for coverage under both Medicare and Medicaid will receive drug coverage through Medicare, the Company may experience a reduction in its Medicaid drug rebate obligations once the Medicare drug benefit becomes available. The Company cannot predict the impact of the Medicare drug benefit on pricing or demand for its products or on its profitability.

The Company believes that federal and/or state governments may continue to enact additional measures aimed at reducing the costs of drugs to the public. The Company cannot predict the nature of such measures or their impact on its profitability.

Other

The Company is also governed by federal, state and local laws of general applicability, such as laws regulating intellectual property, including patents and trademarks, working conditions and equal employment opportunity.

Competition

The generic pharmaceutical industry is very competitive. The Company competes with the original manufacturers of the brand-name equivalents of its generic products, other generic drug manufacturers (including brand-name manufacturers that also manufacture generic drugs) and manufacturers of new drugs that may compete with its generic drugs. The Company believes that, based on retail sales, it ranks within the top 15 generic pharmaceutical companies in the United States that produce solid oral products. Certain of the Company s competitors have greater financial, production and research and development resources and substantially greater name recognition than the Company.

The Company believes the primary factors driving competition in the generic pharmaceutical industry are price, product development, timely FDA approval, manufacturing capabilities, product quality, customer service and reputation. The Company believes it competes favorably with respect to each of these factors. Price is a key competitive factor in the generic pharmaceutical business. To compete effectively on the basis of price and remain profitable, a generic drug manufacturer must manufacture its products in a cost-effective manner. The Company s management approach, particularly its emphasis on cross-functional responsibilities and teamwork, enables it to integrate the various steps of its product development process. The Company believes the success of its integrated approach to product development, its knowledge of the raw materials market and its manufacturing facility in Wilson, North Carolina enable it to compete with its competitors effectively based on price. Additionally, the Company must maintain an adequate level of inventories to meet customer demands. The Company believes it competes effectively with respect to inventory levels. The competition the Company experiences varies among the markets and classes of customers. In accordance with industry practice, the Company allows its customers the right to return products under specific conditions and in compliance with the Company s return policy. Such returns relate primarily to returns of expiring products.

Other competitive factors affecting the Company s business include the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions, which are able to extract price discounts on pharmaceutical

products. As the influence of these entities continues to grow, the Company may continue to face pricing pressure on the products it sells.

Seasonality

The Company s business, taken as a whole, is not materially affected by seasonal factors.

Backlog

As of March 1, 2005, the Company s gross sales value of backlog orders was $5.5 million compared to $22.3 million as of March 1, 2004. The gross sales value of backlog, however, may be substantially reduced by future allowances for contract pricing, rebates, returns and other sales allowances. Provision for such items are recorded at time of shipment. The Company expects the existing backlog will be fully satisfied in 2005. Because of the relatively short lead time required in filling orders for the Company s products and because of the magnitude of future associated sales allowances, backlog amounts do not bear any significant relationship to sales or income for any 12-month period.

Environment

The Company is subject to federal, state, and local laws and regulations relating to the protection of the environment. These evolving laws and regulations may require expenditures over a long period of time to control environmental impacts. The Company has established procedures for the ongoing evaluation of its operations to identify potential environmental exposures and assure compliance with regulatory policy and procedures.

The Company believes that its operations comply in all material respects, except as set forth in the paragraph below, with applicable laws and regulations concerning the environment. While it is impossible to accurately predict the future costs associated with environmental compliance and potential compliance with environmental laws, any compliance is not expected to require significant capital expenditures and has not had, and is not presently expected to have, a material adverse effect on the Company s earnings or competitive position.

The Company is subject to various federal, state, and local laws and regulations relating to air quality control. These regulations are designed to control the release of various compounds and air pollutants. The Company has reported to the State of New York a minor exceedance of certain limits contained in its current State Facility Permit. Anticipated increases in production of certain products will likely necessitate modification of its air permits to ensure ongoing compliance. Management does not believe that these will have a material adverse effect on the Company s financial position, results of operations, or cash flow.

Reorganizational Mergers

Prior to the reorganizational mergers described below, Santo, a company organized in Germany, owned 100% of the outstanding capital stock of Hexal Pharmaceuticals, Inc. (HPI), a Delaware corporation. Santo is under common control with Hexal, the second largest generic pharmaceutical company in Germany. The Company is a party to joint development and technology agreements with Hexal. In September 1995, HPI acquired 50% of the Company s outstanding capital stock. In December 2000, HPI indirectly acquired the remaining 50% of the Company s outstanding capital stock through its acquisition of 100% of the outstanding capital stock of Eon Holdings, Inc. (EHI). On May 21, 2002, the Company was combined with HPI and EHI into a single entity through a series of reorganizational mergers. As a result, Santo owns a majority of the Company s outstanding common stock.

Employees

As of December 31, 2004, the Company employed 539 persons, 266 of whom worked at its then corporate headquarters and manufacturing facility in Laurelton, New York and 273 of whom worked at its manufacturing and research facility in Wilson, North Carolina. In January 2005, the Company relocated its corporate headquarters to Lake Success, New York where it leases approximately 25,000 square feet of office space. The production and maintenance employees at the Company s manufacturing facility in Laurelton, New York are represented by the Drug, Chemical, Cosmetic, Plastics and Affiliated Industries Warehouse Employees Local 815, affiliated with the International Brotherhood of Teamsters, Chauffeurs, Warehousemen and Helpers of America under a labor contract that expires in November 2005. The Company believes that its relations with its employees are good and the Company has no history of work stoppages.

RISK FACTORS

You should carefully consider the following risks regarding the Company. These and other risks could materially and adversely affect the Company s business, operating results or financial condition. You should also refer to the other information contained or incorporated by reference in this report.

The Company s revenues and profits from any particular generic pharmaceutical decline as its competitors introduce their own generic equivalents.

Selling prices of generic drugs typically decline, sometimes dramatically, as additional companies receive approvals for a given product and competition intensifies. To the extent that the Company succeeds in being first to market with a generic version of a significant product, its sales and profitability can be substantially increased in the period following the introduction of such product and prior to additional competitors introduction of an equivalent product. The Company s ability to sustain its sales and profitability on its products over time is dependent on both the number of new competitors for such products and the timing of their approvals. The Company s overall profitability depends on its ability to continuously introduce new products as to which it can be first to market or otherwise can gain significant market share.

The Company s success depends on its ability to successfully develop and commercialize additional pharmaceutical products.

The Company s future results of operations depend to a significant degree upon its ability to successfully commercialize additional generic pharmaceutical products in a timely manner. The Company focuses on developing and commercializing a steady stream of new generic products in multiple therapeutic categories in order to broaden its product line. The Company s customers prefer to purchase products from generic manufacturers that offer a wide product selection. If the Company is unable to offer its customers numerous products that respond to their market-driven need for a variety of generic alternatives, its revenues and profitability may be negatively impacted. If the Company is unable to introduce its products currently in development, then its future operating results will suffer. All of the Company s products must meet regulatory standards and receive regulatory approvals. The development and commercialization process is both time consuming and costly and involves a high degree of business risk. The Company s products currently under development, if and when fully developed and tested, may not perform as expected, necessary regulatory approvals may not be obtained in a timely manner, if at all, and such products may not be able to be successfully and profitably produced and marketed. Delays in any part of the process or the Company s inability to obtain regulatory approval of its products could adversely affect its operating results by restricting its introduction of new products. The continuous introduction of new generic products is critical to the Company s business.

Generic pharmaceuticals are sold to a limited number of customers, the loss of whose business could materially affect the Company s sales.

The Company sells its products directly to national pharmacy chains, mail order customers, mass merchandisers and managed care providers and through drug wholesalers and distributors who, in turn, supply its products to pharmacies, mail order customers, mass-merchandisers, hospitals and governmental agencies. Due to the ongoing consolidation of drug wholesalers and distributors and the growth of national pharmacy chains, there exists an increasingly limited number of customers that comprise a significant share of the market. Sales to the Company s top two customers represented approximately 41% of its net sales in 2004. If the Company were to lose the business of any of these customers, or if any were to experience difficulty in paying the Company on a timely basis, there could be a material adverse effect on its net sales, profitability and cash flows.

The network through which the Company sells its products is continuing to undergo significant consolidation, marked by mergers and acquisitions among drug wholesalers and distributors, the growth of national pharmacy chains and the increasing importance of mail order businesses. As a result, a small number of drug wholesalers, distributors and national pharmacy chains control a significant share of the market. The Company expects that recent and future consolidation of drug wholesalers and retailers and the steady market share gain by mail order businesses will increase pricing and other competitive pressures on it and could have a material adverse effect on sales of its products.

The generic pharmaceutical industry in which the Company operates is competitive, and the Company is particularly subject to the risks of such competition.

The generic pharmaceutical industry in which the Company operates is competitive in part because the products that are sold usually do not benefit from patent protection. The competition which the Company encounters has an effect on its product prices, market share, revenues and profitability. The Company may not be able to differentiate its products from those of its competitors, successfully develop or introduce new products that are less costly or offer better performance than those of its competitors or offer purchasers of its products payment and other commercial terms as favorable as those offered by its competitors.

Because certain of the Company s competitors have substantially greater financial, production, research and development resources and substantially greater name recognition than it has, it is particularly subject to the risks inherent in competing with them. Several of the Company s products face competition from a significant number of generic pharmaceutical companies.

The Company also competes with:

- the original manufacturers of the brand-name equivalents of its generic products, as is the case with Cyclosporine, USP (Modified); and

- manufacturers of new drugs that may compete with its generic products, such as Oxaprozin and Nabumetone, where it competes with newly developed cox-2 inhibitors.

Depending upon how the Company responds to this competition, the effect of such competition may be materially adverse to it.

In some circumstances, the Company grants credits against past sales of its products. This may result in reduced revenues and profitability.

In accordance with industry practice, following a reduction of the Company s prices as a result of competition, it grants its customers a shelf stock credit equal to the decrease in unit price for the product multiplied by the number of units of the product a customer has in inventory at the time the price is

lowered. If new or existing competitors significantly lower the prices of any of the Company s products, it would have to provide significant credits that could reduce its sales and gross margin. In the event that the Company grants substantial credits in the future, the credits might result in a material loss of revenues or profitability. If the Company chooses not to meet the lower price and not give a shelf stock credit, its customers may not sell the units of its product in their inventory and will return those units to it.

The Company is controlled by Santo.

At March 1, 2005, Santo owned approximately 67.5% of the Company s outstanding common stock and Thomas Strüngmann, Ph.D., the Chairman of the Company s Board of Directors and the Co-Chief Executive Officer and Co-President of Hexal, together with his interests in Santo and Hexal, beneficially owned approximately 67.7% of the Company s outstanding common stock. Santo and Dr. Strüngmann are able to control the outcome of stockholder votes, including votes concerning the election of the majority of directors, the adoption or amendment of provisions in the Company s certificate of incorporation or bylaws, the approval of mergers, decisions affecting its capital structure and other significant corporate transactions.

The interests of Santo and Dr. Strüngmann may conflict with your interests. Their control could also have the effect of deterring hostile takeovers, delaying or preventing changes in control or changes in management or limiting the ability of the Company s stockholders to approve transactions that they may deem to be in their best interests.

Some of the Company s generic pharmaceutical products face competition from brand-name manufacturers that sell their own generic products or successfully protect their brand-name products in other ways.

Competition in the generic pharmaceutical market continues to intensify as the pharmaceutical industry adjusts to increased pressures to contain health care costs. Brand-name manufacturers continue to sell their products into the generic market directly by acquiring or forming strategic alliances with generic pharmaceutical companies. No regulatory approvals are required for a brand-name manufacturer to sell directly or through a third party to the generic market. Brand-name manufacturers do not face significant barriers to entry into such markets. In addition, such companies continually seek new ways to defeat generic competition, such as obtaining new patents on drugs whose original patent protection is about to expire, developing and marketing other dosage forms including patented controlled-release products or developing and marketing as over-the-counter products those branded products which are about to lose exclusivity and face generic competition.

Patent litigation is common, can be expensive, may delay or prevent entry of the Company s products into the market, and, in some cases, may result in damages.

Litigation concerning patents, other forms of intellectual property and proprietary technologies is becoming more widespread and can be protracted and expensive and can distract management and other key personnel from performing their business duties for the Company.

Companies that seek to market generic versions of brand-name products can be sued for infringing patents that purportedly cover such products and/or methods of using such products if the proposed marketing is to occur before such patents expire. More specifically, when the Company files an ANDA with the FDA for approval of a generic drug, it may certify that any patent listed by the FDA as covering the brand-name product and/or a method of using that product will expire, in which case the ANDA will not become effective until the expiration of such patent(s). On the other hand, the Company may certify that any patent listed as covering the brand-name product and/or a method of using that product is invalid, is unenforceable, or will not be infringed by the manufacture, sale or use of the generic drug for which the

ANDA is filed. In that case, the Company is required to notify the patent holder and NDA holder that such patent is not infringed, is unenforceable, or is invalid. The patent holder has 45 days from receipt of the notice in which to sue for patent infringement to obtain injunctive relief and, in some instances, to seek attorneys fees.

In the event litigation is commenced by the patent holder or NDA holder, final approval of the ANDA is delayed by 30 months, or such shorter or longer period as may be ordered by the court. The litigation may be costly and time consuming, and these costs may be more easily borne by the Company s competitors than by it. The outcome of litigation is inherently uncertain. Litigation could result in removal from the market, or a substantial delay in, or prevention of, the introduction of the product that is the subject of the Company s ANDA, any of which could have a material adverse effect on its business, financial condition, cash flows, or results of operations.

As of March 1, 2005, the Company was involved in patent litigation in connection with its Paragraph IV certifications for the following six products: Gabapentin capsules and tablets; Itraconazole capsules; Metaxalone tablets; Omeprazole capsules; Albuterol and Ipratropium Inhalation Solution; and Metoprolol Succinate tablets. The Company is unable to predict the outcome of any of these cases. If the Company is not successful in challenging or cannot prove non-infringement of the patents with respect to a brand-name product (and/or its use), it may not be able to market its generic alternative until the expiration of the applicable patent, which is often not for a number of years.

In January 2001, Janssen filed suit against the Company in the U.S. District Court for the Eastern District of New York. The suit claims the Company s filing of its ANDA for Itraconazole capsules infringed a Janssen patent. In July 2004, the Court found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. Janssen s appeal of the District Court s ruling is pending. In February 2005, the Company began selling Itraconazole capsules. A reversal of the District Court s ruling by the Court of Appeals could result in the Company being enjoined from marketing the product which could materially harm profits and cash flows, and result in paying damages, costs, and fees that could have a material adverse impact on the Company s financial performance.

In the future, after the expiration of the 30-month stay and after receiving final approval from the FDA, the Company may attempt to bring products to market without first obtaining non-infringement decisions. This practice is commonly referred to as launching at risk. Launching at risk may allow generic manufacturers to bring a product to market without waiting for lengthy patent infringement litigation to be completed. However, launching at risk can also serve as a basis for claims by the patent holder of willful infringement against the Company. If the Company loses a patent infringement action and willful infringement is found to exist, the damages owed by the Company may be multiplied up to three times, at the Court s discretion, due to such willful infringement. The Company may also be subject to injunctive relief, attorneys fees, costs of litigation and such further relief as a court deems just and proper. Because damages in such instances may be calculated according to the profit lost by the patent holder rather than the profit gained by the Company, and because multiple damages may be awarded, such damages could greatly exceed the Company s actual profits from marketing the infringing drug and could have a material adverse impact on the Company s financial results.

In March 2004, Dey commenced a patent infringement action against the Company in the U.S. District Court for the Central District of California. The complaint alleges that the Company infringed a patent owned by Dey covering Albuterol and Ipratropium Inhalation Solution, System, Kit and Methods for Relieving Symptoms of Chronic Obstructive Pulmonary Disease by filing an ANDA for a product that allegedly uses methods covered by the patent and by using the inventions claimed in the patent.

