EON LABS INC
Form 10-K
March 27, 2003

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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, 2002

Commission File No. 011-31333

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)
227-15 North Conduit Avenue Laurelton, New York	**11413**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(718) 276-8600**

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 ý 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 o No ý

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 28, 2002 was $210,955,190, 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.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date.

Common Stock, $.01 par value	**44,149,548**
Class	Outstanding at March 21, 2003

Documents Incorporated by Reference

Portions of the 2003 Eon Labs, Inc. Proxy Statement are incorporated by reference into Part III. The Proxy Statement will be filed on or about April 15, 2003.

EON LABS, INC.

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FOR THE YEAR ENDED DECEMBER 31, 2002

PART I

Item 1. Business.

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 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, 2002, the Company generated sales and operating income of $244.3 million and $76.0 million, respectively, and had total assets of $329.9 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 10,200,813 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 30,000,000 shares of common stock.

The Company was incorporated under the laws of Delaware in 1992. Its principal executive offices are located at 227-15 North Conduit Avenue, Laurelton, New York 11413, and its telephone number is (718) 276-8600. The Company's website is located at www.eonlabs.com. The information on the website is not intended to be part of this prospectus.

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 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 (the "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 in 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, during which the FDA is prohibited from approving the ANDAs of these generic products. According to the FDA, as of January 2003, the industry average for the length of time to secure FDA approval of an ANDA was approximately 18 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 their 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 and is 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 have its ANDA accepted for filing with the FDA and whose filing includes a Paragraph IV certification may be eligible to receive a 180-day period of market exclusivity 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 have its ANDA accepted for filing by the FDA and whose filing includes a Paragraph IV certification that the 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, require difficult to source raw materials or represent smaller therapeutic niche markets generally result in fewer companies marketing those products 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 AG, as well as from 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 bioequivalence has been successfully established, the Company files an ANDA with the FDA seeking approval of the product. The Company's ANDAs are structured to include all FDA requirements, which helps to facilitate the review process with the FDA and to minimize the amount of time it takes to receive final FDA approval. 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 is successful in overcoming:

developmental, manufacturing or technological challenges, including difficult to source raw materials; and/or

products with 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.

Developmental, Manufacturing And Technological Challenges. The Company has been successful in bringing to market a number of challenging products involving developmental, manufacturing and technological challenges, including Cyclosporine, USP (Modified) and Flutamide.

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 Hatch-Waxman Act, the developer of a bioequivalent drug which is the first to have its ANDA accepted for filing by the FDA, and whose filing includes a certification that the patent is invalid, unenforceable or not infringed, a so-called "Paragraph IV certification," may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity provides 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. 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 December 31, 2002, the Company was involved in patent litigation in connection with its Paragraph IV certifications for the following six products: Buproprion HC1 ER; Gabapentin; Itraconazole; Metaxalone; Mirtazapine; and Omeprazole.

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

Bupropion HCl ER

In November 2000, Glaxo Wellcome Inc. filed suit against the Company in the U.S. District Court for the Southern District of New York for infringing two of its patents based on the Company's filing of an ANDA to market generic bupropion hydrochloride ER (extended release) tablets. In August 2002 the court held that one of Glaxo's patents was invalid and Glaxo subsequently withdrew its appeal from that decision.

With regard to the litigation on the remaining patent, fact and expert discovery are complete and summary judgment motions have been submitted to the court. No trial date has been set. The Court has denied the Company's motion for summary judgment of non-infringement of the patent. The Court of Appeals for the Federal Circuit currently has two other cases before it concerning infringement and interpretation of this patent which could have an impact on this case.

Gabapentin

Pfizer, Inc. 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. Fact and expert discovery have concluded and several dispositive motions have been filed by both parties and are pending.

Itraconazole

Shortly after the Company filed an ANDA for Itraconazole in January 2001, Janssen Pharmaceutica, Inc. filed suit against the Company in the U.S. District Court for the Eastern District of New York for patent infringement. This case is currently entering the final discovery stage before trial and the Company has filed a motion for summary judgment which is pending.

Metaxalone

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 product. The Company asserted affirmative defenses and counterclaims alleging that the patent is invalid and not infringed. The case is in the initial discovery stage and no trial date has been set.

Mirtazapine

Organon, Inc. sued the Company in the U.S. District Court for the District of New Jersey based on the Company's filing of an ANDA to market generic tablets containing mirtazapine but no other active ingredients. The Company maintains that the patent is invalid, non-infringed, and improperly listed in the FDA's Orange Book.

In related litigations the District Court granted summary judgment of non-infringement to at least two other defendants, which Organon appealed. Subsequently, Organon stipulated to the dismissal of litigations against at least two further defendants.

Omeprazole

In May 2000, AstraZeneca A.B. sued the Company for infringement of six patents in the U.S. District Court for the Eastern District of New York based on the Company's filing of an ANDA to market the compound omeprazole. 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 found to be uninfringed in a related litigation against other generic drug companies. Fact discovery is ongoing and is currently scheduled to be completed by June 2, 2003, with all discovery scheduled to be completed by September 22, 2003.

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, 2002, the Company marketed over 100 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 it is also developing several generic products that utilize transdermal patch delivery technology with Hexal AG. 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 2002, the Company received 14 ANDA approvals, including 4 tentative approvals, in multiple therapeutic categories.

The Company is currently involved in the development of more than 38 pharmaceutical products, including 9 new generic product ANDAs pending approval at the FDA as of December 31, 2002, and an additional 4 tentative approvals. Other than Phentermine HCl which represented 23.9% of the Company's total gross sales in 2000 and Phentermine HCl and Fluvoxamine Maleate which represented

18.7% and 12.4%, respectively, of the Company's total gross sales in 2001, no other single product represented more than 10% of the Company's gross sales during the past three years.

Strategic Relationships

The Company has a strategic relationship with the second largest generic pharmaceutical company in Germany, Hexal AG, a company that is under common control with Santo Holding (Deutschland) GmbH ("Santo"). Hexal AG's line of branded generic products is represented in markets worldwide. In addition, Hexal AG 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, the Company develops certain products in conjunction with Hexal AG. In March 2002, the Company entered into a technology agreement with Hexal AG that memorialized a prior relationship. Pursuant to that agreement, Hexal AG 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 AG develops. At the Company's request, it has the right of first refusal to purchase or license from Hexal AG the U.S. sales and marketing rights with respect to all generic pharmaceutical products that Hexal AG develops. The Company also has entered into product-specific strategic alliances with Hexal AG with respect to several products, including Cyclosporine, Flutamide and Omeprazole.

The Company is currently developing a number of generic pharmaceutical products with Hexal AG which utilize a transdermal patch delivery system. Hexal AG's generic estrogen patch delivers estrogen transdermally, and the Company has entered into an agreement with Hexal AG which grants it the exclusive right to seek approval and market a generic estrogen patch for the United States. In addition, the Company and Hexal AG are researching the possible production of other products using a transdermal patch delivery system, including a patch to deliver cardiovascular medication transdermally and a patch to deliver pain relief medication transdermally. If that research results in marketable products, the Company plans to seek FDA approval for those products in the United States. The Company plans to set up manufacturing capabilities for patch products at its facility in Wilson, North Carolina.

The Company sometimes consults with Hexal AG regarding their knowledge of available sources of active pharmaceutical ingredients.

In 2002, the Company spent $13.2 million for research and development compared to $12.2 million in 2001 and $14.9 million in 2000.

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. API manufacturers are required to file a Drug Master File with the FDA. Each individual API must be approved by the FDA as part of the ANDA approval process. API manufacturers are also regularly inspected by the FDA.

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

high quality standards, including cGMPs;

cutting edge chemical and process technologies;

patent know-how; and

flexible processes and capacities which enable them 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 through an ongoing communication process for their mutual benefit.

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 2002, the Company had over 100 customers in the United States. Sales to AmerisourceBergen Corporation and McKesson Corporation represented 32.1% and 15.1%, respectively, of the Company's net sales in 2002. Sales to customers outside of the United States did not exceed 0.2% of the Company's aggregate gross sales for the years 2002, 2001 and 2000.

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 (the "EPA") 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. 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 usually 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 in the blood stream 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 a new dosage form 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, during which the FDA is prohibited from approving generic products. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension. See "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 us 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 a 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 at the time of filing an ANDA with the FDA and the generic drug company intends to market the generic equivalent prior to the expiration of that patent, the generic company files with its ANDA a certification asserting that the patent is invalid, unenforceable and/or not infringed, a so-called "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 NDA for the brand-name drug a notice explaining why it believes that the patents in question are invalid, unenforceable or not infringed. Upon receipt of the notice from the generic company, the patent holder has 45 days during which to bring a patent infringement suit in federal district court against the generic company. The discovery, trial and appeals process in such suits can take several years.

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

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

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 net sales price for the products in question. The Company accrues for future estimated rebates in its consolidated financial statements.

Over the last year, the extension of prescription drug coverage to all Medicare recipients has gained support in Congress. The Company believes that federal and/or state governments may continue to enact measures in the future 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, equal employment opportunity, and environmental protection.

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 has.

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 14, 2003, the gross sale value of backlog orders for the Company was $55.1 million compared to $21.5 million as of March 14, 2002. 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 that during 2003, additional raw materials will become available and that existing backlog will be fully satisfied. 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, it is not believed that those backlog amounts bear significant relationship to sales or income for any twelve-month period.

Environment

The Company believes that its operations comply in all material respects 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.

With respect to environmental clean-up liability, the Company is in the process of evaluating an inquiry it recently received from the United States Environmental Protection Agency ("EPA") concerning its relationship as a possible successor to a party that may be among a substantial number of parties liable for cleanup of the Mattiace Petrochemical Superfund site, a contaminated site currently being addressed by EPA at a cost estimated by the EPA to be approximately $36 million. Based on information available at this time, the Company does not expect this matter to require significant capital expenditures or have a material adverse effect on its earnings or competitive position.

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 AG, the second largest generic pharmaceutical company in Germany. The Company is a party to joint development and technology agreements with Hexal AG. 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, 2002, the Company employed 430 persons, 278 of whom work at its corporate headquarters and manufacturing facility in Laurelton, New York and 152 of whom work at its manufacturing and research facility in Wilson, North Carolina. 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 it expects, 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 three customers represented approximately 55% of its net sales in 2002. 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, and the number of independent drug stores and small drug store chains has decreased. 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 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.

Santo owns approximately 68.0% 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 AG, together with his interests in Santo and Hexal AG, beneficially owns approximately 71.8% of the Company's outstanding common stock. As a result, 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 filing 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 forty-five (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 the date of a court decision of patent invalidity or non-infringement, whichever is earlier. 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 December 31, 2002, the Company was involved in patent litigation in connection with its Paragraph IV certifications for the following six products: Buproprion HC1 ER; Gabapentin; Itraconazole; Metaxalone; Mirtazapine; and Omeprazole. 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 will 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 addition to the ANDA patent litigations, the Company is a defendant in two patent litigations involving its generic Cyclosporine product. On August 30, 2000, Novartis Pharmaceuticals Corporation filed a complaint in the United States 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 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. 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 December 2002, the United States District Court for the District of Delaware granted the Company's motion for summary judgment of non-infringement of the patent. Novartis has appealed this judgment.

On January 26, 2001, Apotex Inc., a Canadian generic pharmaceutical company, filed a complaint in the United States 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. No trial date has been set for this matter. 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.

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, 2002, the Company has been named a party and served in approximately 6,400 lawsuits in connection with its manufacture of phentermine hydochloride. As of December 31, 2002, more than 96% of these cases had been dismissed, and fewer than 190 remained open. 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 allege 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 the individual or the class. 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 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, 2002, 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, phentermine-only and phentermine-PPA product liability lawsuits. Additionally, 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, and continues actively to negotiate defense and indemnity agreements with other retailers of Company phentermine. See Item 3. "Legal Proceedings."

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, 2002 only one such claim remained pending. A second case was served on the Company in February 2003.

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, 2002, all but one PPA case against the Company had been dismissed or discontinued. In early 2003, the Company was named in another lawsuit alleging injury from PPA. Because these two lawsuits were only recently filed, and discovery in them has yet to begin, predicting the ultimate outcome of these actions is not possible.

The Company currently maintains $25 million in the aggregate of claims-made product liability/completed operations insurance, a maximum of $15 million of which is available for any phentermine-related claims (retroactive to June 1998), excluding fenfluramine and dexfenfluramine combination (fen-phen) claims.

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 $75.0 million of supplemental extended reporting period (SERP) coverage. The SERP policy extends the reporting period for claims a minimum of 5 years, but only covers occurrences that happened before the respective cancellation dates. The cancellation date for first $45.0 million of coverage is August 6, 2002. The cancellation date on the remaining layers is June 22, 2001, except for the layer $5.0 million in excess of $55 million, which is also August 6, 2002.

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.

New developments by other pharmaceutical manufacturers could make its 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, including Cyclosporine, USP (Modified), Cholestyramine, USP, Phentermine and Reserpine, USP, 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 have 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 inhibited 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 highly 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 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 its 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 most of 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 containing ingredients no longer approved by the FDA. 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.

In January 2003, the Company received Inspectional Observations Form FDA 483 (the "FDA 483") at its Laurelton facility following the mislabeling of one lot of product that was distributed. The mislabeled lot was recalled. The Company provided a written response to the FDA 483 discussing the implementation of corrective actions and revisions to procedures that the Company believes addresses the concerns and issues raised by the FDA 483. In February 2003, the FDA issued a Warning Letter and requested that the Company clarify and supplement its responses to the FDA 483. The Company has provided its supplemental responses to the FDA. Based on follow-up discussions with the FDA, the Company has been advised that a Current Good Manufacturing Practices inspection will be conducted by the FDA at the Laurelton facility beginning in April 2003.

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.

Proposed FDA regulations and recent FDA guidelines and rules granting pediatric extensions may impair the Company's ability to utilize fully the 180-day generic marketing exclusivity period for patent challenges, substantially diminishing the value of a favorable ruling.

One of the key motivations for challenging patents is the reward of a 180-day period of market exclusivity. Under the Hatch-Waxman Act, the developer of a bioequivalent drug which is the first to have its ANDA accepted for filing by the FDA, and whose filing includes a certification that the patent is invalid, unenforceable and/or not infringed (a so-called "Paragraph IV certification") may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity provides 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.

In August 1999, the FDA issued a notice of proposed rulemaking in which it proposed new regulations for implementing the 180-day generic market exclusivity provision. Additionally, the FDA announced an interim modification to its generic drug exclusivity policies in a March 2000 Industry Guidance. In general, the proposed rule and FDA Industry Guidance would make a generic manufacturer's ability to obtain and benefit from the market exclusivity provisions of the Hatch-Waxman Act more uncertain. If adopted and upheld, the proposed rule could impair the Company's ability to obtain and utilize market exclusivity in patent challenge cases.

In 1997, Congress enacted a new provision designed to reward brand-name manufacturers for conducting research to measure the safety of their products in children. If a brand-name manufacturer has a patent or regulatory exclusivity protecting a product, it is eligible to receive an additional six months of market exclusivity following the expiration of the patent or regulatory exclusivity if it conducts clinical testing of the product on children. This is known as "pediatric exclusivity." Thus, where pediatric exclusivity is granted to a brand-name manufacturer by the FDA, the commencement of generic competition could possibly be delayed by six months.

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 state and federal 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 that restricts 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 them 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. In the event that governmental authorities enact additional legislation or adopt regulations which affect third party coverage and reimbursement, demand for the Company's products may be reduced with a consequent adverse effect, which may be material, on its sales and 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 increasingly stringent requirements or to address contamination attributable to its business or properties.

The federal antitrust authorities, including the Federal Trade Commission, or FTC, have indicated that, in conjunction with an inquiry into alleged anti-competitive practices in the entire pharmaceutical industry, they intend to investigate practices relating to patent challenges and settlements.

The FTC has indicated that the study will enable the Commission to provide a more complete picture of how generic drug competition has developed under the Hatch-Waxman Act. The FTC has already investigated several cases in which manufacturers of brand-name drug products and potential generic competitors have allegedly entered into anticompetitive agreements to delay generic entry, and has taken enforcement action against some alleged anticompetitive agreements. The FTC has indicated that its broader study is designed to shed light on matters such as whether the agreements the FTC has found are isolated instances and whether particular provisions of the Hatch-Waxman Act have operated appropriately to balance the legitimate interests of pharmaceutical companies in protection of their intellectual property and the legitimate interests of generic companies in providing competition. The FTC has indicated it intends to issue special orders to approximately 100 pharmaceutical companies. The Company received its special order dated April 20, 2001. The Company and any other companies receiving such requests had 60 days to respond to the special orders. The Company responded to their request on June 26, 2001 and filed supplementary responses on July 13, 2001 and August 17, 2001. The FTC has stated that it then plans to compile the requested information to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions of the Hatch-Waxman Act have influenced the development of generic drug competition.