In addition to the ANDA patent litigations stemming from the Company s Paragraph IV certifications, the Company is a defendant in two patent litigations involving its generic Cyclosporine product. On August 30, 2000, Novartis Pharmaceuticals Corporation (Novartis Pharmaceuticals) filed a complaint in the U.S. District Court for the District of Delaware alleging among other things that by selling a generic Cyclosporine product the Company has been and is infringing its patent. Novartis Pharmaceuticals is seeking injunctive relief to prevent the alleged acts of infringement, as well as damages, including lost profits, costs and expenses, reasonable attorneys fees and treble damages for willful infringement. The Company s potential liability and expenses in this matter are not covered by insurance. In December 2002, the U.S. District Court for the District of Delaware granted the Company s motion for summary judgment of non-infringement of the patent. In April 2004, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the Delaware District Court that the Company s generic Cyclosporine product does not infringe Novartis Pharmaceuticals patent. Novartis Pharmaceuticals request for a rehearing by the U.S. Appeals Court is still pending. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

On January 26, 2001, Apotex Inc. (Apotex), a Canadian generic pharmaceutical company, filed a complaint in the U.S. District Court for the Eastern District of New York alleging, among other things, that the Company has been and is infringing its patent related to Cyclosporine. Apotex is seeking injunctive relief to prevent alleged acts of infringement, as well as damages, including a reasonable royalty, costs, expenses, reasonable attorneys fees and treble damages for willful infringement. A trial is scheduled for May 2005. The Company s potential liability and expenses in this matter are not covered by insurance. The Company believes that it has meritorious defenses to Apotex claims and is vigorously defending itself. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

On October 29, 2004, the Company began shipping the generic drug Citalopram Hydrobromide. Earlier in October 2004, the Company received a notice from Forest Laboratories, Inc. (Forest) and H. Lundbeck A/S (Lundbeck) that requested certain information from the Company. The notice also included a list of patents that they hold which they allege covers Citalopram Hydrobromide. The Company has not been sued for patent infringement in connection with its sale of Citalopram Hydrobromide.

The Company faces the risk of product liability claims, for which it may be inadequately insured.

Manufacturing, selling and testing pharmaceutical products involve a risk of product liability. Even unsuccessful product liability claims could require the Company to spend money on litigation, divert management s time, damage its reputation and impair the marketability of its products.

The Company has been named as a defendant in several cases in which the plaintiff alleges injury from the use of Phentermine alone, and in one instance the Company was named as a third-party defendant in a medical malpractice case in which negligent prescription of Phentermine was alleged. A number of these claims have been dismissed in the Company s favor, and as of December 31, 2004 only one such claim remained pending.

The Company has been named as a defendant in several lawsuits in which plaintiffs allege that Company-manufactured Amiodarone caused injury or death. As of December 31, 2004, two such claims were pending. In one of the lawsuits, the plaintiffs allege generic Amiodarone manufactured by the Company and several other pharmaceutical companies caused a wrongful death. In the second lawsuit, plaintiffs purporting to represent a class comprised of users of Amiodarone nationwide from 1985 to the present allege injury and seek class certification, damages, refunds, medical monitoring, exemplary

damages and other relief, including injunctive relief, against several of the manufacturers of Amiodarone. As discovery in these cases has yet to begin, predicting the ultimate outcome of these actions in not possible.

The Company has been named as a defendant in a lawsuit in which the plaintiff alleges injury from the use of Company-manufactured Lisinopril/HCTZ. As discovery in this case is just beginning, predicting the ultimate outcome of this action is not possible.

The Company has been named as a defendant in several product liability lawsuits in which plaintiffs allege that Company-manufactured pharmaceuticals containing Phenylpropanolamine (PPA) caused injury. PPA was removed from the market in 2000 at the FDA s request after a study appeared to show a potentially increased risk of hemorrhagic stroke in certain patient cohorts. The Company previously manufactured two low-volume prescription products that contained PPA that were discontinued in 1999 and 2000, respectively.

To date, the Company has been named in five lawsuits alleging injury or wrongful death from the use of Company-manufactured pharmaceuticals containing PPA. As of December 31, 2004, all but two PPA cases against the Company had been dismissed or discontinued. As discovery in these lawsuits is ongoing, predicting the ultimate outcome of these actions is not possible.

The Company s insurance carriers did not renew product liability coverage for products containing PPA. The Company manufactured two low-volume prescription products that contained PPA that were discontinued in 1999 and 2000, respectively. Under the terms of the expiring insurance contracts, the Company elected to purchase $80.0 million of supplemental extended reporting period (SERP) coverage. The SERP policy extends the reporting period for claims a minimum of five years, but only covers occurrences that happened before the respective cancellation dates. The cancellation date for the first $45.0 million of coverage is August 6, 2002. The cancellation date on the remaining layers is June 22, 2001, except for a layer of $5.0 million in excess of $55.0 million, the cancellation date of which is also August 6, 2002.

The Company currently maintains $75.0 million per claim and in the aggregate of claims-made product liability/completed operations insurance for its products, all of which is available for Phentermine-related claims (retroactive to June 1998), excluding Fenfluramine and Dexfenfluramine combination (fen-phen) claims. Under the Company s current product liability/completed operations insurance plan, the Company has a self-insured retention of $10.0 million per claim not to exceed $10.0 million in the aggregate.

The Company s product liability insurance, however, may not be adequate to remove the risk from some or all product liability claims and is subject to the limitations described in the terms of the policies. The Company may not be able to obtain product liability insurance in the future with adequate coverage limits at commercially reasonable prices.

The Company is currently a defendant in a number of multi-defendant lawsuits involving the manufacture and sale of Phentermine HCl and it has exhausted its insurance coverage for those lawsuits.

From May 1997 to December 31, 2004, the Company was named a party and served in approximately 7,100 lawsuits in connection with its manufacture of Phentermine Hydrochloride. As of December 31, 2004, more than 92% of these cases had been dismissed. The actions generally have been brought in various state and federal jurisdictions by individuals in their own right or on behalf of putative classes of persons who claim to have suffered injury or claim that they may suffer injury in the future due to the use of a combination of two prescription diet drugs, Fenfluramine and Phentermine, a combination popularly known as fen-phen. A few lawsuits contain allegations of injury from the use of Phentermine alone, or in combination with other drugs.

The fen-phen lawsuits typically allege that the short- and long-term use of Fenfluramine in combination with Phentermine causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. Some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of an individual plaintiff or a class of plaintiffs. Some actions seeking class certification ask for certain types of equitable relief. The fen-phen lawsuits typically name as a defendant Wyeth (formerly American Home Products Corporation), the manufacturer of two anti-obesity drugs, Fenfluramine and Dexfenfluramine, and also name manufacturers and distributors and retailers of Phentermine. Certain companies that distributed or sold the Company s Phentermine and are named as defendants in certain of these lawsuits seek defense and indemnity from the Company.

As of December 31, 2004, there has been no finding of liability for fen-phen injury against the Company and no payment by the Company to settle any combination-related fen-phen lawsuit. There has been no scientific testimony accepted by any court that establishes a connection between the use of Phentermine either alone or in combination with Fenfluramine and/or Dexfenfluramine and the allegations made by plaintiffs in these lawsuits.

In the second quarter of 2000, the Company exhausted its product liability insurance covering all combination-related Phentermine lawsuits and any non-combination Phentermine lawsuits resulting from claims regarding the ingestion of Phentermine prior to June 1998. Since that time, the Company has funded its own defense in the fen-phen and Phentermine combination lawsuits, as well as certain Phentermine-only lawsuits. Additionally, pursuant to an October 1999 settlement with an insurance carrier, the Company has made insurance coverage claims for fen-phen claims filed on or after June 22, 2003 which allege fen-phen use prior to June 1998. These claims were settled during the third quarter of 2004 for a one-time payment of approximately $1.4 million that will defray future fen-phen defense costs. The Company has agreed to fund or partially fund the defense of certain of its distributors, and to indemnify them provided certain conditions are met. Further, the Company has reached favorable defense agreements with several retailers of Company Phentermine. See Item 3. Legal Proceedings.

New developments by other pharmaceutical manufacturers could make the Company s products or technologies non-competitive or obsolete.

The markets in which the Company competes and intends to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. The Company expects competition to intensify as technological advances are made, including the introduction of biotechnology products. New developments by others may render the Company s products or technologies non-competitive or obsolete.

If the Company is unable to obtain sufficient active pharmaceutical ingredients (APIs) from key suppliers that in some cases may be the only source of finished products or raw materials, then its ability to deliver its products to market may be impeded.

The active compounds for the Company s products, also called active pharmaceutical ingredients or APIs, are purchased from specialized manufacturers throughout the world and are essential to its business and its success. Some of the APIs used in its products, especially its niche market products, are available only from one or a limited number of sources. Those APIs are either difficult to produce or are needed in such limited quantities that additional suppliers are typically not available. For high volume products, including blockbuster drugs, there are generally several API suppliers available. However, even when more than one supplier for a product exists, the Company may elect to list, and in some cases has listed, only one supplier in its ANDAs for such product. The Company attempts to qualify alternative suppliers after it has

introduced a high volume product into the market and has reached an economy of scale, but it may be unable to do so. In the event an existing supplier should lose its regulatory status as an acceptable source, the Company would attempt to locate a qualified alternative; however, it may be unable to obtain the required components or products on a timely basis or at commercially reasonable prices and any change in a supplier not previously approved in its ANDA must then be submitted through a formal approval process with the FDA.

In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales and customers. From time to time, certain of the Company s outside suppliers have experienced regulatory or supply-related difficulties that have impeded their ability to deliver products to it. To the extent such difficulties cannot be resolved within a reasonable time and at a reasonable cost, the resulting delay could have a material adverse effect on the Company s business.

If independent third parties do not accept the Company s products, it may be unable to market them successfully.

The Company s ability to market generic pharmaceutical products successfully depends, in part, on the acceptance of the products by independent third parties including pharmacies, government formularies and other retailers, as well as patients. The Company manufactures a number of safe and effective prescription drugs which are mainly used by patients who have severe health conditions. Although the brand-name products generally have been marketed safely for many years prior to the Company s introduction of a generic alternative, there is a possibility that one of its generic products could be alleged to produce an unanticipated clinical side effect which could result in an adverse effect on its ability to achieve acceptance by managed care providers, pharmacies and other retailers, customers and patients. If these independent third parties do not accept the Company s products, it could have a material adverse effect on its revenues and profitability.

The Company is subject to government regulation that increases its costs and, if it is unable to obtain regulatory approvals, it could prevent the Company from marketing or selling its products.

The Company is subject to extensive pharmaceutical industry regulation. The Company cannot predict the extent to which it may be affected by legislative and other regulatory developments concerning its products.

The Company is dependent on obtaining timely regulatory approvals before marketing its products. Any manufacturer failing to comply with FDA or other applicable regulatory agency requirements may be unable to obtain approvals for the introduction of new products and, even after approval, initial product shipments may be delayed. The FDA also has the authority to revoke drug approvals previously granted and remove from the market previously approved drug products that are no longer regarded as safe and effective for their intended uses or not regarded as having been properly manufactured. The Company s major facilities and products are periodically inspected by the FDA, which has extensive enforcement powers over the activities of pharmaceutical manufacturers, including the power to suspend approval of new drug applications, seize, force to recall and prohibit the sale or import of non-complying products, and halt operations of and criminally prosecute non-complying manufacturers.

Although the Company devotes significant time, effort and expense to addressing the extensive government regulations applicable to its business and obtaining regulatory approvals, it remains subject to the risk of being unable to obtain necessary approvals on a timely basis, if at all. Delays in receiving regulatory approvals could adversely affect the Company s ability to market its products.

If brand-name manufacturers legislative and regulatory efforts to limit the use of generics are successful, then the Company s sales of products subject to these efforts may suffer.

Many brand-name manufacturers have increasingly used federal and state legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent which could extend patent protection for a number of years or otherwise delay the launch of generics;
- submitting Citizen Petitions to request the Commissioner of Food and Drugs to take administrative action with respect to an ANDA approval;
- seeking changes to the United States Pharmacopeia, an industry recognized compendia of drug standards; and
- attaching special patent extension amendments to non-related federal legislation.

In addition, some brand-name manufacturers have engaged in state-by-state initiatives to enact legislation or adopt regulatory requirements that restrict the substitution of some brand-name drugs with generic drugs.

If these efforts to delay generic competition are successful, the Company may be unable to sell its products that are subject to these efforts, which could have a material adverse effect on its sales and profitability.

Reforms in the health care industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for the Company s products.

Increasing expenditures for health care have been the subject of considerable public attention. Both private and governmental entities are seeking ways to reduce or contain health care costs. Numerous proposals that would effect changes in the health care system have been introduced or proposed in Congress and in some state legislatures. The Company cannot predict the nature of the measures that may be adopted or their impact on the marketing, pricing and demand for its products.

The Company s ability to market its products depends, in part, on reimbursement levels for such products and related treatment established by health care providers (including government authorities), private health insurers and other organizations, including health maintenance organizations and managed care organizations. Reimbursement may not be available for some of the Company s products and, even if granted, may not be maintained. Limits placed on reimbursement could make it more difficult for people to buy the Company s products and reduce, or possibly eliminate, the demand for its products. The Company cannot predict the combined effects of changes in third-party reimbursement on its product sales or its profitability.

The manufacture and storage of pharmaceutical and chemical products is subject to environmental regulation and risk.

Because of the chemical ingredients of pharmaceutical products and the nature of their manufacturing process, the pharmaceutical industry is subject to extensive environmental regulation and the risk of incurring liability for damages or the costs of remedying environmental problems. If the Company fails to comply with environmental regulations, to use, discharge or dispose of hazardous materials appropriately or otherwise to comply with the conditions attached to its operating licenses, the licenses could be revoked and it could be subject to criminal sanctions and/or substantial liability or could be required to suspend or modify its manufacturing operations.

Environmental laws and regulations can require the Company to undertake or pay for investigation, clean-up and monitoring of environmental contamination identified at properties that it currently owns or operates or that it formerly owned or operated. Further, they can require the Company to undertake or pay for such actions at offsite locations where it may have sent hazardous substances for disposal. These obligations are often imposed without regard to fault. The Company believes that its operations comply in all material respects with applicable laws and regulations concerning the environment. The Company may be required, however, to increase expenditures to comply with new, different, or increasingly stringent requirements to address modifications or increases in production, or to address contamination attributable to its business or properties.

Provisions of the Company s charter documents and Delaware law could discourage a takeover you may consider favorable or prevent the removal of the Company s current board of directors and management.

Some provisions of the Company s certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that you may consider favorable or prevent the removal of the Company s current board of directors and management. These provisions:

- authorize the issuance of blank check preferred stock;
- provide for a classified board of directors with staggered, three-year terms;
- prohibit cumulative voting in the election of directors;
- prohibit its stockholders from acting by written consent from and after the date that Santo and its affiliates own fewer than 40% of the outstanding shares of its common stock;
- limit the persons who may call special meetings of stockholders; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters to be approved by stockholders at stockholder meetings.

The Company s certificate of incorporation prohibits the amendment of many of these provisions in its certificate of incorporation by its stockholders unless the amendment is approved by the holders of at least 662⁄3% of its shares of common stock.

Delaware law may discourage, delay or prevent someone from acquiring or merging with the Company. Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder, unless:

- the board of directors approved the transaction in which the stockholder became an interested stockholder prior to the date the interested stockholder attained that status; or
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers; or on or subsequent to that date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the holders of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock.

Item 2. Properties.

In January 2005, the Company relocated its corporate headquarters to 1999 Marcus Avenue, Lake Success, New York 11042, where it leases approximately 25,000 square feet of office space and will continue to operate from the two facilities that it owns. The Company s 115,000 square foot facility in Laurelton, New York will continue to operate as a manufacturing and distribution center. The 275,000 square foot facility in Wilson, North Carolina operates as a manufacturing, distribution and research facility. At December 31, 2004, the Wilson facility accounted for approximately 60% of total production. Production levels at the North Carolina facility are expected to increase over time. Future production levels are dependent on a number of factors including new product introductions and the timing of product transfers to the Wilson facility.

The Company believes that its facilities are suitable for its business and will be adequate to meet its current needs. In addition, the Wilson facility may be expanded, if required.

Item 3. Legal Proceedings.

From time to time, the Company is subject to lawsuits and claims which arise out of its operations in the normal course of business, some of which involve claims for damages that are substantial in amount.

Fen-phen Litigation

Since May 1997, the Company and certain of its customers have been named as defendants in numerous product liability lawsuits, some of which are class actions, filed in various state and federal courts in connection with its manufacture of Phentermine Hydrochloride. These lawsuits typically name as a defendant Wyeth (formerly American Home Products Corporation), the manufacturer of two anti-obesity drugs, Fenfluramine and Dexfenfluramine, and also name manufacturers, distributors and retailers of Phentermine. Fenfluramine and Phentermine were prescribed in combination in an off-label use commonly called fen-phen, while Dexfenfluramine was generally prescribed alone, but occasionally in combination with Phentermine. In September 1997, the manufacturer of Fenfluramine and Dexfenfluramine agreed with the FDA to voluntarily withdraw both products from the market. The FDA has not requested that Phentermine be withdrawn from the market.

The plaintiffs in these cases (the fen-phen cases) typically allege that the short- and long-term use of Fenfluramine in combination with Phentermine causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. Some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of the individual or the class. Some actions seeking class certification ask for certain types of equitable relief, including, but not limited to, declaratory judgments and the establishment of a research program or medical surveillance fund. Certain companies that distributed or sold the Company s Phentermine and are named as defendants in certain of these lawsuits seek a defense and indemnity from the Company.

During 2000, the U.S. District Court for the Eastern District of Pennsylvania, the federal court before which all federal cases were consolidated for discovery, found that proposed anti-Phentermine causation testimony by two expert witnesses was not supported by scientific evidence and thus would be barred. These two experts were the only national anti-Phentermine causation experts identified in the consolidated federal litigation, and were to have been generic experts in hundreds of cases. The Court s decision to curb their testimony substantially has resulted in many cases being dismissed. To date, there has been no scientific testimony accepted by any court that establishes a connection between the use of

Phentermine, either alone or in combination with Fenfluramine and/or Dexfenfluramine, and the allegations of injury made by plaintiffs in these lawsuits.

In late 1999, Wyeth, the major defendant in the fen-phen litigation and the former manufacturer of both Fenfluramine and Dexfenfluramine, announced a proposed settlement of all fen-phen claims against it nationwide (excepting only claims for certain serious medical conditions). The U.S. District Court for the Eastern District of Pennsylvania, which supervises discovery of all federal fen-phen cases in a consolidated multidistrict litigation, certified a nationwide settlement class and approved the proposed settlement, which became final in January 2002. This settlement has reduced the number of new cases in which the Company and its distributors have been named as defendants.

As of December 31, 2004, the Company had been named and served in over 7,100 fen-phen product liability cases. More than 92% of these cases have been dismissed, and the Company remains a defendant in approximately 552 pending fen-phen cases. Since the beginning of the fen-phen litigation, only one case has gone to trial with the Company and its distributors as defendants. In that instance, the case against the Company and all the Phentermine defendants, including other Phentermine manufacturers and distributors, was dismissed on motion before the presentation of any evidence.

While the number of lawsuits being filed has decreased substantially, the Company expects additional, similar lawsuits to be filed. The Company and its outside counsel believe that the Company has substantial defenses to these claims, though the ultimate outcome cannot be determined. As of December 31, 2004, there had been no finding of liability for fen-phen injury against the Company and no payment by the Company to settle any combination-related fen-phen lawsuit.

Phentermine Litigation

The Company has been named as a defendant in several cases in which the plaintiffs allege injury from the use of Phentermine alone, and in one instance the Company was named as a third-party defendant in a medical malpractice case in which negligent prescription of Phentermine was alleged. A number of these claims have been dismissed in the Company s favor, and as of December 31, 2004, only one such claim remained pending.

Because discovery has not been completed in this pending case, predicting the ultimate outcome of this action is not possible, and no provision for any related liability has been reflected in the Company s financial statements. The Company believes it has substantial defenses to this claim.

Defense/Indemnity Issues Related to Fen-phen and Phentermine Litigation

In or about April 2000, the Company exhausted its product liability insurance covering all combination-related Phentermine lawsuits and any non-combination Phentermine lawsuits resulting from claims regarding the ingestion of Phentermine prior to June 1998. Since that time, the Company has funded its own defense in such lawsuits. However, pursuant to an October 1999 settlement with an insurance carrier, the Company has made insurance coverage claims for fen-phen claims filed on or after June 22, 2003, which allege fen-phen use prior to June 1998. These claims were settled during the third quarter of 2004 for a one-time payment of approximately $1.4 million that will defray future fen-phen defense costs. Additionally, the Company agreed to fund or partially fund the defense of certain of its distributors and to indemnify them, provided certain conditions are met. Furthermore, the Company has reached favorable defense/indemnity agreements with several retailers of the Company s Phentermine products.

The Company currently maintains $75.0 million per claim and in the aggregate of claims-made product liability/completed operations insurance for its products, all of which is available for Phentermine-related claims (retroactive to June 1998), excluding fen-phen and Phentermine combination claims. Under

the Company s current product liability/completed operations insurance plan, the Company has a self-insured retention of $10,0 million per claim not to exceed $10.0 million in the aggregate.

Other Product Liability Litigation

The Company has been named as a defendant in several other product liability lawsuits in which plaintiffs allege that Company-manufactured pharmaceuticals containing phenylpropanolamine (PPA) caused injury. PPA was removed from the market in 2000 at the FDA s request after a study appeared to show a potentially increased risk of hemorrhagic stroke in certain patient cohorts. The Company previously manufactured two low-volume prescription products that contained PPA that were discontinued in 1999 and 2000.

To date, the Company has been named in five lawsuits alleging injury or wrongful death from the use of Company-manufactured pharmaceuticals containing PPA. As of December 31, 2004, all but two PPA cases against the Company had been dismissed or discontinued: lawsuit filed in 2002 in the New York Supreme Court and a lawsuit filed in 2003 in the U.S. District Court for the Western District of Washington remain pending. Discovery in these lawsuits is ongoing, and predicting the ultimate outcome of these actions is not possible. The Company believes its product liability insurance is adequate to cover existing PPA claims.

In April 2004, the Company was also named as a defendant in a lawsuit alleging injury from the use of Company-manufactured Desipramine, which has been settled for nominal value.

In May 2004, the Company was also named defendant in a product liability lawsuit in the U.S. District Court for the Northern District of Ohio in which the plaintiff alleges injury from the use of Company-manufactured Lisinopril/HCTZ. As the Company product liability insurance policy is a claims made policy, the insurance coverage available to the Company is the amount that was in effect on the date the claim was made. The policies in effect at time the claim was made provided for $50.0 million of coverage with a self-insured retention of $100,000. Discovery in this case continues, and the Company believes it would be premature to express a judgment as to its outcome.

The Company has been named as a defendant in several lawsuits in which plaintiffs allege that Company-manufactured Amiodarone caused injury or death. A lawsuit filed against the Company in 2003 alleging injury from the use of Company-manufactured Amiodarone was settled in July 2004 for nominal value. As of December 31, 2004, the Company remained a defendant in two Amiodarone-related lawsuits. In the first lawsuit, pending in the U.S. District Court for the Middle District of Florida, the plaintiffs allege generic Amiodarone manufactured by the Company and several other pharmaceutical companies caused a wrongful death. In the second lawsuit, pending in the U.S. District Court for the District of New Jersey, plaintiffs purporting to represent a class comprised of users of Amiodarone nationwide from 1985 to the present allege injury and seek class certification, damages, refunds, medical monitoring, exemplary damages and other relief, including injunctive relief, against several of the manufacturers of Amiodarone. Discovery in these cases has not yet begun, and the Company believes it would be premature to express a judgment as to their outcomes.

Patent Infringement Litigation

On August 30, 2000, Novartis Pharmaceuticals filed a complaint in the U.S. District Court for the District of Delaware alleging, among other things, that the Company s generic Cyclosporine product infringes a patent owned by Novartis Pharmaceuticals. The Company obtained a non-infringement opinion with regard to its product prior to marketing it, and believes that there is no merit to the allegations in the complaint. Novartis Pharmaceuticals is seeking injunctive relief to prevent the Company s alleged acts of infringement, as well as an unspecified amount of damages, costs and expenses, reasonable attorneys fees and treble damages for willful infringement. The Company s potential liability and expenses in this matter

are not covered by insurance. In December 2002, the U.S. District Court for the District of Delaware granted the Company s motion for summary judgment of non-infringement of the patent. In April 2004, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the Delaware District Court that the Company s generic Cyclosporine product does not infringe Novartis Pharmaceuticals patent. Novartis Pharmaceuticals request for a rehearing by the U.S. Appeals Court is still pending. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

On January 26, 2001, Apotex, a Canadian generic pharmaceutical company, filed a complaint in the U.S. District Court for the Eastern District of New York alleging, among other things, that the Company has been and is infringing its patent related to Cyclosporine. Apotex is seeking injunctive relief to prevent alleged acts of infringement, as well as damages, including a reasonable royalty, costs, expenses, reasonable attorneys fees and treble damages for willful infringement. A trial is scheduled for May 2005. The Company s potential liability and expenses in this matter are not covered by insurance. The Company believes that it has meritorious defenses to Apotex claims and is vigorously defending itself. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

In November 2000, GlaxoWellcome Inc. (Glaxo) filed suit against the Company in the U.S. District Court for the Southern District of New York alleging infringement of two patents based on the Company s filing of an ANDA to market generic Bupropion Hydrochloride 100mg and 150mg ER (extended release) tablets. In April 2004, a Stipulation and Order was entered in the U.S. District Court for the Southern District of New York, terminating all pending claims and counterclaims in a patent infringement litigation that Glaxo brought against the Company in November 2000, concerning the Company s Bupropion HCl, ER 100 mg and 150 mg tablets. Under the terms of the Stipulation and a separate Settlement Agreement, Glaxo agreed to drop any further effort to pursue its claim that the Company s Bupropion HCl, ER 100 mg and 150 mg tablets infringe Glaxo s patents. In April 2004, the Company received $3.0 million as part of the Settlement Agreement. The $3.0 million received has been be recorded as other income by the Company in the quarter ended June 30, 2004.

In January 2001, Janssen filed suit against the Company in the U.S. District Court for the Eastern District of New York. The suit claims the Company s filing of its ANDA for Itraconazole capsules infringed a Janssen patent. In July 2004, the Court found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. Janssen s appeal of the District Court s ruling is pending. In February 2005, the Company began selling Itraconazole capsules. A reversal of the District Court s ruling by the Court of Appeals could result in the Company being enjoined from marketing the product which could materially harm profits and cash flows, and result in paying damages, costs, and fees that could have a material adverse impact on the Company s financial performance.

In August 2001, the Company was successful in defending itself in the U.S. District Court for the District of Massachusetts against a patent infringement claim involving Nabumetone. At the conclusion of the trial, the Company filed a motion to recover the legal fees it incurred in defending the action. The motion was stayed pending the appeal of the District Court s ruling. The Court of Appeals affirmed the District Court decision in August 2002. In May 2003, the Company and the original plaintiff reached agreement regarding the Company s motion to recover legal fees. Under the agreement, the Company was reimbursed $3.5 million for legal fees it had incurred in defending itself. The $3.5 million recovery of legal fees has been reflected in the Company s other selling, general and administrative expenses in the quarter ended June 30, 2003.

In February 2004, the Company stipulated to an order dismissing its complaint against Glaxo for malicious prosecution of Glaxo s earlier suit against the Company, which claimed that the Company s Nabumetone product infringed Glaxo s patent. The Company received $10.0 million in exchange for agreeing to a dismissal of its complaint. The $10.0 million payment received has been recorded as other income in the quarter ended March 31, 2004.

In February 2004, Pfizer filed suit in the U.S. District Court for the Eastern District of New York alleging that the Company infringed a patent held by Pfizer by filing an ANDA to market the generic drug Gabapentin in tablet form. This case has been consolidated with other related cases now pending in the U.S. District Court for the District of New Jersey.

In March 2004, Dey commenced a patent infringement action against the Company in the U.S. District Court for the Central District of California. The complaint alleges that the Company infringed a patent owned by Dey covering Albuterol and Ipratropium Inhalation Solution, System, Kit and Methods for Relieving Symptoms of Chronic Obstructive Pulmonary Disease by filing an ANDA for a product that allegedly uses methods covered by the patent and by using the inventions claimed in the patent. Discovery in this case is ongoing.

In April 2004, AstraZeneca filed suit against the Company in the U.S. District Court of Delaware, alleging that the Company infringed patents held by AstraZeneca by filing an ANDA to market the generic drug Metoprolol Succinate in tablet form. The case has been consolidated for discovery purposes in the Eastern District of Missouri (St. Louis). Discovery is ongoing. Motions for summary judgment of patent invalidity have been filed and are pending.

On October 29, 2004, the Company began shipping the generic drug Citalopram Hydrobromide. Earlier in October 2004, the Company received a notice from Forest and Lundbeck that requested certain information from the Company. The notice also included a list of patents that they hold which they allege covers Citalopram Hydrobromide. The Company has not been sued for patent infringement in connection with its sale of Citalopram Hydrobromide.

Other Litigation

In January 2005, the Company filed a declaratory judgment action against Pfizer regarding generic Azithromycin. The Company filed an ANDA to market 250mg, 500mg, and 600mg tablets. The complaint seeks declaration of non-infringement of Pfizer s patent Nos. 6,268,489 and 5,605,889. The litigation is pending in the U.S. District Court for the Southern District of New York. On or about February 23, 2005, Pfizer filed a motion to dismiss the complaint.

Subsequent to the public announcement of the execution of the Merger Agreement on February 21, 2005, eight purported class actions were filed one in the Supreme Court of the State of New York and seven in the Court of Chancery of the State of Delaware naming as defendants the Company, Novartis AG, Thomas Strüngmann, Ph.D., Bernhard Hampl, Ph.D., Mark R. Patterson, Frank F. Beelitz and Douglas M. Karp. (In three of those actions, Novartis was also named as a defendant, in two of those actions Merger Sub was also named as a defendant and in one of those actions Santo was also named as a defendant.)

The actions, purportedly on behalf of all public stockholders of the Company other than the defendants, in substance allege that the terms of the Offer and Merger are unfair to the Company s public stockholders because the value of the Company s publicly held common stock is greater than the $31 per share price that will be offered to the Company s public stockholders in the Offer and, if a majority of the Public Shares are purchased in the Offer, will be paid for the remaining Public Shares in the Merger. All of the complaints assert claims for breach of fiduciary duty and, in their prayers for relief, seek, among other things, to enjoin the Offer and the Merger.

The seven Delaware actions are captioned as follows: Ellen Wiehl v. Eon Labs, Inc., et al., C.A. No. 1116-N (Del. Ch. Feb. 22, 2005); Paulena Partners LLC v. Eon Labs, Inc., et al., C.A. No. 1117-N (Del. Ch. Feb. 22, 2005); Robert Kemp, IRRA v. Eon Labs, Inc., et al., C.A. No. 1119-N (Del. Ch. Feb. 22, 2005); Peter J. Calcagno v. Eon Labs, Inc., et al., C.A. No. 1125-N (Del. Ch. Feb. 23, 2005); Erste Sparinvest Kapitalanlagegesellschaft MBH v. Eon Labs, Inc., et al., C.A. No. 1134-N (Del. Ch. Mar. 1, 2005); Huntsinger v. Eon Labs, Inc., et al., C.A. No. 1136-N (Del. Ch. Mar. 1, 2005); and Jason Hung v. Eon Labs, Inc. et al., C.A. No. 1139-N (Del. Ch. Mar. 3, 2005). The New York action is captioned as follows: Christopher Pizzo v. Novartis AG et al., No. 600680/05 (Sup. Ct. Feb. 23, 2005).

The plaintiff in the Huntsinger case filed a motion for expedited proceedings, which was the subject of a scheduling conference on March 4, 2005. The Court did not rule on the motion to expedite proceedings, and further indicated that it would hold a hearing on a motion for consolidation and organization of plaintiffs counsel that had been filed earlier that day by counsel in the Wiehl, Calcagno, Kemp, Sparinvest and Hung cases. The Court heard arguments on the consolidation and organization motion on March 10, 2005, and took the matter under advisement.

The Company has until April 4, 2005, to answer, move, or otherwise respond to the complaint in the New York action.

The Company and its directors believe that all of the actions are without merit and intend to vigorously defend them.

Item 4. Submission of Matters to a Vote of Security Holders.

None.

PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

The Company s common stock is listed on The NASDAQ National Market trading under the symbol ELAB. As of the close of business on March 11, 2005, there were approximately 23 holders of record of the Company s common stock. The following table sets forth the high and low sales prices of the common stock for the fiscal periods indicated, as reported on The NASDAQ National Market:

2004	**High**	**Low**
First Quarter	$ 33.54	$ 22.37
Second Quarter	$ 44.46	$ 32.40
Third Quarter	$ 40.08	$ 21.70
Fourth Quarter	$ 27.83	$ 21.73

2003	**High**	**Low**
First Quarter	$ 13.49	$ 9.98
Second Quarter	$ 18.59	$ 13.37
Third Quarter	$ 20.88	$ 15.09
Fourth Quarter	$ 27.39	$ 19.07

Dividends

The Company did not pay cash dividends on its common stock during 2004, 2003 or 2002 and does not intend to pay any cash dividends in the foreseeable future. Additionally, the Merger Agreement restricts the Company s ability to declare, set aside or pay dividends until the effective time of the Merger (other than dividends from its direct or indirect wholly owned subsidiaries to it or a wholly owned subsidiary in the ordinary course of business).