It is possible that the FTC may make recommendations to the FDA or others, may adopt procedural notification devices, or may bring enforcement actions as to specific agreements it concludes are anticompetitive. Given the early stage of the inquiry, the Company cannot conclude whether and how this inquiry will affect its long-range business. Any limitations on the 180-day exclusivity provisions may decrease the Company's opportunities for generic exclusivity in the future.

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 66$^{2}/_{3}$% 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 Delaware General Corporation Law 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;
- 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.

The Company operates from its 115,000 square foot headquarters in Laurelton, New York, which accommodates manufacturing, sales and distribution, and its 275,000 square foot manufacturing, distribution and research facility in Wilson, North Carolina, which the Company purchased in December 2000, both of which the Company owns. The Company currently manufactures a majority of its products at the Laurelton facility, but has transferred and will continue to transfer the manufacturing of selected products to the Wilson facility.

The Company's research and development team operates out of 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.

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

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.

From May 1997 to December 31, 2002, the Company has been named a party and served in approximately 6,400 lawsuits in connection with its manufacture of phentermine hydochloride. As of December 31, 2002, more than 96% of these cases had been dismissed, and fewer than 190 remained open. 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 allege 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 the individual or the class. 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 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, 2002, 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, phentermine-only and phentermine-PPA product liability lawsuits. Additionally, 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, and continues actively to negotiate defense and indemnity agreements with other retailers of Company phentermine.

On August 30, 2000, Novartis Pharmaceuticals Corporation filed a complaint in the United States District Court for the District of Delaware alleging among other things that the Company's generic Cyclosporine product infringes a patent owned by Novartis. 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 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. An adverse outcome in this litigation could result in the Company's being unable to market Cyclosporine, which could materially harm its profits and cash flows, and could result in our paying damages, costs, expenses and fees that could have a material impact on our financial performance. In December 2002, the United States District Court for the District of Delaware granted the Company's motion for summary judgment of non-infringement of the patent. Novartis has appealed the

judgment. The ultimate outcome of this lawsuit cannot be determined at this time.

On January 26, 2001, Apotex Inc., a Canadian generic pharmaceutical company, filed a complaint in the United States District Court for the Eastern District of New York alleging among other things that the Company's generic Cyclosporine product infringes its patent. The Company has filed an answer and counterclaim to the complaint and intends to vigorously defend the lawsuit. Apotex is seeking injunctive relief to prevent the Company's alleged acts of infringement, as well as an unspecified amount of damages, including a reasonable royalty, costs, expenses, reasonable attorneys' fees and treble damages for willful infringement. No trial date has been set for this matter. The Company's potential liability and expenses in this matter are not covered by insurance. An adverse outcome in this litigation could result in our being unable to market Cyclosporine, which could materially harm our profits and cash flow, and could result in our paying damages, costs, expenses and fees that could have a material impact on our financial performance. The ultimate outcome of this lawsuit cannot be determined at this time.

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

None.

PART II.

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

The Company's common stock is listed on The Nasdaq National Market and began trading under the symbol ELAB on May 23, 2002. As of the close of business on March 21, 2003, there were approximately 25 holders of record of the Company's common stock. The following table sets forth for the fiscal periods indicated the high and low sales prices of the common stock, as reported on The Nasdaq National Market:

2002	HIGH	LOW
First Quarter	N/A	N/A
Second Quarter(1)	$ 18.00	$ 14.50
Third Quarter	$ 23.29	$ 12.70
Fourth Quarter	$ 25.38	$ 17.56

(1) Beginning May 23, 2002

The Company did not pay cash dividends on its common stock during 2002 or 2001 and does not intend to pay any cash dividends in the foreseeable future.

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 Securities and Exchange Commission on May 23, 2002 and the Company commenced the offering on that date. After deducting underwriting discounts and commissions and the offering expenses, the net proceeds from the offering to the Company were 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 AG; (ii) $10.0 million has been used to repay debt incurred in connection with the acquisition of Eon Holdings, Inc.; 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 to fund working capital, increased 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.

Item 6. Selected Financial Data.

The following table sets forth selected historical financial data as of and for the years ended December 31, 2002, 2001, 2000, 1999 and 1998 which are derived from the Company's consolidated financial statements, which have been audited by PricewaterhouseCoopers LLP, its independent certified public accountants. The selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operation", 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 AG, 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. As presented in this report, the term "predecessor company" refers to the Company and its operations for periods prior to January 1, 2000, and does not reflect the reorganization. The term "successor company" is used to describe the Company and its operations for periods after January 1, 2000 and reflects the reorganization.

	Year Ended December 31,				
	Successor Company			Predecessor Company	
	2002	2001	2000	1999	1998
	(Dollars in thousands, except for per share data)				
CONSOLIDATED STATEMENT OF INCOME DATA:					
Net sales	$ 244,269	$ 165,443	$ 119,693	$ 77,981	$ 55,787
Cost of sales	118,591	73,312	56,559	39,576	27,782
Gross profit	125,678	92,131	63,134	38,405	28,005
Operating expenses					
Selling, general and administrative					
Amortization of goodwill and other intangibles(2)	3,760	7,120	639		
Deferred stock appreciation rights compensation		9,837	6,197	1,626	1,479
Other selling, general and administrative	32,706	25,322	20,890	18,640	8,774
Research and development expenses	13,239	12,224	14,936	10,889	8,755
Total operating expenses	49,705	54,503	42,662	31,155	19,008
Operating income	75,973	37,628	20,472	7,250	8,997
Other income and expense					
Interest income	854	462	1,311	950	849
Interest expense	(3,857)	(9,318)	(1,892)	(60)	(88)
Other income (expense), net	113	44	398	(2)	(28)
Total other income (expense)	(2,890)	(8,812)	(183)	888	733

	Year Ended December 31,				
Income before income taxes	78,083	28,816	20,289	8,138	9,730
Provision for income taxes	29,820	13,025	9,300	3,127	4,058
Net income	$ 43,263	$ 15,791	$ 10,989	$ 5,011	$ 5,672
PER SHARE DATA					
Basic	$ 1.62	$	$	$	$
Diluted	$ 1.06	$ 0.49	$ 0.36	$ 0.17	$ 0.19
Weighted average common shares Outstanding					
Basic	26,630,789				
Diluted	40,648,533	32,130,729	30,120,000	30,000,000	30,000,000
OTHER DATA					
Cash and investments	87,284	17,624	6,378	21,095	17,320
Total assets	329,871	219,402	196,903	58,401	49,565
Long-term debt including current portion	4,530	116,867	123,110	333	635
Total stockholders' equity	258,154	46,991	11,895	43,342	38,331
Net cash provided by (used in)					
Operating activities	$ 28,529	$ 30,032	$ 14,077	$ 5,676	$ 5,418
Investing activities	(33,319)	(4,275)	(87,704)	(1,599)	(2,287)
Financing activities	49,489	(14,511)	58,910	(302)	(273)

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

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 not 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 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.

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:

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. Sales are shown net of discounts, rebates, contract pricing adjustments and returns, which are estimated based on our experience. Discounts, rebates and contract pricing adjustments are recorded as a reduction of sales based on agreed upon terms with the Company's customers at the time of sale. The Company calculates a reserve for discounts and rebates based upon actual sales under such arrangements. Reserves for contract pricing adjustments represent the difference between the prices wholesalers are billed by the Company and the prices billed to their customers to whom the Company has given contract prices. In determining a reserve for contract pricing adjustments, the Company takes into account an estimate of the percentage of product sales subject to such pricing adjustments based on historical trends. Historical trends are adjusted for new product introductions and changes in wholesaler or contract prices.

Shelf stock adjustments are provided following a reduction in the prices of any of the Company's products due to the competitive environment. Such adjustments are credited to the Company's customers based on their on-hand inventory quantities. Reserves are generally established when the Company reduces its prices.