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2004, regarding the number of shares of Common Stock that may be issued under the Company s equity compensation plans.

Plan Category	**Number of securities to be issued upon exercise of outstanding options**	**Weighted-average exercise price of outstanding options ($)**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)**
Equity compensation plans approved by security holders(1)	4,311,680	10.70	1,480,800 (2)
Equity compensation plans not approved by security holders			
Total	4,311,680	10.70	1,480,800

(1) Includes the Company s 2001 Stock Option Plan, which was approved by the Company s stockholders prior to its initial public offering, and the Company s 2003 Stock Incentive Plan, which was approved by the Company s stockholders at the Company s 2003 Annual Meeting of Stockholders.

(2) Consists of 23,000 options available for future issuance under the Company s 2001 Stock Option Plan and 1,457,800 options available for future issuance under the Company s 2003 Stock Incentive Plan.

Stock Option Plans

The Company s 2001 Stock Option Plan provides for the granting of nonqualified stock options (options which are not tax-qualified under Section 422 of the Internal Revenue Code of 1986, as amended) to the Company s employees, directors, consultants and advisors, and employees, directors, consultants and advisors of its affiliates of up to 6,000,000 options (which amount is adjustable upon the occurrence of certain events) to purchase Common Stock, of which 23,000 options are available for future grants as of December 31, 2004.

At the Company s Annual Meeting of Stockholders held on May 15, 2003, the Company s 2003 Stock Incentive Plan was approved by the stockholders, making available the issuance of a maximum of 2,000,000 shares of Common Stock in connection with awards granted under such plan, provided that no more than 400,000 shares of Common Stock be issued to any one person pursuant to awards of options or stock appreciation rights during any one year. At December 31, 2004, 1,457,800 options to purchase Common Stock were available for grant under the 2003 Stock Incentive Plan.

The Option Subcommittee of the Compensation Committee of the Board of Directors administrates both the 2001 Stock Option Plan and the 2003 Stock Incentive Plan. Pursuant to the terms of the plans, the exercise price for options granted thereunder will not be less than 100% of the fair market value of a share on the date of grant unless the Option Subcommittee in its discretion and due to special circumstances determines otherwise. Options under the plans are generally granted for a 10-year term, but may terminate earlier if the option holder s employment with the Company terminates before the end of such 10-year period. In the event of a change in control, under the 2001 Stock Option Plan, the Option Subcommittee, in its discretion, may provide that all outstanding options granted will immediately vest, while under the 2003 Stock Incentive Plan, outstanding awards will automatically vest.

Use of Proceeds from Initial Public Offering

In June 2002, the Company closed an initial public offering of its common stock. The Registration Statement on Form S-1 (File No. 333-83638) was declared effective by the SEC on May 23, 2002 and the Company commenced the offering on that date. After deducting underwriting discounts and commissions and the offering expenses, net proceeds from the offering to the Company totaled approximately $139.2 million.

The Company has used proceeds from the offering as follows: (i) $66.9 million has been used to repay debt due to Hexal; (ii) $10.0 million has been used to repay debt incurred in connection with the acquisition of EHI; and (iii) $2.0 million has been used for general working capital purposes. The remaining $60.3 million of the proceeds to the Company from the offering are invested in cash investments and short-term investment grade debt securities. The Company anticipates using the balance of the proceeds from the offering for general corporate purposes, including funding working capital, increasing research and development to expand the Company s product offerings and the potential acquisition of product lines or companies. The Company has no present understandings, commitments or agreements with respect to any acquisitions. The Company has not determined the amounts it plans to spend on any of the areas listed above or the timing of these expenditures.

Purchases of Equity Securities by the Company

During the quarter ended December 31, 2004, the Company did not repurchase any shares of its Common Stock, either as part of a publicly announced plan or program or otherwise. No publicly announced plans or programs are currently in place under which the Company may purchase shares of its Common Stock.

Item 6. Selected Financial Data.

The following table sets forth selected historical financial data as of and for the years ended December 31, 2004, 2003, 2002, 2001, and 2000. The data are derived from the Company s consolidated financial statements, which have been audited by PricewaterhouseCoopers LLP, the Company s independent registered public accounting firm (PwC). The selected consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations, the Consolidated Financial Statements and the Notes to Consolidated Financial Statements included elsewhere in this report.

Prior to the reorganization mergers described below, Santo owned 100% of the outstanding capital stock of HPI. Santo is under common control with Hexal, the second largest generic pharmaceutical company in Germany. In September 1995, HPI acquired 50% of the Company s capital stock. In December 2000, HPI indirectly acquired the remaining 50% of the Company s capital stock through its acquisition of 100% of the outstanding capital stock of EHI. On May 21, 2002, a reorganization occurred in which EHI merged into HPI, which subsequently merged into the Company. As a result, Santo owns a majority of the Company s outstanding common stock. This reorganization has been accounted for as a merger of entities under common control and the accounts of the companies have been combined in a manner similar to a pooling of interests, effective January 1, 2000.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(Dollars in thousands, except for per share data)				
CONSOLIDATED STATEMENT OF INCOME DATA:					
Net sales	$ 430,959	$ 329,538	$ 244,269	$ 165,443	$ 119,693
Cost of sales	190,602	154,387	122,351	77,072	56,880
Gross profit	240,357	175,151	121,918	88,371	62,813
Operating expenses					
Selling, general and administrative					
Amortization of goodwill				3,360	318
Deferred stock appreciation rights compensation				9,837	6,197
Other selling, general and administrative	46,043	37,296	32,706	25,322	20,890
Research and development	21,666	22,510	13,239	12,224	14,936
Total operating expenses	67,709	59,806	45,945	50,743	42,341
Operating income	172,648	115,345	75,973	37,628	20,472
Other income and expense					
Interest income	2,461	1,411	854	462	1,311
Interest expense		(300)	(3,857)	(9,318)	(1,892)
Other income, net(2)	13,046	228	113	44	398
Total other income (expense)	15,507	1,339	(2,890)	(8,812)	(183)
Income before income taxes	188,155	116,684	73,083	28,816	20,289
Provision for income taxes	68,804	46,549	29,820	13,025	9,300
Net income(3)	$ 119,351	$ 70,135	$ 43,263	$ 15,791	$ 10,989
PER SHARE DATA(1)					
Basic	$ 1.34	$ 0.79	$ 0.81	$	$
Diluted	$ 1.32	$ 0.77	$ 0.53	$ 0.25	$ 0.18
Weighted average common shares outstanding					
Basic	88,772,514	88,479,942	53,261,578		
Diluted	90,673,611	90,520,586	81,297,066	64,261,458	60,240,000
OTHER DATA					
Cash and investments	$ 195,752	$ 159,133	$ 87,284	$ 17,624	$ 6,378
Total assets	545,174	441,545	329,871	219,402	196,903
Long-term debt including current portion			4,530	116,867	123,110
Total stockholders equity	443,524	328,780	258,154	46,991	11,895
Net cash provided by (used in)					
Operating activities	$ 60,957	$ 90,589	$ 32,598	$ 32,867	$ 14,206
Investing activities	(35,404)	(102,883)	(35,445)	(4,916)	(87,833)
Financing activities	(10,100)	(6,177)	47,546	(16,705)	58,910

(1) Per share data has been retroactively restated to reflect the impact of the 2-for-1 split with respect to the Company s Common Stock, effective as of June 1, 2004.

(2) In 2004, includes the receipt of a $10,000 payment to settle all patent infringement litigation related to Nabumetone, or $0.07 per share, and the receipt of a $3,000 bond related to the settlement of all patent infringement litigation involving Buproprion HCl, ER 100mg and 150mg tablets, or $0.02 per share.

(3) In 2002, the Company adopted Statement of Financial Accounting Standard No. 142, Goodwill and Other Intangible Assets. Had this pronouncement been retroactively applied, net income would have increased approximately $3,200 and $300 and diluted earnings per share would have increased $0.05 and less than $0.01 in 2001 and 2000, respectively.

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the Selected Financial Data and the Company s consolidated financial statements and related notes appearing elsewhere in this annual report. This discussion and analysis contains forward-looking statements based on the Company s current expectations, assumptions, estimates and projections.

Forward-Looking Statements

This report contains forward-looking statements. To the extent that any statements made in this report contain information that is not historical, these statements are essentially forward-looking. Generally, these statements can be identified because they use words like anticipates, believes, expects, future, intends, plans, and similar terms. These statements are only the Company s current expectations. Although the Company does make forward-looking statements unless it believes it has a reasonable basis for doing so, it cannot guarantee their accuracy, and actual results may differ materially from those it anticipated due to a number of uncertainties, many of which are unforeseen, including, among others, the risks it faces as described elsewhere in this report. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report.

Overview

The Company is a generic pharmaceutical company engaged in developing, licensing, manufacturing, selling and distributing a broad range of prescription pharmaceutical products primarily in the United States. The Company focuses primarily on drugs in a broad range of solid oral dosage forms, utilizing both immediate and sustained release delivery, in tablet, multiple layer tablet, film-coated tablet and capsule forms. The Company does not depend on any single drug or therapeutic category for a majority of its sales.

Proposed Merger

On February 20, 2005, the Company entered into the Merger Agreement with Novartis, Merger Sub and, solely with respect to its guarantee of Novartis s and Merger Sub s obligations thereunder, Parent. Pursuant to the Merger Agreement, Merger Sub will commence a tender offer to purchase all of the issued and outstanding shares of the Company s Common Stock (other than those shares owned by Santo), at $31.00 per share.

In connection with the execution of the Merger Agreement, Novartis, Santo and Parent entered into the Santo Agreement, pursuant to which Novartis agreed to purchase, and Santo agreed to sell, all of the Santo Shares, representing approximately 67.5% of the outstanding shares of Common Stock, for 1.3 billion in cash on the terms and subject to the conditions set forth therein.

The Offer is not conditioned upon any minimum number of shares being tendered, but is contingent upon the contemporaneous (or immediately subsequent) closing of the Santo Purchase pursuant to the Santo Agreement. In addition to certain customary conditions, the closing of the Santo Purchase is conditioned on the acquisition by Novartis (Deutschland) GmbH of all of the outstanding shares and partnership interests of Hexal, including shares held directly and indirectly by Dr. Thomas Strüngmann, the Chairman of the Board of Directors of the Company and an indirect significant stockholder of Santo, and Dr. Andreas Strüngmann, an indirect significant stockholder of Santo. Additionally, the Santo Purchase is subject to customary regulatory approvals, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Following the completion of the Offer and the purchase of the Santo Shares, if a majority of the outstanding shares of Common Stock other than the Santo Shares are purchased in the Offer, in accordance with the DGCL, Merger Sub will be merged with and into the Company and any remaining shares of Common Stock will be acquired by Merger Sub.

The Merger Agreement provides that upon consummation of the Offer, the Confidentiality Agreement, dated February 11, 2005, between the Company and Novartis (which currently restricts the ability of Novartis and its affiliates to acquire Public Shares without approval of a majority of the special committee of independent board members, which was appointed to review the Offer and the Merger, and of the Company s Board of Directors) will be amended to provide that Novartis and its affiliates will be permitted to make acquisitions of Public Shares that are voluntary to the holders of Public Shares (such as by means of legally permissible open market purchases or tender offers), but, prior to February 11, 2006, Novartis and Merger Sub will not be permitted to cause a merger transaction (or other business combination) to be effected which would cancel Public Shares unless (i) a majority of the outstanding Public Shares vote in favor of such a transaction or (ii) Novartis and its subsidiaries, at that time, own at least 90% of the outstanding Common Stock; provided, that the consideration to be received by the holders of Public Shares in any such transaction described in (ii) above must be at least equal to $31.00 per Public Share. Following the completion of the Offer and until the earlier of the consummation of the Merger and February 11, 2006, Novartis and Merger Sub are required to use their reasonable best efforts to keep the Common Stock quoted for trading on the NASDAQ National Market unless the Company is no longer required to be registered under the Exchange Act, or no longer satisfies NASDAQ s listing standards (other than standards entirely within the Company s control).

At the effective time of the Merger, each issued and outstanding share of Common Stock (other than shares owned by Novartis, any of its subsidiaries (including Merger Sub) or any of its affiliates, any shares held in the treasury of the Company and shares held by stockholders who properly demand appraisal and comply with the provisions of Section 262 of the DGCL, relating to dissenters rights of appraisal) will be converted into the right to receive an amount equal to the Offer Price. Following the consummation of the Merger, the Company will continue as the surviving corporation and will be a wholly owned subsidiary of Novartis.

Critical Accounting Policies

The Company s critical accounting policies are those policies that are important to the portrayal of its financial condition and results of operations and require management s subjective judgments. As a result, these judgments are subject to an inherent degree of uncertainty. The Company bases its judgments on its experience and various other assumptions that the Company believes to be reasonable under the circumstances. On an ongoing basis, the Company evaluates its estimates, including those related to revenues, returns, inventories, income taxes and litigation. The Company s actual results could differ from these estimates under different assumptions or conditions. The Company believes the following accounting policies to be critical:

Revenue Recognition

Sales are recognized when the products are received by the customer, which represents the point when the risks and rewards of ownership are transferred to the customer. When the Company recognizes revenue from product sales, the Company records estimates for contract pricing adjustments, rebates, discounts, expected product returns and other sales allowances. These allowances are recorded as a reduction of product sales. Contract pricing adjustments, rebates and discounts are recorded as a reduction of sales based on agreed-upon terms with the Company s customers at the time of sale.

Reserves for Contract Pricing Adjustments, Rebates and Discounts

Reserves for contract pricing adjustments and rebates represent the difference between prices wholesalers are billed by the Company for products sold and the contract prices billed by wholesalers to their customers (the Company s indirect customers) for the products. These contract pricing and rebate reserve estimates are based on agreements between the Company and its indirect customers or between

the Company and the wholesalers and are recorded as a reduction in sales at the time of sale. In determining a reserve for contract pricing adjustments and rebates, the Company estimates the amount of such pricing adjustments by product based on historical trends and changes in wholesaler or contract prices. As part of the Company s review of this estimation process, the Company obtains inventory reports from key wholesalers to determine the level of inventory in that distribution channel to compare with inventory levels used in its estimation process. The Company calculates a reserve for discounts based upon actual sales under such discount arrangements. No revisions were made to the methodology used in determining these provisions during the year ended December 31, 2004.

As of December 31, 2004 and 2003, accounts receivable are presented net of allowances for contract pricing adjustments, rebates and discounts of $138.0 million and $94.7 million, respectively. When allowances against a specific customer account exceed that customer s receivable balance, the net credit balance for that customer is included in accrued liabilities. The amounts reclassified to accrued liabilities are $15.0 million and $20.8 million at December 31, 2004 and 2003, respectively. The increase in aggregate allowances is due to an increase in sales, principally the result of new product introductions. No revisions were made to the methodology used in determining these provisions during the year ended December 31, 2004.

Reserve for Product Returns

The Company s policy is to accept customer returns of products, which consist primarily of products whose expiration date has been exceeded, upon appropriate approval by authorized personnel of the Company. The majority of the Company s products have a two to three year expiration date. Estimates for returns, which are recorded as a reduction of sales at the time of sale, relate primarily to products expected to be returned upon expiration. The Company utilizes historical trends to estimate the amount of products expected to be returned. As of December 31, 2004 and 2003, the Company has a reserve for product returns of $25.6 million and $35.0 million, respectively. The decrease in the reserve is attributed primarily to the issuance of credits for returns of specific products unrelated to product expiration, but instead resulting from the loss of a significant contract by a wholesaler. There were no revisions made to the methodology used in determining these provisions during the year ended December 31, 2004.

Pricing Adjustments, Promotions and Allowances and Medicaid Rebates

Shelf stock adjustments are recorded following a reduction in the price of the Company s products due to changes in the competitive environment. Such adjustments are credited to the Company s customers based on their on-hand inventory quantities at the time of the reduction in price. Reserves are generally established when prices are actually reduced. As of December 31, 2004, there was a liability for a shelf stock adjustment of $0.8 million for which a credit had not yet been issued. As of December 31, 2003 there were no liabilities recorded for shelf stock adjustments.

The Company typically provides sales incentives to its customers at the time of a new product launch to obtain distribution and market share. Since most of these promotional arrangements do not require a minimum purchase level, they are recorded as a reduction of sales upon shipment of the customer s initial order. The Company also participates in trade show and other promotions where additional discounts may be given as an incentive for the customer to purchase products. Such discounts and incentives are recorded as a reduction of sales at the time of sale of the related product. Since the Company allows customers to return short-dated or expired products with appropriate approval, it is in the Company s interest to ensure that its customers do not maintain excess inventory levels. The Company evaluates unusually large orders to ensure that customers inventories are not in excess of their ordinary course of business inventory levels.

As of December 31, 2004 and 2003, the reserve for promotions and allowances was $18.0 million and $12.4 million, respectively. The increase in the reserve for promotions and allowances is attributed

primarily to promotions for new products launched during 2004. During the year ended December 31, 2004, the Company recorded an adjustment to reduce its reserve related to promotions by $1.8 million. The reduction was attributed to certain promotional programs in the final stages of their program lives and for which an accrual was no longer considered necessary.

All generic pharmaceutical manufacturers whose products are covered by the Medicaid program are required to rebate to each state a percentage of their average manufacturer s price for the products dispensed. Many states also have implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. The Company estimates these rebates based on historical trends of sales for such products in each state. The reserve for Medicaid rebates at December 31, 2004 and 2003 was $8.0 million and $4.9 million, respectively.

Reserve for Pending Litigation Claims

In determining whether liabilities should be recorded for pending litigation claims, the Company must assess the allegations made and the likelihood that it will successfully defend itself. When the Company believes it is probable that it will not prevail in a particular matter, it will then make an estimate of the amount of liability based in part on advice of outside legal counsel. There were no liabilities recorded for pending claims as of December 31, 2004 and 2003.

Year Ended December 31, 2004 Compared with Year Ended December 31, 2003

Net sales. Net sales increased 30.8% to $431.0 million in 2004 from $329.5 million in 2003. The increase in net sales is attributable to the introduction of new products during 2004. The most significant product was Bupropion HCl, ER 100mg and 150 mg tablets. The introductions of Fosinopril, Benazepril HCl, Benazepril/HCTZ and Citalopram and the full-year impact of products introduced in late 2003, such as Mirtazipine, Midodrine HCl and Metolazone USP, also contributed to the sales growth. The favorable impact of new product introductions was partially offset by price declines on selected existing products.

Gross profit. Gross profit increased $65.2 million to $240.4 million in 2004 from $175.2 million in 2003. Gross profit as a percentage of net sales increased to 55.8% in 2004 from 53.2% in 2003. The Company s gross profit margins are dependent on several factors, including product sales mix, cost, volume and competitive activity. The increase in the 2004 gross profit is attributable primarily to the introduction of Bupropion during 2004, and an increase in utilization of manufacturing capacity, offset by price decreases on selected products.

Other selling, general and administrative. Other selling, general and administrative expenses increased $8.7 million to $46.0 million in 2004 from $37.3 million in 2003. Expenses for 2003 were reduced by the recovery of $3.5 million in legal fees related to Nabumetone litigation. Excluding the recovery of legal fees, other selling, general and administrative expenses were $40.8 million for 2003. Excluding the recovery, the increase in expense was the result of increases of $2.0 million in compensation costs, $2.2 million in insurance expense due to higher product liability and directors and officer insurance premiums, $0.9 million in professional fees for audit, tax, and consulting principally due to compliance with the Sarbanes-Oxley Act of 2002 and a net increase in other expenses of $0.1 million.

Research and development. Research and development expenses decreased $0.8 million to $21.7 million in 2004 from $22.5 million in 2003. The decrease is principally attributed to decreases in bio-study expenses, and contracted product development expenses relating to the completion of defined milestones under third-party product development agreements, partially offset by other expenses. The decrease in these expenses is related principally to the timing of such expenditures.

Operating income. Operating income increased $57.3 million to $172.6 million in 2004 from $115.3 million in 2003. The increase in operating income is the result of increased sales and gross profit, partially offset by increases in total operating expenses.

Interest income (expense). Interest income was $2.5 million for 2004. Net interest income was $1.1 million in 2003. Interest income was higher as a result of higher investment balances. There was no interest expense during 2004, as there was no outstanding debt.

Other income, net. Other income for the year ended December 31, 2004 was $13.0 million, including a $10.0 million settlement received from Glaxo in exchange for the Company agreeing to the dismissal of its complaint against Glaxo for the malicious prosecution of its earlier suit against the Company, which claimed the Company s Nabumetome product infringed Glaxo s patent. Other income for the period also includes a $3.0 million bond received from Glaxo to settle all patent infringement litigation relating to Buproprion HCl, ER 100mg and 150mg tablets. Other income for the year ended December 31, 2003 was approximately $0.2 million.

Taxes on income. Taxes on income increased $22.3 million to $68.8 million in 2004 from $46.5 million in 2003. The increase is the result of higher pre-tax income during 2004. The effective tax rate decreased to 36.6% from 39.9%. The decrease in the effective tax rate during 2004 is attributable to: the reversal of tax contingencies; lower local and state income taxes, resulting in part from the recognition of state tax credits; and the benefit of investing in tax exempt securities. The reversal of tax contingencies totaling $1.6 million was recorded in connection with the acceptance of certain Voluntary Disclosure Agreements filed with various state and local tax jurisdictions.

Net income. Net income increased $49.2 million to $119.4 million in 2004 from $70.1 million in 2003 for the reasons described above.

Year Ended December 31, 2003 Compared with Year Ended December 31, 2002

Net sales. Net sales increased 34.9% to $329.5 million in 2003 from $244.3 million in 2002. The increase in net sales is attributable primarily to the increase in unit volume of several existing products, the full year impact of products introduced in 2002 and sale of products introduced after December 31, 2002. Several existing products including Lovastatin, USP, Cholestyramine, USP, and Labetalol, HCl, had significant increases in unit volumes. Products introduced in 2002 that had increased unit volumes in 2003 due to the full year impact include Lisinopril, USP, Lisinopril/HCTZ, Tizanidine HCl, and a Dextroamphetamine and Amphetamine Mixed Salts product. Nabumetone, a product also introduced in early 2002, also had a significant increase in unit volume. The increase is primarily related to an increase in market share. Products introduced subsequent to December 31, 2002 include Mirtazipine, Midodrine HCl, Nefazodone HCl, and Metolazone USP.

Gross profit. Gross profit increased $53.2 million to $175.2 million in 2003 from $121.9 million in 2002. Gross profit as a percentage of net sales increased to 53.2% in 2003 from 49.9% in 2002. The Company s gross profit margins are dependent on several factors, including product sales mix, cost, volume and competitive activity. In 2003, the increase in margin percent is attributable primarily to an increase in utilization of manufacturing capacity, lower raw material costs and a $1.4 million decrease in expense related to write-downs of slow-moving or unusable inventory. Inventory write-downs were lower in 2003 as compared to 2002, as 2002 included a $2.4 million write-down of a raw material that will not be utilized in production.

Other selling, general and administrative. Other selling, general and administrative expenses increased $4.6 million to $37.3 million in 2003 from $32.7 million in 2002. Expenses for 2003 were reduced by the recovery of $3.5 million in legal fees related to Nabumetone litigation. Excluding the recovery of legal fees, other selling, general and administrative expenses were $40.8 million for 2003, representing an increase of $8.1 million compared to 2002. However, other selling, general and administrative expenses, excluding the recovery of legal fees in 2003, decreased as a percentage of net sales to 12.4% compared to 13.4% in 2002. The increase in expense was the result of increases of $1.0 million in compensation costs, $2.5 million in insurance expense due to higher premiums, $1.4 million in freight and sales commissions, $2.2 million in legal costs principally due to patent challenges and $1.0 million in other expenses.

Research and development. Research and development expenses increased $9.3 million to $22.5 million in 2003 from $13.2 million in 2002. The increase is attributable to an increase in generic product development costs of $9.8 million, offset by a decrease of $0.5 million related to certain basic research contracts unrelated to the Company s business that were transferred in March 2002 to an unrelated entity. The increase in generic drug development costs is principally attributed to increases in the number of bio-studies, materials and expenses relating to the completion of defined milestones under third-party product development agreements. These increases reflect an acceleration of the Company s product development program.

Operating income. Operating income increased $39.4 million to $115.3 million in 2003 from $76.0 million in 2002. The increase in operating income was the result of increased sales and gross profit, partially offset by increases in other selling, general and administrative and research and development expenses.

Interest income (expense). Net interest income was $1.1 million in 2003 compared to net interest expense of $3.0 million in 2002. A decrease in outstanding debt, primarily attributable to the elimination of $92.1 million of intercompany debt in June 2002, decreased interest expense by $3.6 million. Interest income increased by $0.6 million as a result of higher investment balances.

Taxes on income. Taxes on income increased $16.7 million to $46.5 million in 2003 from $29.8 million in 2002. The increase was the result of higher pre-tax income during 2003. The effective tax rate decreased to 39.9% from 40.8%, principally due to lower state and local income taxes.

Net income. Net income increased $26.9 million to $70.1 million in 2003 from $43.3 million in 2002 for the reasons described above.

Quarterly Results of Operations

The following table presents a summary of the Company s unaudited quarterly consolidated results of operations for each of the four quarters in 2004, 2003 and 2002. The unaudited interim financial statements include all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such information when read in conjunction with the Company s audited consolidated financial statements and related notes. Per share data has been retroactively restated to reflect the impact of the 2-for-1 split with respect to the Company s Common Stock, effective as of June 1, 2004. The Company s quarterly operating results have varied in the past, may continue to do so and are not necessarily indicative of results for any future period. Additionally, future results may differ substantially from historical results pending the consummation of the offer and the Merger.

	First Quarter(1)	Second Quarter	Third Quarter	Fourth Quarter
	(Dollars in thousands, except per share data)			
2004				
Net sales	$ 104,229	$ 106,962	$ 109,778	$ 109,990
Gross profit	$ 61,308	$ 62,926	$ 59,591	$ 56,532
Net income	$ 32,317	$ 28,788	$ 28,089	$ 30,156
Earnings per share(1)				
Basic	$ 0.36 (3)	$ 0.32 (4)	$ 0.32	$ 0.34
Diluted	$ 0.36 (3)	$ 0.32 (4)	$ 0.31	$ 0.33
2003				
Net sales	$ 70,857	$ 78,681	$ 85,011	$ 94,989
Gross profit	$ 37,472	$ 40,660	$ 46,635	$ 50,384
Net income	$ 15,107	$ 18,032	$ 17,819	$ 19,177
Earnings per share(1)				
Basic	$ 0.17	$ 0.20 (2)	$ 0.20	$ 0.22
Diluted	$ 0.17	$ 0.20 (2)	$ 0.20	$ 0.21
2002				
Net sales	$ 48,198	$ 52,000	$ 75,351	$ 68,720
Gross profit	$ 22,273	$ 27,363	$ 39,330	$ 32,952
Net income	$ 6,346	$ 9,504	$ 14,183	$ 13,230
Earnings per share(1)				
Basic	$	$ 0.26	$ 0.16	$ 0.15
Diluted	$ 0.09	$ 0.12	$ 0.16	$ 0.15

(1) The sum of earnings per share for the four quarters may not equal earnings per share for the full year due to changes in the average number of common shares outstanding.

(2) Includes recovery of $3.5 million of legal fees, or $0.02 per share.

(3) Includes the receipt of $10.0 million payment to settle all patent infringement litigation related to Nabumetone, or $0.07 per share.

(4) Includes the receipt of $3.0 million bond related to the settlement of all patent litigation involving Bupropion HCl, ER 100mg and 150mg tablets or $0.02 per share.

Liquidity and Capital Resources

Cash and cash equivalents were $59.5 million at December 31, 2004, as compared to $43.9 million at December 31, 2003. Additionally, the Company had investments in marketable debt securities of $136.3 million at December 31, 2004, as compared to $115.3 million at December 31, 2003.

The Company s initial public offering in June 2002 generated proceeds of $139.2 million, net of offering expenses. The Company has used the proceeds from the offering as follows: (i) $66.9 million has been used to repay debt due to Hexal; (ii) $10.0 million has been used to repay debt incurred in connection with the acquisition of EHI; and (iii) $2.0 million has been used for general working capital purposes. At December 31, 2004, the remaining balance of $60.3 million of the proceeds was available for general corporate purposes.

The Company has a three-year $25 million credit facility which expires on December 31, 2007. Under this facility, the Company can borrow at the adjusted LIBOR rate plus 1.5%, the bank s prime rate or a fixed rate (as set by the bank). The credit facility, which is for working capital purposes, had no outstanding borrowings against it at December 31, 2004 and December 31, 2003.

Stockholders equity increased to $443.5 million at December 31, 2004 from $328.8 million at December 31, 2003. The increase in stockholders equity is comprised of: an increase of $6.4 million (including tax benefits) from the exercise of stock options; net earnings of $119.4 million for the year ended December 31, 2004; and amortization of deferred stock-based compensation costs of $0.2 million, offset by the net purchases of $11.2 million of treasury shares.

In 2004, cash increased by $15.6 million. Operations generated $61.0 million of cash, comprised of net earnings of $119.4 million, non-cash items totaling $53.0 million offset by an increase in working capital of $111.4 million. Working capital is defined as current assets (excluding cash and cash equivalents, investments and restricted cash) less current liabilities. The increase in working capital resulted primarily from increases in accounts receivable of $75.7 million, inventory of $16.0 million, prepaid expenses and other assets of $12.6 million, and decreases in accounts payable and accrued liabilities of $7.3 million. The increases in accounts receivable and inventory are attributed to increased sales. The increase in prepaid expenses and other assets is primarily the result of prepaid taxes. The decrease in accounts payable and accrued liabilities is primarily due to a decrease in customer returns and credits.

In 2003, cash decreased by $18.5 million. Operations generated $90.6 million of cash, comprised of net earnings of $70.1 million, non-cash items totaling $20.3 million and a decrease in working capital of $0.1 million. The decrease in working capital resulted primarily from a decrease in prepaid expenses and other assets totaling $2.5 million and increases in accounts payable and accrued liabilities of $43.1 million. The decrease in prepaid expenses and other assets is primarily the result of a lower royalty receivable owed to the Company under a licensing arrangement. The increase in accounts payable and accrued liabilities is primarily due to an increase in customer returns, credits and allowances. Increases in accounts receivable and inventory of $31.0 million and $14.5 million, respectively, substantially offset the decreases in working capital. The increases in accounts receivable and inventory are attributed to increased sales.

Investing activities consumed $35.4 million of cash in 2004. Approximately $21.3 million was used to purchase short-term investment grade debt instruments and $14.1 million was used for capital expenditures. The capital expenditures included primarily the purchase of equipment to support increased production in the Company s Wilson facility.

Investing activities consumed $102.9 million of cash in 2003. Approximately $90.4 million was used to purchase short-term investment grade debt instruments and $12.5 million was used for capital expenditures. The capital expenditures included primarily the purchase of equipment to support increased production in the Company s Wilson facility.

Financing activities consumed $10.1 million of cash in 2004. The purchase of treasury shares consumed $11.2 million. Financing activities generated $1.1 million, of which $1.0 million represents cash proceeds received from employees who exercised stock options, with the remaining proceeds related to other financing activities.

Financing activities consumed $6.2 million of cash in 2003. Repayment of acquisition debt and the purchase of treasury shares consumed $4.8 million and $2.6 million, respectively. Financing activities generated $1.2 million, of which $0.6 million represents cash proceeds received from employees who exercised stock options, with the remaining proceeds related to other financing activities.

The Company is involved in various product liability and patent litigation not covered by insurance. Adverse rulings in litigation related to product liability could result in the Company paying damages and expenses that could have a material adverse effect on the Company s financial performance.

An adverse outcome in patent litigation with Novartis and Apotex involving the Company s generic Cyclosporine product could result in the Company not being able to market this product, which could materially harm its profits and cash flows and could result in the Company paying damages, costs, expenses and fees that could have a material adverse impact on its financial performance. In December 2002, the U.S. District Court for the District of Delaware granted the Company s motion for summary judgment of non-infringement of the Novartis patent. In April 2004, the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the Delaware District Court that the Company s generic Cyclosporine product does not infringe Novartis patent. Novartis request for a rehearing by the U.S. Appeals Court is still pending. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

In January 2001, Janssen filed suit against the Company in the U.S. District Court for the Eastern District of New York. The suit claims the Company s filing of its ANDA for Itraconazole capsules infringed a Janssen patent. In July 2004, the Court found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. Janssen s appeal of the District Court s ruling is pending. In February 2005, the Company began selling Itraconazole capsules. A reversal of the District Court s ruling by the Court of Appeals could result in the Company being enjoined from marketing the product which could materially harm profits and cash flows, and result in paying damages, costs, and fees that could have a material adverse impact on the Company s financial performance.