Estimates for returns, which are recorded at the time of sale, relate primarily to returns of expiring products. The Company utilizes historical trends to estimate the amount of products to be returned due to product expiration.

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.

Year Ended December 31, 2002 Compared with Year Ended December 31, 2001

Net sales. Net sales increased 47.6% to $244.3 million in 2002 from $165.4 million in 2001. The net sales increase was attributable primarily to sales of products that were introduced after December 31, 2001. These products include Metformin HCl, Nabumetone, Lisinopril, USP, Lisinopril/HCTZ, Tizanidine HCl, Nizatidine, USP, and a Dextroamphetamine and Amphetamine Mixed Salts product. Other factors impacting sales for the year ended December 31, 2002 included an increase in unit volumes of existing products and changes in product mix and unit prices. The change in product mix and unit prices had an unfavorable impact principally due to a decline in both unit volume and selling prices of Fluvoxamine Maleate and a decline in unit volume of Phentermine HCl, USP. Additional competitive activity caused the decrease in Fluvoxamine Maleate unit volume and price. Phentermine HCl, USP sales in the year ended December 31, 2001 reflected an increase in unit volume from the refilling of distribution channels following a shortage of the product in the market due to the limited availability of the active pharmaceutical ingredient. Also reflected in net sales is royalty income of $3.4 million and $2.8 million for 2002 and 2001, respectively, from an exclusive product distribution and supply agreement.

Gross profit. Gross profit increased by $33.5 million to $125.7 million in 2002 from $92.1 million in 2001. The increase in gross profit was attributed primarily to the introduction of new products, including high volume products. Gross profit as a percentage of net sales decreased to 51.5% in 2002 from 55.7% in 2001. The decrease was primarily due to a decrease in sales and margins for Phentermine HCl, USP and Fluvoxamine Maleate, in 2002, as a result of additional competitive activity. In addition, royalty income from an exclusive product distribution and supply agreement increased gross margin by 0.7% and 0.8% in 2002 and 2001, respectively. Gross profit also reflects royalty expense to Hexal AG of $3.1 million and $3.9 million in 2002 and 2001, respectively, in connection with the Company's sale of Cyclosporine, USP (Modified). The Company's gross profit margins are dependent on several factors, including product sales mix, cost, volume and competitive activity.

Amortization of goodwill and other intangibles. Amortization of goodwill and other intangibles decreased $3.4 million to $3.8 million in 2002 from $7.1 million in 2001. The decrease was the result of the adoption of SFAS No. 142 "Goodwill and Other Intangible Assets", which the Company adopted on January 1, 2002. Under SFAS No. 142, goodwill and intangibles with indefinite lives are no longer amortized, but are evaluated annually for impairment. Therefore, the Company is no longer required to amortize its goodwill and workforce intangible assets.

Deferred stock appreciation rights compensation. Deferred stock appreciation rights compensation was $9.8 million in 2001. There were no charges for stock appreciation rights in 2002

because the Company's Stock Appreciation Rights Plan was converted to a Stock Option Plan as of September 30, 2001.

Other selling, general and administrative. Other selling, general and administrative expenses increased $7.4 million to $32.7 million in 2002 from $25.3 million in 2001. As a percentage of sales, other selling, general and administrative expenses decreased 1.9% to 13.4% in 2002 from 15.3% in 2001. The increase was principally due to increases of $2.6 million in compensation costs (which included $0.8 million of deferred compensation), $3.5 million in insurance, $1.3 million in freight and $1.2 million in other expenses, offset by a decrease of $1.2 million in legal expenses. The decrease in legal expenses is the net impact of a decrease in phentermine litigation expenses of $2.8 million offset by an increase of $1.6 million in other legal expenses, principally related to patent challenges.

Research and development. Research and development expenses increased $1.0 million to $13.2 million in 2002 from $12.2 million in 2001. The increase was attributable to an increase of $2.4 million related to generic drug development offset by a decrease of $1.4 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 was principally attributed to increases in costs related to personnel, bio-studies, materials and supplies.

Operating income. Operating income increased $38.3 million to $76.0 million in 2002 from $37.6 million in 2001. The increase in operating income was the result of increased sales and gross profit, the elimination of deferred stock appreciation rights compensation expense and lower amortization expense for goodwill and other intangibles, offset by an increase in other selling, general and administrative and research and development costs.

Interest income (expense). Net interest expense decreased $5.9 million to $3.0 million in 2002 from $8.9 million in 2001. The decrease in interest expense was primarily the result of a decrease in outstanding debt during 2002. A portion of the proceeds from the Company's initial public offering were used to repay debt.

Taxes on income. Taxes on income increased $16.8 million to $29.8 million in 2002 from $13.0 million in 2001. The increase was the result of higher pre-tax income during 2002. The effective tax rate decreased to 40.8% from 45.2% due principally to the elimination of non-deductible goodwill amortization in 2002.

Net income. Net income increased $27.5 million to $43.3 million in 2002 from $15.8 million in 2001 for the reasons described above.

Year Ended December 31, 2001 Compared with Year Ended December 31, 2000

Net sales. Net sales increased 38.2% to $165.4 million in 2001 from $119.7 million in 2000. The net sales increase was primarily attributable to the full year impact of products introduced in 2000, the launch of new products in 2001 and a net increase in sales of existing products launched before 2000. The full year impact of 2000 product introductions that contributed to the increase include, among others, Cyclosporine, USP (Modified), Fluvoxamine Maleate and Bisoprolol Fumarate. New products launched during 2001 that contributed to the increase in net sales include, among others, Oxaprozin, Flutamide, USP, Lovastatin, USP, and Methimazole, USP. Net sales of existing products launched before 2000 were higher primarily because of increased Phentermine HCl, USP sales. Higher Phentermine HCl, USP sales reflected increased demand, the refilling of distribution channels and improved selling prices resulting from a shortage of the product in the market due to the limited availability of the active pharmaceutical ingredient. Also reflected in net sales in 2001 is royalty income of $2.8 million from an exclusive product distribution and supply agreement.

Gross profit. Gross profit as a percentage of net sales increased to 55.7% in 2001 from 52.7% in 2000. This increase in margin was due to increased sales of Phentermine HCl, USP and Fluvoxamine Maleate which had margins higher than most of our other products. In addition, 2001 sales include $2.8 million of royalty income from an exclusive product distribution and supply agreement which increased gross margin by 0.8%. Gross profit also reflects royalty expense to Hexal AG of $3.9 million and $1.1 million in 2001 and 2000, respectively, in connection with the Company's sale of Cyclosporine, USP (Modified). The Company's gross profit margins are dependent on several factors, including product sales mix, costs, volumes and competitive activity.

Amortization of goodwill and other intangibles. Amortization of goodwill and other intangibles increased $6.5 million to $7.1 million in 2001 from $0.6 million in 2000. The goodwill and other intangibles arose as a result of the acquisition in December 2000 by HPI of the remaining 50% interest in the Company. The year 2001 includes a full year of amortization and 2000 includes one month of amortization.

Deferred stock appreciation rights compensation. Deferred stock appreciation rights compensation increased $3.6 million to $9.8 million in 2001 from $6.2 million in 2000. The increase was due to the increased value of the Company.

Other selling, general and administrative. Other selling, general and administrative expenses increased $4.4 million to $25.3 million in 2001 from $20.9 million in 2000. As a percentage of net sales, other selling, general and administrative expenses decreased 2.1% to 15.3% in 2001 from 17.5% in 2000. The increase in other selling, general and administrative expenses relate primarily to an increase in legal expenses of $1.7 million relating to an increase in patent litigation costs offset by a decrease in Phentermine HCl, USP litigation costs, an increase in compensation cost of $1.4 million (which includes amortization of $0.3 million of deferred stock compensation), a $0.4 million increase in distribution costs due to increased sales volume and an increase in other costs of $0.9 million.

Research and development. Research and development expenses decreased $2.7 million to $12.2 million in 2001 from $14.9 million in 2000. In 2000, there was $2.5 million of in-process research and development that was written off as part of the acquisition of EHI, offset by a $0.8 million cancellation payment that was received in connection with the termination of a research and development relationship.

Operating income. Operating income increased $17.2 million to $37.6 million in 2001 from $20.5 million in 2000 primarily because of increased sales and improved gross margins offset by higher expenses for amortization, deferred stock appreciation rights and selling, general and administrative.