The Company does not currently have or anticipate any short-term funding requirements outside of the ordinary course of its business, and the Company does not have or anticipate any liquidity concerns. The Company s principal future cash requirements are associated with increased working capital to support future growth, capital expenditures and legal defense costs. The Company anticipates that its operating cash flows and current cash balances together with its available borrowings under its credit facility will be sufficient to meet all of its cash requirements for both the short-term and foreseeable future.

Impact of Recently Issued Accounting Standards

The Company applies the recognition and measurement principles of Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, in accounting for its long-term stock-based incentive plans. No compensation cost related to grants of stock options was reflected in net income, as all options granted under the plans had an exercise price equal to the market price. In accordance with the recently issued FAS 123(R), the Company will record an expense for the value of stock options beginning in July 2005. The Company is reviewing the various implementation methods available under this pronouncement.

In December 2004, the FASB issued SFAS No. 153, Exchange of Nonmonetary Assets an amendment of APB Opinion No. 29. This Statement precludes companies from using the similar productive assets criteria to account for nonmonetary exchanges at book value with no gain or loss being recognized. Effective for fiscal periods beginning after June 15, 2005, all companies will be required to use fair value for most nonmonetary exchanges, recognizing gain or loss, if the transaction meets a commercial-substance criteria. The Company does not expect this Standard to have a significant impact on its consolidated financial statements.

In December 2004, the FASB issued FSP FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 to provide accounting guidance on the appropriate treatment of tax benefits generated by the enactment of the Act. The FSP requires that the manufacturer s deduction be treated as a special deduction in accordance with SFAS 109 and not as a tax rate reduction. The Company is awaiting final tax regulations from the IRS before completing its assessment of the impact of adopting FSP FAS 109-1 on its consolidated financial statements.

In November 2004, the FASB issued Statement No. 151, Inventory Costs, an amendment of ARB 43, Chapter 4, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage). ARB 43 allowed some of these abnormal costs to be carried as inventory whereas the new Standard requires that these costs be recognized in income as incurred. This Statement is effective for fiscal years beginning after June 15, 2005. The Company is currently evaluating what effect, if any, this Standard will have on its consolidated financial statements.

In January 2003, the FASB issued Fin No. 46, Consolidation of Variable Interest Entities (as revised by Fin No. 46R). This interpretation, as revised, provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities (VIEs), in which an investor is subject to a majority of the risk of loss from the VIEs activities, or is entitled to receive a majority of the VIEs residual returns. This interpretation also provides guidance with respect to the disclosure of VIEs in which an investor maintains an interest, but is not required to consolidate. The provisions of the interpretation were effective immediately for all VIEs created after January 31, 2003, or in which the Company obtains an interest after that date. For VIEs created before February 1, 2003, the provisions were effective July 1, 2003. In November 2003, the Company invested $1.15 million for 50% ownership in an entity formed to provide research and development services for the Company as well as third parties. It has been determined that such investee is deemed a VIE, which has been consolidated in the Company s financial statements. The net assets and result of operations of this entity were not material to the Company in 2004. Creditors, or beneficial interest holders, of the consolidated VIE have no recourse to the general credit of the Company.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(amounts in thousands of dollars)				
Long-Term Debt Obligations					
Capital (Finance) Lease Obligations					
Operating Lease Obligations	9,476	870	1,774	1,822	5,010
Purchase Obligations(1)	55,214	49,736	3,984	1,494	
Other Long-Term Liabilities Reflected on the Company s Balance Sheet under GAAP					
Total	64,690	50,606	5,758	3,316	5,010

(1) Purchase obligations include commitments of approximately $43 million relating to inventory items. The balance is attributable to non-inventory items, including fixed assets, research and development materials, supplies and services.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The following discusses the Company s exposure to market risk related to changes in interest rates, equity prices and foreign currency exchange rates. The Company does not believe that its exposure to market risk is material.

As of December 31, 2004, the Company had cash and cash equivalents of $59.5 million. Cash equivalents are interest-bearing investment grade securities, primarily short-term, highly liquid investments with maturities at the date of purchase of less than 90 days. In addition, the Company currently owns $136.3 million in publicly traded debt securities with an average maturity of approximately 116 days, which are subject to market fluctuations.

These investments are subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical increase in the market interest rates by 10 percent from the rates in effect on the date of this Form 10-K would cause the fair value of these short-term investments to decline by an immaterial amount. The Company has the ability to hold these investments until maturity, and therefore it does not expect the value of these investments to be affected to any significant degree by the effect of a sudden change in market interest rates. Declines in interest rates over time will, however, reduce the Company s interest income.

The Company currently does not have any significant foreign currency exchange rate risk.

Item 8. Financial Statements and Supplementary Data.

The information required to be presented by this item is presented on pages F-1 through F-30 of this Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company s management performed an evaluation, under the supervision and with the participation of its Chief Executive Officer and Chief

Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation, the Company s management, including its Chief Executive Officer and Chief Financial Officer, concluded that the Company s disclosure controls and procedures were effective as of the end of the period covered by this report.

Management s Report on Internal Control Over Financial Reporting

The Company s management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Under the supervision and with the participation of management, including the Company s Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Because of inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Based on the evaluation under the aforementioned framework, the Company s management concluded that the Company s internal control over financial reporting was effective as of December 31, 2004. PricewaterhouseCoopers LLP, the Company s external auditor and an independent registered public accounting firm, has attested to management s assessment of the effectiveness of the Company s internal control over financial reporting as of December 31, 2004, as stated in PricewaterhouseCoopers LLP s report which is included herein.

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company s internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The Board of Directors of the Company (the Board) is comprised of Dr. Bernhard Hampl, Dr. Thomas Strüngmann, Mr. Frank Beelitz, Mr. Douglas Karp and Mr. Mark Patterson. The Board has determined that Messrs. Karp and Patterson are independent as defined by applicable listing standards of the National Association of Securities Dealers, Inc. (the NASD) and the standards set forth by the SEC. A majority of the Board is not comprised of independent directors because, under NASD rules, a controlled company is exempt from this requirement. The Company is a controlled company because more than 50% of the Company s voting power is held by Santo.

Director nominees are selected by the entire Board in connection with recommendations received from Board members and in accordance with the Company s Restated Certificate of Incorporation. The Company does not have a separate nominating committee because, under NASD rules, a controlled company is not required to establish a separate nominating committee.

The Company s Restated Certificate of Incorporation provides that the Board shall be divided into three classes, each class of the same or nearly the same number of directors and each elected for a three-year term. The term of Class III directors is scheduled to expire at the 2005 Annual Meeting of Stockholders, the term of Class I directors is scheduled to expire at the 2006 Annual Meeting of Stockholders and the term of Class II directors is scheduled to expire at the 2007 Annual Meeting of Stockholders.

Biographical Information for Directors

Class I Directors

Frank F. Beelitz (age 61) has been a Director since February 2002. Mr. Beelitz has been the General Partner of Beelitz & Cie, an investment banking advisory firm, since July 2000. Mr. Beelitz was a Managing Director of Lehman Brothers Inc. and was a member of the management board and co-head of Lehman Brothers Bankhaus AG from July 1993 to July 2000. Prior to joining Lehman Brothers Inc., Mr. Beelitz was a Managing Director with Salomon Brothers Inc. and a member of the management board and co-head of Salomon Brothers AG for seven years. Mr. Beelitz received a degree in banking from Bethmann Schule and received a Certificat d Etudes Francaises from the Universite de Grenoble, France.

Douglas M. Karp (age 49) has been a Director since October 2002. Mr. Karp has been the Managing Partner and Co-Chief Executive Officer of Tailwind Capital Partners (and its predecessor Thomas Weisel Capital Partners) since April 2003. Mr. Karp was the Managing Partner of Pacific Partners LLC, a private equity and advisory firm focused on communications, media and technology companies, from August 2000 until April 2003. Prior to joining Pacific Partners, Mr. Karp was a Managing Director and member of the Operating Committee at E.M. Warburg Pincus & Co., LLC where he was responsible for a private equity portfolio of approximately $14 billion and focused on communications and media companies and financial restructurings from May 1991 to August 2000. Prior to joining Warburg, he served as a Managing Director of Mergers and Acquisitions at Salomon Brothers Inc. from October 1986 to May 1991. In addition to the Company, Mr. Karp serves on the Board of Directors of Primus Telecommunications Group, Inc. and several private companies. Mr. Karp received a B.A. degree from Yale University and a J.D. from Harvard Law School.

Class II Director

Thomas Strüngmann, Ph.D. (age 55) has served as the Company s Chairman of the Board since September 1995. Dr. Strüngmann co-founded Hexal in 1986 and has served as its Co-Chief Executive Officer and Co-President since then. Dr. Strüngmann served as Chief Executive Officer of Durachemie GmbH from April 1979 to May 1986. Dr. Strüngmann received a B.S. degree in economics from the University of Munich and a Ph.D. from the University of Augsburg, Germany.

Class III Directors

Bernhard Hampl, Ph.D. (age 55) has served as the Company s Chief Executive Officer since October 1995 and a Director since September 1995. In January 1996, Dr. Hampl became the Company s President. From May 1995 to October 1995, Dr. Hampl was employed by Hexal to evaluate the possibility of establishing a U.S. subsidiary. From April 1980 until May 1995, Dr. Hampl held various positions with both Cyanamid GmbH and its business unit Durachemie GmbH, including: Department Head of Research and Development, where he was responsible for research and development activities in Germany for the medical, agricultural and veterinary business of Cyanamid GmbH; Technical Director, where he was responsible for quality, manufacturing, logistics, research and development; and Plant Director. Dr. Hampl was significantly involved in an internal task force formed to restructure the European

operations of Cyanamid GmbH. Dr. Hampl received his Bachelor s Degree in Pharmaceutical Sciences and a Ph.D. in Pharmaceutical Chemistry from Ludwig Maximillian University of Munich.

Mark R. Patterson (age 53) has been a Director since October 2002. Mr. Patterson has served as the Chairman of MatlinPatterson Asset Management LLC and MatlinPatterson Global Advisers LLC, which manages $3.8 billion in distressed investment funds, since July 2002. From March 1994 to July 2002, he was a Managing Director of Credit Suisse First Boston Corporation, and served as its Vice Chairman from 2000 to 2002. In addition to the Company, Mr. Patterson is on the Board of Oxford Automotive, Inc. Mr. Patterson received degrees in law and economics from South Africa s Stellenbosch University and an MBA from New York University s Stern School of Business.

Biographical Information for Non-Director Executive Officers and Other Members of Senior Management

William F. Holt (age 61) has served as the Company s Vice President, Finance, Secretary, Treasurer and Chief Financial Officer since November 1995. Prior to joining the Company, Mr. Holt was Chief Financial Officer for Pavion Limited and Yorx International, Inc. and held a variety of financial positions with American Cyanamid Company. Earlier, he was an audit manager with Coopers & Lybrand. Mr. Holt received a B.S. degree from Seton Hall University.

Frank J. Della Fera, R.Ph. (age 47) has served as the Company s Vice President, Sales and Marketing since October 1996. Prior to joining the Company, Mr. Della Fera held several positions in the field of sales and marketing, including the position of Senior Regional Sales Director for Dura Pharmaceuticals, Inc. from November 1990 to October 1996. Mr. Della Fera served in management and business development capacities for Ben Venue Laboratories, Inc. and American Regent Laboratories Inc. He began his career with Eli Lilly and Company as a field sales representative and was promoted to Hospital Sales Specialist during his tenure. Mr. Della Fera received a B.S. degree in Pharmacy from the College of Pharmacy, St. John s University.

Sadie M. Ciganek (age 54) has served as the Company s Vice President, Regulatory Affairs since August 1995. From May 1993 to August 1995, Ms. Ciganek served as the Company s Director, Quality Assurance. Prior to joining the Company, Ms. Ciganek held positions with American Cyanamid Company in the area of clinical supplies, including Manager, Global Clinical Supplies, from August 1982 to May 1993. Ms. Ciganek received a B.S. degree in chemistry from Slippery Rock University.

Pranab K. Bhattacharyya, Ph.D. (age 66) has served as the Company s Vice President, Quality Management and Analytical Services since August 1996. From September 1995 to August 1996, Dr. Bhattacharyya served as the Company s Vice President, Quality Management. Dr. Bhattacharyya has over 25 years of experience in the pharmaceutical industry in quality control, compliance and regulatory submissions. Prior to joining the Company, Dr. Bhattacharyya was employed with Hoffmann-LaRoche Inc. for 20 years, where he served in several managerial positions in pharmaceutical research and quality control. Dr. Bhattacharyya received B.S. and M.S. degrees in Physics from Calcutta University, India and a Ph.D. in Physical Chemistry from Columbia University.

David H. Gransee (age 53) has served as the Company s Controller and Assistant Secretary since its inception in 1992. Prior to joining the Company, Mr. Gransee had over 15 years of financial experience, including positions with Arthur Andersen & Co. as a Staff Auditor and with IC Industries. At IC Industries, Mr. Gransee held positions in the Corporate Audit Department, as well as management positions with its multi-national subsidiary Abex Corporation. Mr. Gransee received a B.S. degree in accounting from DePaul University.

William B. Eversgerd (age 63) has served as one of the Company s Vice Presidents since its inception in 1992 and has served as the Company s Vice President, Plant Facilities since December 1995. Prior to

joining the Company, Mr. Eversgerd had over 20 years experience in various areas in the pharmaceutical industry. Mr. Eversgerd received a B.S. degree from Southern Illinois University.

Jeffrey S. Bauer, Ph.D. (age 43) has served as the Company s Vice President, Business Development since December 2001. Dr. Bauer served as Director, R&D/Strategic Development for IVAX Pharmaceuticals, Inc. from January 2001 to December 2001. From November 1998 to January 2001, he was Director, Technical Affairs for Zenith Goldline Pharmaceuticals, Inc. (a wholly owned subsidiary of IVAX Corporation). Dr. Bauer was Vice President, Active Pharmaceutical Ingredients for IVAX Corporation from 1997 to November 1998. Dr. Bauer held positions with Applied Analytical Industries, Inc. from January 1994 to December 1997, including most recently the position of Technical Director, New Business Development. Dr. Bauer received a B.S. degree in Biology from Tufts University, a M.S. degree in Forensic Toxicology from Duquesne University and a Ph.D. in Pharmacology from the University of North Carolina at Chapel Hill.

Leon Shargel, Ph.D., R.Ph. (age 63) has served as the Company s Vice President, Biopharmaceutics since April 2001. Dr. Shargel has been an Adjunct Associate Professor in the Department of Pharmaceutical Sciences at the University of Maryland since July 1995. Prior to joining the Company, Dr. Shargel was Vice President and Technical Director with the National Association of Pharmaceutical Manufacturers from November 1997 to April 2001. From April 1996 to November 1997, Dr. Shargel was Senior Research Pharmacist at Johns Hopkins Bayview Medical Center. Dr. Shargel has written over 100 publications, including several textbooks in pharmacy. Dr. Shargel received a B.S. in Pharmacy from the University of Maryland and a Ph.D. degree in Pharmacology from the George Washington University Medical Center.

Rathnam Kumar (age 53) has served as the Company s Vice President, Manufacturing since August 2002. Mr. Kumar served as the Company s Director of Manufacturing and Validations from September 2000 to August 2002, as the Company s Director of Formulations and Process Development from August 1996 to March 1999 and as the Company s Manager of New Technologies from April 1995 to August 1996. From April 1999 to September 2000, he was Vice President of Research and Development with Able Laboratories, Inc. Mr. Kumar received a B.S. degree in Chemistry from the University of Bombay in India.

Shashank Upadhye (age 35) has served as the Company s Vice President, Intellectual Property Counsel since September 2004. Prior to joining the Company, Mr. Upadhye was associated with Lord, Bissell & Brook from June 2003 to August 2004, where he had extensive involvement in Hatch Waxman proceedings for patent and regulatory litigation and served as the primary appellate brief writer for two Supreme Court and three Federal Circuit cases. From May 2000 to June 2003, Mr. Upadhye was associated with Sonnenschein, Nath & Rosenthal where he served as a brief writer in three Federal Circuit cases with extensive involvement in ANDA generic drug patent infringement cases. From August 1998 to April 2000, he served as the Patent and Trademark Counsel to Cook Group, Inc. Mr. Upadhye was an Adjunct Professor of Patent Law at Purdue University in the latter half of 1999. Mr. Upadhye was Co-Editor of the Patent Law Journal (Aspen Law Press) and has eight full-length law review articles and one newspaper article published. Mr. Upadhye received B.S. and B.A. degrees from Brock University of Ontario, Canada, a J.D. from the New England School of Law and a L.L.M. degree in Intellectual Property from The John Marshall Law School.

Audit Committee

Messrs. Karp and Patterson comprise the Company s Audit Committee, both of whom are independent of the Company and its management, as defined by the applicable listing standards of the NASD and the standards set forth by the SEC. The Board has determined that both members of the Audit Committee are audit committee financial experts, as defined by applicable SEC guidelines, having attained

such expertise through the education and experience discussed in the respective member s biographical information under Biographical Information for Directors. Mr. Beelitz was a member of the Audit Committee until he resigned his position, effective as of March 11, 2005. On March 15, 2005, the Company provided notice to NASDAQ that it was not in compliance with the requirement under NASD listing standards that listed companies maintain an audit committee of at least three members. Under these standards, the Company has until the earlier of its next annual stockholder meeting or March 11, 2006 to comply with NASD audit committee requirements.

The Audit Committee is empowered to exercise all powers and authority of the Board with respect to the Company s annual audit, accounting policies, financial reporting, transactions with affiliates and internal control over financial reporting. In February 2004, the Board restated the Audit Committee s charter. The charter specifies the scope of the Audit Committee s responsibilities and how it carries out those responsibilities. A copy of the restated charter is attached as Appendix A to the Company s annual proxy statement for its 2004 Annual Meeting of Stockholders.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, as amended, requires the Company s directors and executive officers, and persons who own more than 10% of a registered class of the Company s equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file.

During the year ended December 31, 2004, three Forms 4 were filed in an untimely manner on behalf of Frank F. Beelitz, relating to six transactions in Common Stock or options to purchase Common Stock. To the Company s knowledge, based solely on a review of the copies of such reports furnished to the Company or written representations that any such reports were timely filed or that no such reports were required, during the year ended December 31, 2004, all other Section 16(a) filing requirements applicable to its executive officers, directors, and greater-than-10% beneficial owners were satisfied.

Code of Conduct

The Company has adopted a Code of Conduct, as defined under SEC rules, which is applicable to all of its directors, officers and employees. The Code of Conduct can be found on the Company s web site at *www.eonlabs.com*.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth summary information concerning the total compensation awarded to or earned by the Company s chief executive officer and each of the Company s four other most highly compensated executive officers whose total annual salary and bonus exceeded $100,000 (referred to herein as Named Executive Officers) in the years ended December 31, 2004, 2003 and 2002.

		Annual Compensation			Long-Term Compensation
Name and Principal Position	Year	Paid Salary ($)	Bonus Earned (Paid in Subsequent Year) ($)	All Other Compensation ($)(1)	Securities Underlying Options / SARs (#)
Bernhard Hampl, Ph.D.,	2004	330,750	1,000,000	6,150	150,000
President and Chief Executive Officer	2003	313,343	1,250,000	6,000	65,000
	2002	298,154	1,000,000	5,500	60,000
William F. Holt,	2004	211,996	290,000	6,150	60,000
VP, Finance, Secretary, Treasurer and	2003	199,190	350,000	6,000	40,000
Chief Financial Officer	2002	177,077	330,000	5,500	35,000
Frank J. Della Fera, R.Ph.,	2004	211,364	210,000	6,150	40,000
Vice President, Sales and Marketing	2003	200,930	200,000	6,000	40,000
	2002	181,962	185,000	5,500	35,000
Jeffrey S. Bauer, Ph.D.,	2004	187,425	162,000	6,150	50,000
Vice President, Business Development	2003	177,520	190,000	6,000	25,000
	2002	169,424	70,000	25,500 (2)	50,000
Sadie M. Ciganek,	2004	188,017	129,000	6,150	20,000
Vice President, Regulatory Affairs	2003	179,887	75,000	6,000	25,000
	2002	153,500	70,000	4,581	20,000

(1) Consists of contributions to the Named Executive Officer s 401(k) account.

(2) Consists of relocation reimbursement expenses.

Stock Option Grants Table

The following table sets forth certain information concerning individual grants of options to purchase Common Stock made to the Named Executive Officers during 2004. These figures do not represent the Company s estimate or projection of future Common Stock prices.

	Stock Option Grants in 2004 Individual Grants					
					Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term ($)	
Name	Number of Securities Underlying Options Granted	Percentage of Total Options Granted to Employees in 2004(%)	Exercise Price Per Share ($)	Expiration Date	5%	10%
Bernhard Hampl, Ph.D.	150,000	29.4118	29.32	2/23/2014	2,764,921	7,006,301
William F. Holt	60,000	11.7647	29.32	2/23/2014	1,105,968	2,802,520
Frank J. Della Fera, R.Ph.	40,000	7.8431	29.32	2/23/2014	737,312	1,868,347
Jeffrey S. Bauer, Ph.D.	50,000	9.8039	29.32	2/23/2014	921,640	2,335,434
Sadie M. Ciganek	20,000	3.9216	29.32	2/23/2014	368,656	934,173

Aggregate Stock Option Exercise Table

The following table sets forth information regarding the exercise of options by the Named Executive Officers during 2004. The table also shows the number and value of unexercised options held by the Named Executive Officers as of December 31, 2004. The values of unexercised options are based on a fair market value of $27.00 per share of Common Stock on December 31, 2004.

			Number of Securities		Value of Unexercised
	Shares	Value	Underlying Options at		In-The-Money Options at
	Acquired on	Realized	December 31, 2004(#)		December 31, 2004($)(2)
Name	Exercise (#)	(#)(1)	Exercisable	Unexercisable	Exercisable	Unexercisable
Bernhard Hampl, Ph.D.	230,000	7,042,653	1,121,000	326,000	28,611,732	2,274,480
William F. Holt	100,000	2,888,350	495,000	166,000	12,520,814	1,358,430
Frank J. Della Fera, R.Ph.	84,000	2,488,360	160,000	146,000	3,662,620	1,358,430
Jeffrey S. Bauer, Ph.D.	20,000	397,026	30,000	150,000	440,350	1,416,000
Sadie M. Ciganek	10,800	393,863	36,800	84,000	661,210	808,800

(1) The values realized are based on the fair market value of Common Stock on the date of exercise less the option exercise price.

(2) The values are based on the fair market value of Common Stock on December 31, 2004, less the applicable option exercise price.

Director Compensation

Directors who are not employed by the Company receive $4,000 for each Board meeting attended and $2,500 for each committee meeting held on a date different than a Board meeting. The Company also reimburses directors for reasonable expenses in connection with attending Company Board and committee meetings. The Company may, in its discretion, grant stock options and other equity awards to non-employee directors from time to time pursuant to stock incentive plans. Additionally, Messrs. Karp and Patterson, who comprise the Special Committee of the Board formed in connection with the Offer, the Merger and the Merger Agreement, are each entitled to $45,000 for their service on such committee, in addition to receiving $2,500 per meeting thereof.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee, which is responsible for the compensation policies of the Company with respect to its executive officers, was comprised during the year ended December 31, 2004 of Drs. Strüngmann and Hampl and Messrs. Karp and Patterson. Dr. Hampl is the Company s President and Chief Executive Officer. Dr. Strüngmann is the Co-Chief Executive Officer and Co-President of Hexal. See Item 13. Certain Relationships and Related Transactions for information regarding certain transactions between the Company and Dr. Strüngmann. Because the Company is a controlled Company, it is exempt from the requirement under NASD rules that its Compensation Committee be composed solely of independent directors. None of these individuals serves as a member of the board of directors or on the compensation committee of any company that has another individual who is an executive officer serving on the Board or its Compensation Committee.

Employment Agreements with CEO and Other Named Executive Officers

As of February 11, 2005, the Company entered into amended and restated employment agreements with Bernhard Hampl, Ph.D., William F. Holt and Jeffrey S. Bauer, Ph.D. and an employment agreement with Frank J. Della Fera. Pursuant to the respective terms of these agreements: Dr. Hampl, serves as the President, Chief Executive Officer and Director of the Company; Mr. Holt serves as the Vice President Finance, Secretary, Treasurer and Chief Financial Officer of the Company; Dr. Bauer serves as the

Vice President, Business Development of the Company; and Mr. Della Fera serves as the Vice President, Sales and Marketing of the Company. Dr. Hampl s, Mr. Holt s, Dr. Bauer s and Mr. Della Fera s annual base salaries as of February 2, 2004 were $330,750, $211,996, $187,425 and $211,364, respectively. Each current employment agreement provides the Board with the discretion to increase such amounts. Each of these agreements provide for a three-year term of employment commencing on February 11, 2005.

Notwithstanding the employment term described above, each of the aforementioned executives employment will end on the earlier to occur of: (i) a termination of their employment due to death or disability; (ii) a termination by the Company with or without cause; or (iii) a termination by the executive with or without good reason.

Upon any termination of employment, Dr. Hampl, Mr. Holt, Dr. Bauer and Mr. Della Fera are each entitled to all amounts accrued but unpaid through the date of termination with respect to salary, any unpaid bonus for the fiscal year that ended prior to the date of termination and any accrued but unused vacation days and unreimbursed expenses.

In addition to the payments in the previous paragraph, prior to a change in control, upon a termination of employment by the Company without cause or by the executive for good reason, Dr. Hampl, Mr. Holt, Dr. Bauer and Mr. Della Fera are each entitled to: (i) an amount equal to 12 months salary (less any applicable withholding or similar taxes) at the rate in effect on the date of such termination, such amount to be payable in substantially equal monthly installments from the date of such termination through the date two months from end of the Company s fiscal year following the year of such termination (the Severance Term); (ii) an aggregate amount equal to the bonus payable or paid to the executive in respect of the completed fiscal year which has ended prior to the date of termination, payable in substantially equal monthly installments during the Severance Term; (iii) a lump-sum payment equal to 12 times the monthly cost of health continuation coverage for the executive and his dependents, as provided under COBRA and as determined on the date of termination; and (iv) vesting of all options that would have otherwise vested in the 12 months after such termination assuming no termination has occurred.

If such termination by the Company without cause or by Dr. Hampl, Mr. Holt, Dr. Bauer or Mr. Della Fera with good reason occurs in connection with, or following, a change in control, in lieu of the aforementioned amounts, the executives are each entitled to: (i) a lump-sum payment equal to two times (a) current annual base salary and (b) the bonus received the year prior to such termination; (ii) a lump-sum payment equal to 24 times the monthly cost of health benefits; and (iii) immediate vesting of all outstanding options. Good reason is defined to include delivery by the executive of written notice of resignation at any time and for any reason during the period commencing on the nine-month anniversary of a change in control and ending on the 11-month anniversary of such change in control. Dr. Hampl, Mr. Holt, Dr. Bauer and Mr. Della Fera are also entitled to full 280G gross-up protection such that they will receive additional gross-up payments to make them whole in the event that taxes are imposed under Section 4999 of the Internal Revenue Code of 1986, as amended.

Dr. Hampl s, Mr. Holt s, Dr. Bauer s and Mr. Della Fera s agreements also contain one- year non-competition and non-solicitation provisions following a termination of employment.

Additionally, on February 11, 2005, the Company entered into an amended and restated employment agreement with Sadie M. Ciganek. Pursuant to the terms of the amended and restated employment agreement, Ms. Ciganek serves as the Vice President, Regulatory Affairs of the Company. Ms. Ciganek s annual base salary as of February 2, 2004 was $188,017 and her current employment agreement provides the Board with the discretion to increase such amount. Ms. Ciganek s agreement has a three-year term commencing on February 11, 2005.

Notwithstanding the employment term described above, Ms. Ciganek s employment will end on the earlier to occur of: (i) a termination of her employment due to death or disability; or (ii) a termination by the Company with or without cause.

Upon any termination of employment, Ms. Ciganek is entitled to all amounts accrued but unpaid through the date of termination with respect to salary, any unpaid bonus for the fiscal year that ended prior to the date of termination and any accrued but unused vacation days and unreimbursed expenses.

In addition to the payments in the previous paragraph, upon a termination of employment by the Company without cause prior to a change in control, Ms. Ciganek is entitled to: (i) an amount equal to 12 months salary (less any applicable withholding or similar taxes) at the rate in effect on the date of such termination, such amount to be payable in substantially equal monthly installments from the date of such termination through the Severance Term; (ii) an aggregate amount equal to the bonus payable or paid to Ms. Ciganek in respect of the completed fiscal year which has ended prior to the date of termination, payable in substantially equal monthly installments during the Severance Term; (iii) a lump-sum payment equal to 12 times the monthly cost of health continuation coverage for Ms. Ciganek and her dependents, as provided under COBRA and as determined on the date of termination; and (iv) immediate vesting of all options that would have vested in the 12 months after such termination.

Upon a termination of employment by the Company without cause following a change in control, in lieu of the aforementioned amounts, Ms. Ciganek is entitled to: (i) a lump-sum payment equal to two times (a) current annual salary and (b) the bonus received the year prior to such termination; (ii) a lump-sum payment equal to 24 times the monthly cost of health benefits; and (iii) immediate vesting of all outstanding options.

Ms. Ciganek s agreement also contains one-year non-competition and non-solicitation provisions following a termination of employment.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

See Market for Registrant s Common Equity, Related Stockholder Matters and Issues Purchases of Equity Securities for information regarding securities authorized for issuance under equity compensation plans.

The following table sets forth certain information known to the Company regarding the beneficial ownership of Common Stock as of March 11, 2005 for:

- each person known by the Company to beneficially own more than 5% of Common Stock;
- each of the Company s directors;
- Named Executive Officers; and
- all of the Company s directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of Common Stock that could be issued upon the exercise of outstanding options held by that person that are currently exercisable or exercisable within 60 days of March 11, 2005 are considered outstanding. These shares, however, are not considered outstanding when computing the percentage ownership of each other person.

Except as indicated in the footnotes to this table and pursuant to state community property laws, each stockholder named in the table has sole voting and investment power for the shares shown as beneficially owned by them. Percentage of ownership is based on 88,850,364 shares of Common Stock outstanding on March 11, 2005.

Number of Shares Beneficially Owned on March 11, 2005

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned (#)	Percentage of Common Stock Beneficially Owned (%)
Stockholders Owning Approximately 5% or More		
Santo Holding (Deutschland) GmbH Konigstrasse la 70173 Stuttgart, Germany	60,000,000	67.5
Thomas Strüngmann, Ph.D.(1) Industriestrasse 25, 83607 Holzkirchen, Germany	60,137,122	67.7
Andreas Strüngmann, M.D.(2) Industriestrasse 25, 83607 Holzkirchen, Germany	60,137,122	67.7
Current Directors and Named Executive Officers(3)		
Bernhard Hampl, Ph.D.(4), (5)	1,151,000	1.3
Thomas Strüngmann, Ph.D.(1)	60,137,122	67.7
William F. Holt(4), (5)	507,000	*
Frank J. Della Fera, R.Ph.(4), (5)	168,000	*
Jeffrey S. Bauer, Ph.D.(4), (5)	40,000	*
Sadie M. Ciganek(4), (5)	40,800	*
Frank F. Beelitz(4), (5)	48,000	*
Douglas M. Karp(4), (5)	48,000	
Mark R. Patterson(4), (5), (6)	71,000	*
All of the Company s current executive officers and directors as a group (15 persons)	62,350,022	70.2

* Represents beneficial ownership of less than one percent of Common Stock.

(1) Includes 60,000,000 shares held by Santo and 137,122 shares held by Hexal. By virtue of his control of Santo and Hexal, Thomas Strüngmann, Ph.D. may be deemed to be a beneficial owner of all shares held by Santo and Hexal. Dr. Thomas Strüngmann disclaims beneficial ownership of these shares.

(2) Includes 60,000,000 shares held by Santo and 137,122 shares held by Hexal. By virtue of his control of Santo and Hexal, Andreas Strüngmann, M.D. may be deemed to be a beneficial owner of all shares held by Santo and Hexal. Dr. Andreas Strüngmann disclaims beneficial ownership of these shares.

(3) Unless otherwise indicated, the address of each director and named executive officer is c/o Eon Labs, Inc., 1999 Marcus Avenue, Lake Success, New York 11042.

(4) Includes shares of Common Stock issuable upon exercise of options granted under the Company s 2001 Stock Option Plan that are vested and exercisable within 60 days of March 11, 2005.

(5) Includes shares of Common Stock issuable upon exercise of options granted under the Company s 2003 Stock Incentive Plan that are vested and exercisable within 60 days of March 11, 2005.

(6) Includes 23,000 shares Mr. Patterson purchased on the open market.

Changes in Control

On February 20, 2005, the Company entered into the Merger Agreement with Novartis, Merger Sub, and, solely with respect to its guarantee of Novartis s and Merger Sub s obligations thereunder, Parent. For additional detail regarding the Merger Agreement and related transactions, see Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation.