Interest income (expense). In 2001, net interest expense was $8.9 million compared to $0.6 million in 2000. Interest expense increased $7.4 million primarily as a result of $104.1 million of debt utilized to acquire EHI in December 2000. Interest income in 2001 decreased by $0.8 million as a result of lower average cash investment balances due to the purchase of a new facility at a cost of $25.8 million in December 2000.

Taxes on income. Income tax expense increased $3.7 million to $13.0 million in 2001 from $9.3 million in 2000. The effective tax rate decreased to 45.2% in 2001 from 45.8% in 2000 as 2000 included a non-recurring write-off of $2.5 million of in-process research and development which was not tax-deductible, partially offset by non-deductible amortization in 2001.

Net income. Net income increased $4.8 million to $15.8 million in 2001 from $11.0 million in 2000 primarily 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 2002 and 2001. 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. 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.

2002	First Quarter(1)	Second Quarter	Third Quarter	Fourth Quarter
	(Dollars in thousands, except per share data)			
Net sales	$ 48,198	$ 52,000	$ 75,351	$ 68,720
Gross profit	$ 23,213	$ 28,303	$ 40,270	$ 33,892
Net income	$ 6,346	$ 9,504	$ 14,183	$ 13,230
Earnings per share(1)				
Basic	$	$ 0.51	$ 0.33	$ 0.30
Diluted	$ 0.19	$ 0.25	$ 0.31	$ 0.29
2001				
Net sales	$ 39,096	$ 42,586	$ 42,545	$ 41,216
Gross profit	$ 20,708	$ 26,207	$ 23,655	$ 21,561
Net income	$ 2,680	$ 5,368	$ 3,643	$ 4,100
Earnings per share(1)				

2001				
Basic	$	$	$	$
Diluted	$ 0.08	$ 0.17	$ 0.11	$ 0.12

(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.

Liquidity and Capital Resources

Cash and cash equivalents were $62.3 million at December 31, 2002, as compared to $17.6 million at December 31, 2001. Additionally, the Company had investments in marketable debt securities of $25.0 million at December 31, 2002.

The Company's initial public offering 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 AG; (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, 2002, the remaining balance of $60.3 million of the proceeds was available for general corporate purposes.

At December 31, 2002, the Company's total debt of $4.5 million was classified as current and is shown under the balance sheet caption "current portion of note payable." The debt represents the remaining balance on a note issued in connection with the acquisition of EHI. At December 31, 2002, the note had a remaining discounted value of $4.5 million and a face value of $4.8 million. A principal payment of $4.8 million is due on September 30, 2003. The payment is subject to acceleration under the note agreement if certain EBITDA levels are reached. The Company has EBITDA levels in excess of the acceleration thresholds and paid the balance in March 2003.

On February 8, 2002, the Company secured a three-year $25 million credit facility with a borrowing cost of LIBOR plus 1.5% or the bank's prime rate. The credit facility, which is for working capital purposes, had no outstanding borrowings against it at December 31, 2002.

Stockholders' equity increased to $258.2 million at December 31, 2002 from $47.0 million at December 31, 2001. Stockholders' equity was increased by the net proceeds from the Company's initial public offering of $139.2 million, $25.2 million from the capitalization of Hexal AG debt, $2.3 million (including tax benefits) from the exercise of employee stock options, earnings of $43.3 million for 2002 and $1.2 million for the amortization of deferred compensation costs.

In 2002, the Company generated net cash of $44.7 million. Operations generated $28.5 million of cash, comprised of net earnings of $43.3 million, non-cash items totaling $57.0 million and an increase in working capital of $71.7 million. The increase in working capital resulted primarily from an increase in accounts receivable in 2002 of $65.2 million due to higher sales. Cash was also used to fund increases in inventory, prepaid expenses and other assets totaling $18.0 million. Inventory increased to support higher sales. The increase in prepaid expenses is the result of higher insurance premiums. Increases in accounts payables and accrued liabilities of $11.4 million partially offset the working capital increases.

In 2001, the Company generated net cash of $11.2 million. Operations generated $30.0 million of cash, comprised of net earnings of $15.8 million, non-cash items totaling $11.1 million and a reduction in working capital of $3.2 million. The reduction in working capital resulted primarily from a decrease in accounts receivable in 2001 of $11.8 million due to a higher level of year end sales in 2000 vs. 2001 as a result of new product introductions.

Investing activities consumed $33.3 million of cash in 2002. Approximately $24.9 million was used to purchase short-term investment grade debt instruments with the balance of $8.4 million used for capital expenditures. The capital expenditures included primarily the purchase of equipment to support increased production and building improvements in the Company's Wilson facility. Investing activities in 2001 consumed $4.3 million of cash related to capital expenditures primarily for manufacturing equipment and building modifications in the Company's Wilson facility.

Financing activities provided cash of $49.5 million in 2002 and used $14.5 million of cash in 2001. In 2002, financing activities were impacted primarily by $139.2 million in net proceeds from the Company's initial public offering, $66.9 million in repayments on loans from

Hexal AG and $25.2 million used to pay installments on the EHI acquisition note. Additional sources of cash in 2002 included $1.9 million related to an increase in advances from an affiliate, $0.4 million of proceeds from the exercise of stock options and a $0.1 million reduction in restricted cash. In 2001, the Company used $10.0 million to pay an installment on the acquisition note and $7.5 million to repay the working capital loan from Hexal AG outstanding at the end of 2000. The $17.5 in total debt repayments was partially offset by an increase in advances from an affiliate of $2.2 million and a decrease of $0.8 million in restricted cash.

The Company is involved in various litigation matters in which the potential liabilities and/or related expenses are not covered by insurance. In addition, an adverse outcome in patent litigation with Novartis and Apotex involving cyclosporine capsules could result in the Company being unable to market this product which would materially harm its profits and cash flows and could result in the Company paying damages, cost, expenses, and fees that could have a material adverse impact on its financial performance. In December 2002, the United States District for the District of Delaware granted the Company's motion in the Novartis case for summary judgment of non-infringement of the patent. Novartis has appealed the judgment.

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, legal defense costs and debt service. The Company anticipates that its operating cash flows, together with its available borrowings under its credit facility and current cash balances will be sufficient to meet all of its working capital, capital expenditures and debt service requirements for both the short-term and foreseeable future.

Impact of Recently Issued Accounting Standards

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards (SFAS) No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets, which have finite lives, must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. The Company has completed its impairment assessment and determined that there is no impairment of goodwill or identifiable intangibles upon initial adoption of SFAS No. 142. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The value of the Company's existing products is an intangible asset with a finite life that is being amortized over 10 years. The Company's goodwill and workforce intangibles were amortized over 15 and 5 year lives, respectively, through December 31, 2001. Had this pronouncement been retroactively applied, net income would have increased approximately $3.2 million and $0.3 million in 2001 and 2000, respectively, and diluted earnings per share would have increased $0.10 per share and $0.01 per share, in 2001 and 2000, respectively. In 2002, the Company transferred the net book value of its workforce intangible of $1.1 million to goodwill, resulting in goodwill of $47.1 million. The recorded amount of the existing products intangible of $37.6 million, before accumulated amortization of $6.9 million as of December 31, 2002, will be amortized through 2010 with annual charges of $3.8 million.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," that replaces SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of." SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001. The adoption of SFAS No. 144 did not have a material impact on the measurement of its long-lived assets.

In April 2002, the FASB issued SFAS No. 145 "Rescission of FAS Nos. 4, 44, and 64, Amendment of SFAS 13, and Technical Corrections as of April 2002." This Statement amends SFAS No. 13, *Accounting for Leases,* to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions as well as other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 is effective for fiscal years beginning after December 31, 2002. It is not anticipated that the adoption of SFAS No. 145 will have a material impact on the consolidated financial statements.

In June 2002, the FASB issued SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 is effective for fiscal years beginning after December 31, 2002. It is not anticipated that the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148 "Accounting for Stock-Based Compensation Transition and Disclosure" that amends FASB Statement No. 123 "Accounting for Stock-Based Compensation." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 amends the disclosure requirements of APB Opinion No. 28, "Interim Financial Reporting" and Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reporting results. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148, except for the disclosure requirements, had no impact on the consolidated financial statements. The additional required disclosure is found in footnote 11.