Item 13. Certain Relationships and Related Transactions.

Prior to the reorganizational mergers described below, Santo owned 100% of the outstanding capital stock of HPI. Santo is under common control with Hexal, the second largest generic pharmaceutical company in Germany. The Company is a party to joint development and technology agreements with Hexal. In September 1995, HPI acquired 50% of the Company s outstanding capital stock. In December 2000, HPI indirectly acquired the remaining 50% of the Company s outstanding capital stock through its acquisition of 100% of the outstanding capital stock of EHI. On May 21, 2002, the Company was combined with HPI and EHI into a single entity through a series of reorganizational mergers. As a result, Santo owns a majority of the outstanding Common Stock.

Thomas Strüngmann, Ph.D., the Chairman of the Board of the Company and the Co-Chief Executive Officer and Co-President of Hexal, is an indirect significant stockholder and director of Santo, a privately held entity that owns 60,000,000 shares of Common Stock, representing approximately 67.5% of the Company s outstanding capital stock. Dr. Strüngmann is an indirect significant stockholder and member of the board of directors of Hexal, a privately held entity, which owns 137,122 shares of Common Stock, representing ownership of approximately 0.15% of the Company s outstanding capital stock. Therefore, Dr. Strüngmann may be deemed to be the beneficial owner of 60,137,122 shares of Common Stock, representing ownership of approximately 67.7% of the Company s outstanding capital stock. Dr. Strüngmann disclaims beneficial ownership of these shares.

Transactions between Eon Labs, Inc. and Hexal

In 2004, the Company had net sales of $2.2 million of products to subsidiaries of Hexal. The Company purchased products and supplies from Hexal and its subsidiaries in the aggregate of $2.1 million in 2004.

The Company has an agreement with Hexal regarding Cyclosporine. Pursuant to that agreement, the Company has been granted an exclusive and perpetual license to use patented technology from Hexal and pays Hexal a royalty on its sales of Cyclosporine, which was developed using that licensed technology. Pursuant to that agreement s royalty arrangement, the Company expensed $3.2 million in 2004.

In March 2003, the Company memorialized its agreement with Hexal regarding the sale of Cyclosporine products to a third party. Pursuant to that agreement the Company has been granted an exclusive license to use patented technology from Hexal to sell Cyclosporine to the third party outside of the United States, which was developed using that licensed technology. The Company makes royalty payments to Hexal on such sales as described above. The Company also sells the active pharmaceutical ingredient cyclosporine to the third party and retains an administrative fee from such sales, forwarding the remainder to Hexal. Pursuant to this agreement, the Company was obligated to forward $0.6 million to Hexal in connection with such sales made in 2004.

In March 2002, the Company entered into a five-year technology agreement with Hexal. Pursuant to that agreement, Hexal cooperates with the Company with respect to the development, manufacture and sale in the United States of, and the sharing of certain information relating to, certain generic pharmaceutical products that Hexal develops. At the Company s request, it has the right of first refusal to purchase or license from Hexal, at a fair and reasonable price, the U.S. sales and marketing rights with respect to any generic pharmaceutical products that Hexal develops. The Company has entered into

several underlying product agreements for the rights to several products. The Company expensed $1.0 million in 2004 as provided in the underlying agreements.

During 2004, Hexal incurred certain miscellaneous expenses on behalf of the Company totaling $0.1 million. The Company reimbursed Hexal accordingly. Also during 2004, the Company incurred miscellaneous expenses on behalf of Hexal and Santo of $0.6 million and $0.1 million, respectively. The Company has been reimbursed from Hexal and Santo for these expenditures.

It is the Company s current policy that all transactions or series of transactions with officers, directors, 5% stockholders and their affiliates in which the amount exceeds $60,000 be entered into only if they are approved by the Audit Committee, are on terms no less favorable to the Company than could be obtained from unaffiliated parties and are reasonably expected to benefit the Company.

Item 14. Principal Accountant Fees and Services.

Independent Registered Public Accounting Firm Fees

Audit Fees

Fees for the 2004 and 2003 annual audit and the reviews of the 2004 and 2003 Forms 10-Q were $843,560 (of which an aggregate of $393,560 was billed through December 31, 2004) and $568,308, respectively. The increase in audit fees is due to compliance requirements related to the Sarbanes-Oxley Act of 2002.

Audit-related Fees

Audit-related fees for the calendar year 2004 were $365,758, which consisted of billing for services provided primarily related to assistance in connection with the implementation of Rule 404 of the Sarbanes-Oxley Act of 2002 (relating to internal control over financial reporting) and the audit of the Company s Savings Incentive Plan.

Audit-related fees for the calendar year 2003 were $26,875, which consisted of the audit of the Company s Savings Incentive Plan.

Tax Fees

During 2004 and 2003, PwC billed the Company an aggregate of $360,028 and $393,280, respectively, in tax fees, which related primarily to assistance with the preparation of returns and tax consultations.

All Other Fees

During 2004 and 2003, PwC did not bill the Company for other fees.

All of the above services were approved by the Company s Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

Documents filed as part of this Form 10-K.

(1) Financial Statements: See page F-1 of this Form 10-K, which includes an index to the consolidated financial statements.

(2) Financial Statement Schedules: None.

(3) Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of February 20, 2005, by and among Novartis Corporation, Zodnas Acquisition Corp., Eon Labs, Inc. and for purposes of Section 10.12 thereof only, Novartis AG, was filed as Exhibit 2.1 to the Company s current report on Form 8-K, filed on February 22, 2005 and is incorporated herein by reference.
3.1	Restated Certificate of Incorporation of Eon Labs, Inc. was filed as Exhibit 3.1 to the Company s June 30, 2002 Form 10-Q and is incorporated herein by reference.
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of Eon Labs, Inc. was filed as Exhibit 3.1 to the Company s June 30, 2004 Form 10-Q and is incorporated herein by reference.
3.3	Restated Bylaws of Eon Labs, Inc. was filed as Exhibit 3.2 to the Company s Annual Report on Form 10-K for the year ended December 31, 2002 and is incorporated herein by reference.
4.1	Form of Stock Certificate was filed as Exhibit 4.1 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638), filed on May 6, 2002 and is incorporated herein by reference.
10.1	Technology Agreement, dated as of March 20, 2002, by and between Hexal AG and Eon Labs, Inc. was filed as Exhibit 10.4 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638), filed on April 5, 2002 and is incorporated herein by reference.
10.2	Amended and Restated Credit Agreement, dated as of July 30, 2004, by and among Eon Labs, Inc., Eon Pharma, LLC and JPMorgan Chase Bank was filed as Exhibit 10.1 to the Company s September 30, 2004 Form 10-Q and is incorporated herein by reference.
10.3	Eon Labs, Inc. Stock Option Plan was filed as Exhibit 10.8 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638), filed on March 1, 2002 and is incorporated herein by reference.
10.4	Agreement, effective as of November 10, 2002, by and between Eon Labs, Inc. and the Drug, Chemical, Cosmetic, Plastics and Affiliated Industries Warehouse Employees Local 815, Affiliated with the International Brotherhood of Teamsters was filed as Exhibit 10.9 to the Company s Annual Report on Form 10-K for the year ended December 31, 2002 and is incorporated herein by reference.
10.5	Product Royalty Agreement, dated as of March 20, 2002 between Hexal AG and Eon Labs, Inc. was filed as Exhibit 10.11 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638) filed on April 5, 2002 and is incorporated herein by reference.
10.6	Joint Development Agreement, dated as of March 20, 2002, between Hexal AG and Eon Labs, Inc. was filed as Exhibit 10.12 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638), filed on April 5, 2002 and is incorporated herein by reference.
10.7	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Bernhard Hampl was filed as Exhibit 10.1 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.8	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Jeffrey S. Bauer was filed as Exhibit 10.2 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.

10.9	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Pranab K. Bhattacharyya was filed as Exhibit 10.3 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.10	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Sadie M. Ciganek was filed as Exhibit 10.4 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.11	Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Frank J. Della Fera was filed as Exhibit 10.5 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.12	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and William B. Eversgerd was filed as Exhibit 10.6 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.13	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and David H. Gransee was filed as Exhibit 10.7 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.14	Amended and Restated Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and William F. Holt was filed as Exhibit 10.8 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.15	Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Rathnam Kumar was filed as Exhibit 10.9 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.16	Employment Agreement, dated as of February 11, 2005, by and between Eon Labs, Inc. and Shashank Upadhye was filed as Exhibit 10.10 to the Company s current report on Form 8-K, filed on February 17, 2005 and is incorporated herein by reference.
10.17	Agreement for Purchase and Sale of Stock, dated as of February 20, 2005, by and among Novartis Corporation, Santo Holding (Deutschland) GmbH and for purposes of Section 12 thereof only, Novartis AG, was filed as Exhibit 10.1 to the Company s current report on Form 8-K, filed on February 22, 2005 and is incorporated herein by reference.
10.18	Confidentiality Agreement, dated as of February 11, 2005, by and between Novartis Corporation and Eon Labs, Inc., was filed as Exhibit 10.2 to the Company s current report on Form 8-K, filed on February 22, 2005 and is incorporated herein by reference.
21.1	List of Subsidiaries was filed as Exhibit 21.1 to the Company s Registration Statement on Form S-1/A (Reg. No. 333-83638), filed on May 21, 2002 and is incorporated herein by reference.
23.1	Consent of PricewaterhouseCoopers LLP filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith.
32.2	Certification of the 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.

SIGNATURES

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

EON LABS, INC.
By: /s/ BERNHARD HAMPL
Bernhard Hampl, Ph.D.
President, Chief Executive Officer and Director

Date: March 16, 2005

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 in the capacities and on the dates indicated.

Signature	Title	Date
/s/ BERNHARD HAMPL Bernhard Hampl, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2005
/s/ THOMAS STRÜNGMANN Thomas Strüngmann, Ph.D.	Chairman of the Board of Directors	March 16, 2005
/s/ WILLIAM F. HOLT William F. Holt	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2005
/s/ DAVID H. GRANSEE David H. Gransee	Controller	March 16, 2005
/s/ FRANK F. BEELITZ Frank F. Beelitz	Director	March 16, 2005
/s/ DOUGLAS M. KARP Douglas M. Karp	Director	March 16, 2005
/s/ MARK R. PATTERSON Mark R. Patterson	Director	March 16, 2005

INDEX TO THE FINANCIAL STATEMENTS OF EON LABS, INC. AND SUBSIDIARIES

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Eon Labs, Inc:

We have completed an integrated audit of Eon Labs, Inc. s 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

In our opinion, the consolidated financial statements listed in the accompanying index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Eon Labs, Inc and Subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements 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 of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Report on Internal Control over Financial Reporting appearing in Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting 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 effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the

assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP
New York, New York
March 14, 2005

Eon Labs, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2004 and 2003
(dollars in thousands, except per share amounts)

	2004	2003
Assets		
Current assets		
Cash and cash equivalents	$ 59,500	$ 43,852
Investments	136,252	115,281
Accounts receivable, net	68,010	35,678
Inventories	72,465	56,441
Deferred tax assets, net	62,955	56,439
Prepaid expenses and other current assets	20,788	8,096
Total current assets	419,970	315,787
Property, plant and equipment, net	52,481	50,409
Goodwill	42,734	46,934
Other intangible assets, net	22,247	26,007
Other assets	7,742	2,408
Total assets	$ 545,174	$ 441,545
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 11,987	$ 13,612
Accrued liabilities	81,265	89,226
Total current liabilities	93,252	102,838
Long-term liabilities		
Deferred tax liabilities, net	7,355	9,136
Deferred revenue	151	200
Other	892	591
Total liabilities	101,650	112,765
Commitments and contingencies (Notes 10 and 13)		
Stockholders equity		
Common stock, par value $.01 per share; 100,000,000 shares authorized; 88,982,924 and 44,361,912 shares issued; 88,830,564 and 44,299,812 shares outstanding at December 31, 2004 and 2003, respectively	890	444
Preferred stock, par value $.01 per share; 5,000,000 shares authorized; none issued		
Additional paid-in capital	192,767	194,951
Retained earnings	255,125	135,774
Accumulated other comprehensive (loss) income	(8)	5
	448,774	331,174
Less: Unearned deferred stock-based compensation		(184)
Treasury stock at cost; 152,360 and 62,100 shares at December 31, 2004 and 2003, respectively	(5,250)	(2,210)
Total stockholders equity	443,524	328,780
Total liabilities and stockholders equity	$ 545,174	$ 441,545

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

Eon Labs, Inc. and Subsidiaries
Consolidated Statements of Income
For the years ended December 31, 2004, 2003 and 2002
(dollars in thousands, except per share amounts)

	2004	2003	2002
Net sales	$ 430,959	$ 329,538	$ 244,269
Cost of sales	190,602	154,387	122,351
Gross profit	240,357	175,151	121,918
Operating expenses			
Selling, general and administrative	46,043	37,296	32,706
Research and development	21,666	22,510	13,239
Total operating expenses	67,709	59,806	45,945
Operating income	172,648	115,345	75,973
Other income and expense			
Interest income	2,461	1,411	854
Interest expense		(300)	(3,857)
Other income, net	13,046	228	113
Total other income (expense)	15,507	1,339	(2,890)
Income before income taxes	188,155	116,684	73,083
Provision for income taxes	68,804	46,549	29,820
Net income	$ 119,351	$ 70,135	$ 43,263
Net income per common share (see Note 3)			
Basic	$ 1.34	$ 0.79	$ 0.81
Diluted	$ 1.32	$ 0.77	$ 0.53
Weighted average common shares outstanding			
Basic	88,772,514	88,479,942	53,261,578
Diluted	90,673,611	90,520,586	81,297,066

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

Eon Labs, Inc. and Subsidiaries
Consolidated Statements of Stockholders Equity and Comprehensive Income
For the years ended December 31, 2004, 2003 and 2002
(dollars in thousands)

	Number of Shares Series A Convertible Preferred Stock	Series A Convertible Preferred Stock	Number of Shares Common Stock	Common Stock	Additional Paid-in Capital	Retained Earnings	Unearned Deferred Stock-Based Compensation	Accumulated Other Comprehensive Income	Treasury Stock	Total Stockholders Equity
Balance, December 31, 2001	30,000,000	$ 300		$	$ 26,101	$ 22,376	$ (1,786)	$	$	$ 46,991
Stock conversion	(30,000,000)	(300)	30,000,000	300						
Amortization of unearned deferred stock-based compensation							1,154			1,154
Shares issued under initial public offering			10,200,813	102	139,135					139,237
Conversion of debt to equity			1,678,561	17	25,161					25,178
Warrants exercised			1,680,528	17	(17)					
Shares issued under stock option plan, including tax benefit from exercise of non-qualified options of $1,904			517,380	5	2,282					2,287
Net income						43,263				43,263
Unrealized gains on available-for-sale securities								44		44
Comprehensive Income										$ 43,307
Balance, December 31, 2002		$	44,077,282	$ 441	$ 192,662	$ 65,639	$ (632)	$ 44	$	$ 258,154
Amortization of unearned deferred stock-based compensation							448			448
Shares issued under stock option plan, including tax benefit from exercise of non-qualified options of $2,110			284,630	3	2,675					2,678
Common stock acquired for treasury			(72,500)						(2,596)	(2,596)
Treasury shares reissued in connection with stock options exercised			10,400		(386)				386	
Net income						70,135				70,135
Unrealized losses on available-for-sale securities								(39)		(39)
Comprehensive Income										$ 70,096
Balance, December 31, 2003		$	44,299,812	$ 444	$ 194,951	$ 135,774	$ (184)	$ 5	$ (2,210)	$ 328,780
Amortization of unearned deferred stock-based compensation							184			184
Shares issued under stock option plan, including tax benefit from exercise of non-qualified options of $5,385			129,550	1	6,412					6,413
Common stock acquired for treasury			(187,130)						(11,191)	(11,191)
Treasury shares reissued in connection with stock options exercised			208,100		(8,151)				8,151	
Stock split (2-for-1)			44,380,232	445	(445)					
Net income						119,351				119,351
Unrealized losses on available-for-sale securities								(183)		(183)
Gain on foreign currency translation								170		170
Comprehensive Income										$ 119,338
Balance, December 31, 2004		$	88,830,564	$ 890	$ 192,767	$ 255,125	$	$ (8)	$ (5,250)	$ 443,524

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

Eon Labs, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the years ended December 31, 2004, 2003 and 2002
(dollars in thousands)

	2004	2003	2002
Cash flows from operating activities			