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, 2002, the Company had cash and cash equivalents of $62.3 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. These investments are subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical increase or decrease 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 insignificant 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 owns $25.0 million in publicly traded debt securities which are subject to market fluctuations.

The Company currently does not have any international operations or any significant liabilities denominated in foreign currencies, and currently does not enter into forward exchange contracts or other financial instruments with respect to foreign currency. Accordingly, 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-28 of this Annual Report on Form 10-K.

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

None.

PART III.

Item 10. Directors and Executive Officers of the Registrant.

The information is incorporated herein by reference to the Company's definitive 2003 Proxy Statement.

Item 11. Executive Compensation.

The information is incorporated herein by reference to the Company's definitive 2003 Proxy Statement.

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

The information is incorporated herein by reference to the Company's definitive 2003 Proxy Statement.

Item 13. Certain Relationships and Related Transactions.

The information is incorporated herein by reference to the Company's definitive 2003 Proxy Statement.

PART IV.

Item 14. Controls and Procedures.

As of date within the 90-day period prior to the filing of this annual report (the "Evaluation Date"), an evaluation was performed under the supervision and with the participation of the Company's management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including the Chief Executive Officer and the Chief Financial Officer, concluded that the Company's disclosure controls and procedures were effective as of the Evaluation Date. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect the internal controls subsequent to the Evaluation Date.

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K.

(a)

Documents filed as part of this Form 10-K.

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

(2) Financial Statement Schedules: None.

(3) Exhibits

Exhibit No.	Description
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	Restated Bylaws of Eon Labs, Inc. filed herewith.
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	Employment Agreement by and between Eon Labs, Inc. and Bernhard Hampl, Ph.D. was filed as Exhibit 10.1 to the Company's Regiistration Statement on Form S 1/A (Reg. No. 333-83638), filed on March 1, 2002 and is incorporated herein by reference.
10.2	Employment Agreement by and between Eon Labs, Inc. and William F. Holt. was filed as Exhibit 10.2 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.
10.3	Employment Agreement by and between Eon Labs, Inc. and Jeffrey S. Bauer, Ph.D. filed herewith.
10.4	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.

10.5 Credit Agreement, dated as of February 8, 2002, by and among Eon Labs, Inc., Eon Pharma, LLC and JPMorgan Chase Bank was filed as Exhibit 10.5 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.

10.6 Amendment to Credit Agreement, dated as of November 1, 2002, by and among Eon Labs, Inc., Eon Pharma, LLC and JPMorgan Chase Bank filed herewith.

10.7 Amendment and Waiver to Credit Agreement, dated as of March 18, 2003, by and among Eon Labs, Inc., Eon Pharma, LLC and JPMorgan Bank filed herewith.

10.8 Eon Labs, Inc. Stock Option Plan was filed as Exhibit 10.2 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.

10.9 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 filed herewith.

10.10 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.

10.11 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.

10.12 Exclusive Distribution and Supply Agreement by and between Upsher-Smith Laboratories, Inc. and Eon Labs, Inc., dated as of December 13, 2002, was filed as Exhibit 10.3 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.

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.

(b)

Reports on Form 8-K during the quarter ended December 31, 2002: No reports on Form 8-K were filed during the quarter ended December 31, 2002.

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

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

Signature	Title	Date

Signature	Title	Date
/s/ BERNHARD HAMPL Bernhard Hampl, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2003
/s/ THOMAS STRÜNGMANN Thomas Strüngmann, Ph.D.	Chairman of the Board of Directors	March 27, 2003
/s/ WILLIAM F. HOLT William F. Holt	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 27, 2003
/s/ DAVID H. GRANSEE David H. Gransee	Controller	March 27, 2003
/s/ FRANK F. BEELITZ Frank F. Beelitz	Director	March 27, 2003
/s/ DOUGLAS M. KARP Douglas M. Karp	Director	March 27, 2003
/s/ MARK R. PATTERSON Mark R. Patterson	Director	March 27, 2003

CERTIFICATIONS

I, Bernhard Hampl, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Eon Labs, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a)

designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ BERNHARD HAMPL

Bernhard Hampl, Ph.D.
Chief Executive Officer and President

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I, William F. Holt, certify that:

1. I have reviewed this annual report on Form 10-K of Eon Labs, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4.

The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

(c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ WILLIAM F. HOLT

William F. Holt
Chief Financial Officer

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

Report of Independent Accountants

To the Board of Directors and Stockholders of Eon Labs Inc.
(formerly Eon Labs Manufacturing, Inc.):

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) on page 33 present fairly, in all material respects, the financial position of Eon Labs, Inc. (formerly Eon Labs Manufacturing, Inc.) and Subsidiaries at December 31, 2002 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 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 auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, 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.

As discussed in Note 3, the Company changed the manner in which it accounts for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, "Goodwill and Other Intangible Assets", on January 1, 2002.

PricewaterhouseCoopers LLP

New York, New York
February 14, 2003

Eon Labs, Inc. and Subsidiaries

Consolidated Balance Sheets

December 31, 2002 and 2001

(dollars in thousands, except per share amounts)

	2002	2001
Assets		
Current assets		
Cash and cash equivalents	$ 62,323	$ 17,624
Investments	24,961	
Accounts receivable, net	23,822	27,290
Inventories	41,946	31,192
Deferred tax assets	43,648	19,566

	2002	2001
Prepaid expenses and other current assets	10,402	5,355
Due from related party	280	200
Total current assets	207,382	101,227
Property, plant and equipment, net	42,788	38,496
Goodwill and other intangible assets, net	76,701	78,805
Other assets	3,000	874
Total assets	$ 329,871	$ 219,402
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 10,974	$ 10,430
Accrued liabilities	48,785	37,301
Current portion of note payable	4,530	24,400
Total current liabilities	64,289	72,131
Long-term liabilities		
Long-term portion of note payable		2,353
Deferred tax liabilities	6,998	7,153
Deferred revenue	430	660
Loans and advances from Hexal AG		90,114
Total liabilities	71,717	172,411
Commitments and contingencies (Notes 10 and 13)		
Stockholders' equity		
Common stock, par value $.01 per share; 70,000,000 shares authorized and 44,077,282 outstanding at December 31, 2002, and no shares authorized or outstanding at December 31, 2001	441	
Preferred stock, par value $.01 per share; Series A convertible; no shares authorized or outstanding at December 31, 2002, and 35,000,000 shares authorized, 30,000,000 issued and outstanding at December 31, 2001		300
Preferred stock, par value $.01 per share; 5,000,000 shares authorized and no shares issued or outstanding at December 31, 2002, and no shares authorized, issued or outstanding at December 31, 2001		
Additional paid-in capital	192,662	26,101
Retained earnings	65,639	22,376
Accumulated other comprehensive income	44	
	258,786	48,777
Less: Unearned deferred stock-based compensation	(632)	(1,786)
Total stockholders' equity	258,154	46,991
Total liabilities and stockholders' equity	$ 329,871	$ 219,402

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, 2002, 2001 and 2000

(dollars in thousands, except per share amounts)

	2002	2001	2000
Net sales	$ 244,269	$ 165,443	$ 119,693
Cost of sales	118,591	73,312	56,559
Gross profit	125,678	92,131	63,134
Operating expenses			
Selling, general and administrative expenses:			
Amortization of goodwill and other intangibles	3,760	7,120	639
Deferred stock appreciation rights compensation		9,837	6,197
Other selling, general and administrative expenses	32,706	25,322	20,890
Research and development expenses	13,239	12,224	14,936
Total operating expenses	49,705	54,503	42,662
Operating income	75,973	37,628	20,472
Other income and expense			
Interest income	854	462	1,311
Interest expense	(3,857)	(9,318)	(1,892)
Other income, net	113	44	398
Total other expense	(2,890)	(8,812)	(183)
Income before income taxes	73,083	28,816	20,289
Provision for income taxes	29,820	13,025	9,300
Net income	$ 43,263	$ 15,791	$ 10,989
Net income per common share			
Basic	$ 1.62	$	$
Diluted	$ 1.06	$ .49	$ .36
Weighted average common shares outstanding			
Basic	26,630,789		
Diluted	40,648,533	32,130,729	30,120,000

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

Eon Labs, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity

For the years ended December 31, 2002, 2001 and 2000

(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	Total Stockholders' Equity
Balance, December 31, 2000	30,000,000	$ 300		$	$ 5,010	$ 6,585	$	$	$ 11,895
Conversion from stock appreciation rights plan to stock option plan					21,091		(2,134)		18,957
Amortization of unearned deferred stock-based compensation							348		348
Net income						15,791			15,791
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

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, 2002, 2001 and 2000

(dollars in thousands)

	2002	2001	2000
Cash flows from operating activities			
Net income	$ 43,263	$ 15,791	$ 10,989
Adjustments to reconcile net income to net cash provided by operating activities:			
Provision for accounts receivable allowances	68,628	(9,446)	14,476
Depreciation and amortization	7,899	10,495	2,294
Deferred income taxes	(24,064)	(9,140)	(14,384)
Deferred compensation	1,154	10,185	6,197
Amortization of deferred revenue	(230)	(215)	
Amortization of discount on note payable	1,149	2,646	240
Write-off of purchased research and development			2,450
Interest paid in-kind	2,463	6,553	1,522
Changes in assets and liabilities:			
Accounts receivable	(65,160)	11,773	(32,529)
Inventories	(10,754)	(12,620)	(5,751)
Prepaid expenses and other current assets	(5,116)	(1,963)	112
Other assets	(2,126)	(423)	(316)
Accounts payable	544	3,204	1,631
Accrued liabilities	10,879	2,867	26,396
Deferred revenue		325	750
Net cash provided by operating activities	28,529	30,032	14,077
Cash flows from investing activities			
Capital expenditures	(8,431)	(4,275)	(27,704)
Cash payments to acquire EHI			(60,000)
Purchases of investments	(24,888)		
Net cash used in investing activities	(33,319)	(4,275)	(87,704)
Cash flows from financing activities			
Payments on note	(25,201)	(10,000)	(10,000)
Advances from related parties, net	1,943	2,194	1,743
(Decrease) increase in loans payable to Hexal AG	(66,942)	(7,500)	67,500
Decrease in restricted cash	69	795	
Payments under capital lease obligation			(333)
Proceeds from initial public offering of common stock	139,237		
Proceeds from exercises of stock options	383		
Net cash provided by (used in) financing activities	49,489	(14,511)	58,910
Net increase (decrease) in cash and cash equivalents	44,699	11,246	(14,717)
Cash and cash equivalents at beginning of year	17,624	6,378	21,095
Cash and cash equivalents at end of year	$ 62,323	$ 17,624	$ 6,378
Supplemental disclosure of cash flow information:			
Cash paid during the year for			

	2002	2001	2000
Interest	$ 11,173	$ 899	$ 39
Income taxes	56,379	23,642	15,458

See Note 16 for other supplemental cash flow information.

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

Eon Labs, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

(Dollars in thousands, except per share amounts)

1. Nature of Operations

Eon Labs, Inc. (formerly Eon Labs Manufacturing, Inc.) and Subsidiaries (the "Company") is a generic pharmaceutical company engaged in the development, licensing, manufacturing, selling and distribution of a broad range of prescription pharmaceutical products primarily in the United States. The Company's products are sold to drug wholesalers, national drug chains and mail order accounts, as well as large HMOs. The Company operates in one business reporting segment.

2. Basis of Presentation

The consolidated financial statements of the Company include the accounts of Eon Labs, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Change of Company Ownership

Prior to the reorganization described below, Hexal Pharmaceuticals, Inc. ("HPI"), a wholly-owned United States subsidiary of Santo Holding (Deutschland) GmbH ("Santo" or the "Parent"), which is under common control with Hexal AG, owned 50% of the outstanding capital stock of the Company. The remaining 50% was owned by Eon Holdings, Inc. ("EHI"), whose principal asset was its 50% ownership of the Company.

On December 5, 2000, HPI acquired all of the outstanding stock of EHI, giving HPI effective ownership of 100% of the Company. Prior to the acquisition, HPI and EHI were unrelated entities. The purchase price HPI paid for EHI was approximately $109 million consisting of $60 million in cash, which was funded through a loan from Hexal AG, $44 million in a non-interest-bearing note (net of $6.1 million discount) and warrants with an approximate value of $4.9 million at the time of issuance. The acquisition resulted in a step-up of the assets of the Company. Except for goodwill, the step-up represents 50% of the difference between historical cost and the fair value of the assets. Goodwill represents the excess of the purchase price over the fair value of 50% of the adjusted net assets acquired. The allocation of the purchase price to step-up of assets was as follows:

Inventory	$ 2,365
Property, plant and equipment	2,615
Acquired in-process research and development	2,450
Value of existing products	37,600
Intangibles workforce	1,450
Goodwill	47,514

The Company expensed the in-process research and development of $2,450 and recorded deferred income taxes of $13,577 for the difference between the financial statement basis and tax basis of certain assets. The Company has recorded an increase in its deferred tax assets of $6 million representing the tax benefit of net operating losses and other temporary differences which are available for use by the Company on a consolidated basis.

Effective May 21, 2002, in conjunction with an initial public offering of the Company's common stock, the Company was combined with HPI and EHI into a single entity through a series of reorganization mergers. EHI was merged with and into HPI and HPI was subsequently

merged with

and into the Company. This reorganization was accounted for as a merger of entities under common control and the accounts of the companies were combined in a manner similar to a pooling of interests effective January 1, 2000.

3. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with original maturities of three months or less to be cash equivalents.

Investments

The Company invests in publicly traded debt securities which are categorized as securities available-for-sale and are carried at fair value, with unrealized gains and losses excluded from income and recorded to stockholders' equity. The market value of such securities exceeded book value by $0.04 million at December 31, 2002. Accordingly, recording comprehensive income items (unrealized gains on marketable securities) increases net income by $0.04 million for the year ended December 31, 2002.

Inventories

Inventories are stated at the lower of cost (on a first-in, first-out basis) or market.

Property, Plant and Equipment

Property, plant and equipment is stated at cost, less accumulated depreciation. Depreciation of property, plant and equipment is calculated on a straight-line basis over the estimated useful lives of the assets. Useful lives of property, plant and equipment are as follows: building and improvements 25 years and machinery and equipment 5 to 7 years. Expenditures for repairs and maintenance are expensed as incurred; expenditures for major renewals and betterments are capitalized. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and a gain or loss on disposition is reflected in current operations. Property, plant and equipment is reviewed for impairment whenever events or changes in circumstances indicate that the related carrying amount may not be recoverable. If such assets are determined to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value is determined using current market prices or anticipated cash flows discounted at a rate commensurate with the risks involved. Management does not believe that there are any impairments in property and equipment at December 31, 2002.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the realizability of accounts receivable including contractual allowances, rebates and chargebacks and

other estimates for long-lived assets, inventories, returns, Medicaid rebates and deferred tax assets. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentration of credit risk consist of cash deposits and accounts receivable.

The Company performs periodic credit evaluations of its customers' financial condition and, generally, requires no collateral. The Company believes it mitigates its risk with respect to accounts receivable by purchasing credit insurance in varying amounts on its larger customers. For the year ended December 31, 2002, sales to the Company's two customers with more than 10% of the Company's total sales aggregated approximately 47%. For the years ended December 31, 2001 and 2000, sales to the Company's three largest customers, which each represented more than 10% of total sales, was approximately 35% and 53%, respectively. The Company's three largest customers represented approximately 33% of total accounts receivable at December 31, 2002.

Reliance on Suppliers

Some materials used in the Company's manufactured products are currently available only from one or a limited number of suppliers. Even when more than one supplier for a product exists, the Company at times has listed only one supplier in the Company's Abbreviated New Drug Applications ("ANDA") for some products. This includes products that have historically accounted for a significant portion of the Company's revenues. In the event an existing supplier named in the Company's ANDA application for a product should lose its regulatory status as an acceptable source, the Company would attempt to locate a qualified alternative; however the Company may be unable to obtain the required components or products on a timely basis or at commercially reasonable prices. Additionally, any change in a supplier not previously approved in the Company's abbreviated new drug application must then be submitted through a formal approval process with the Food and Drug Administration.

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. Discounts, rebates and contract pricing adjustments are recorded as a reduction of sales based on agreed upon terms with the Company's customers at the time of sale. The Company calculates a reserve for discounts and rebates based upon actual sales under such arrangements. Reserves for contract pricing adjustments represent the difference between the prices wholesalers are billed by the Company and the prices billed to their customers to whom the Company has given contract prices. In determining a reserve for contract pricing adjustments, the Company takes into account an estimate of the percentage of product sales subject to such pricing adjustments based on historical trends. Historical trends are adjusted for new product introductions and changes in wholesaler or contract prices.

Included in net sales in 2002 and 2001 is royalty income of $3.4 million and $2.8 million, respectively.

Accounts receivable is presented net of allowances for discounts, rebates, contract pricing adjustments and doubtful accounts, which were $75.5 million and $6.9 million at December 31, 2002 and 2001, respectively.

Shelf stock adjustments are provided following a reduction in the prices of any of the Company's products due to the competitive environment. Such adjustments are credited to the Company's customers based on their on-hand inventory quantities. Reserves are generally established when the Company reduces its prices.

Estimates for returns, which are recorded at the time of sale, relate primarily to returns of expiring products. The Company utilizes historical trends to estimate the amount of products to be returned due to product expiration.

Research and Development

Research and development activities are expensed as incurred.

Advertising

Advertising costs are expensed as incurred. Advertising expenses for the years ended December 31, 2002, 2001 and 2000 were approximately $0.5 million, $0.4 million and $0.6 million, respectively.

Income Taxes

Deferred income taxes are recognized for the future tax consequences of temporary differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during

the period in deferred tax assets and liabilities.

Long-Lived Assets

The Company accounts for the carrying values of long-lived assets and certain identifiable intangible assets by evaluating the future cash flows expected to result from the use of the asset and its eventual disposition. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized. Management does not believe there are any impairments in long-lived assets at December 31, 2002.

Stock-Based Compensation

In October 1995, the FASB issued SFAS No. 123 "Accounting for Stock-Based Compensation" ("SFAS No. 123"). SFAS No. 123 allows companies which have stock-based compensation arrangements with employees to adopt a new fair-value basis of accounting for stock options and other equity instruments, or to continue to apply the existing accounting required by Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees." The Company intends to continue to account for stock-based compensation arrangements under APB Opinion No. 25. Compensation cost is measured based on the change in the value of the stock appreciation rights award

and is recognized over the service period, which is usually the vesting period. Changes in the amount of the related liability due to fair value changes in the stock price after the service period are compensation cost of the period in which the change occurs.

Net Income Per Common Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution of stock options, warrants, and the conversion of preferred stock. Details of the calculations are as follows:

	Years Ended December 31,		
	2002	2001	2000
Net income per share basic:			
Net income	$ 43,263	$ 15,791	$ 10,989
Weighted average shares basic	26,630,789		
Net income per share basic	$ 1.62	$	$
Net income per share diluted:			
Net income	$ 43,263	$ 15,791	$ 10,989
Weighted average shares outstanding basic	26,630,789		
Effect of preferred stock prior to conversion	11,671,233	30,000,000	30,000,000
Effect of warrants prior to conversion	653,794	1,680,528	120,000
Dilutive effect of stock options	1,692,717	450,201	
Weighted average shares diluted	40,648,533	32,130,729	30,120,000
Net income per share diluted	$ 1.06	$ 0.49	$ 0.36

Shipping and Handling Costs

The Company classifies shipping and handling costs as part of selling, general and administrative expenses. Shipping and handling costs were $3.2 million, $1.8 million and $1.3 million in 2002, 2001 and 2000, respectively.

New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The Company's existing products are intangible assets with finite lives that are being amortized over

10 years. The Company's goodwill and workforce intangibles were amortized through 2001 over 15 and 5 year lives, respectively.

In 2002, the Company ceased amortization of goodwill and its workforce intangibles. Had this pronouncement been retroactively applied, net income would have increased approximately $3.2 million and $0.3 million in 2001 and 2000, respectively, and diluted earnings per share would have increased $0.10 per share and $0.01 per share, in 2001 and 2000, respectively. Additionally, in 2002, the Company transferred the net book value of its workforce intangible of $1,136 to goodwill. The recorded amount of the existing product intangible of $37,600 will be amortized through 2010 with annual charges of $3,760.

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," that replaces SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of." SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001. Adoption of SFAS No. 144 did not have a material impact on the measurement of its long-lived assets.

In April 2002, the FASB issued SFAS No. 145 "Rescission of FAS Nos. 4, 44, and 64, Amendment of SFAS No. 13, and Technical Corrections as of April 2002." This Statement amends SFAS No. 13, Accounting for Leases, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions as well as other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 is effective for fiscal years beginning after December 31, 2002. The Company does not anticipate that the adoption of SFAS No. 145 will have a material impact on the consolidated financial statements.

In June 2002, the FASB issued SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." SFAS No. 146 is effective for fiscal years beginning after December 31, 2002. The Company does not anticipate that the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148 "Accounting for Stock-Based Compensation Transition and Disclosure" that amends SFAS No. 123 "Accounting for Stock-Based Compensation." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 amends the disclosure requirements of APB Opinion No. 28, "Interim Financial Reporting" and Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reporting results. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148

except for the disclosure requirements, had no impact on the consolidated financial statements. The additional required disclosure is found in Note 11.

4. Inventories

Inventories consist of the following:

	December 31,	
	2002	2001
Raw material	$ 19,937	$ 16,909
Work-in-process	9,655	6,026
Finished goods	12,354	8,257
	$ 41,946	$ 31,192

5. Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31,	
	2002	2001
Land	$ 2,711	$ 2,711
Buildings and improvements	27,812	25,417
Machinery and equipment	29,524	23,633
	60,047	51,761
Less accumulated depreciation	17,259	13,265
	$ 42,788	$ 38,496

Depreciation expense was $4.1 million, $3.4 million and $1.7 million in 2002, 2001 and 2000, respectively.

6. Goodwill and Other Intangible Assets

Intangible assets consist of the following components:

	December 31,	
	2002	2001
Value of existing products	$ 37,600	$ 37,600
Less accumulated amortization	(11,519)	(7,759)
Value of existing products, net	26,081	29,841
Goodwill	50,620	48,964
	$ 76,701	$ 78,805

Amortization expense was $3.8 million, $7.1 million and $0.6 million in 2002, 2001 and 2000, respectively.

7. Income Taxes

The provision for income taxes consists of the following:

	Years ended December 31,		
	2002	2001	2000
Current:			
Federal	$ 46,224	$ 19,266	$ 19,706
State and local	7,660	3,302	3,378
Deferred:			
Federal	(20,614)	(8,146)	(11,789)
State and local	(3,450)	(1,397)	(1,995)
	$ 29,820	$ 13,025	$ 9,300

Reconciliations between the statutory federal income tax rate and the Company's effective income tax rate are as follows:

	Years Ended December 31,		
	2002	2001	2000
Federal income tax statutory rates	35.0%	35.0%	35.0%
State and local income taxes, net of federal benefit	5.0%	6.0%	6.0%
In-process research and development expense			4.8%
Non-deductible goodwill amortization		4.2%	
Other	0.8%		
	40.8%	45.2%	45.8%

The components of the net deferred tax assets are as follows:

	December 31,	
	2002	2001
Current deferred tax assets		
Inventory capitalization and provisions	$ 1,363	$ 508
Provision for accounts receivable allowances	40,475	13,190
Start-up costs	606	621
Prepaid insurance	(1,106)	
Reserve for Medicaid rebates	1,622	820
Other assets	252	205
Other liabilities, not currently deductible	1,042	4,843
	44,254	20,187
Less valuation allowance	(606)	(621)
Deferred tax assets	43,648	19,566
Non-current deferred tax liabilities		

	December 31,	
Property, plant and equipment	(639)	(117)
Deferred compensation	5,946	7,915
Step-up of fixed assets	(864)	(975)
Step-up of intangibles	(12,361)	(14,212)
Original issue discount on notes payable	(80)	236
State tax credits	804	
Other noncurrent assets	196	
Deferred tax liabilities	(6,998)	(7,153)
Net deferred tax assets	$ 36,650	$ 12,413

The Company has not recorded a potential deferred tax asset of $10 million representing the benefit of net operating losses of EHI which may be available for use by the Company on a consolidated basis. This benefit is pending approval by taxing authorities. Upon approval, such amounts will be recorded as a deferred tax asset with an offsetting reduction to goodwill.

8. Notes Payable

In connection with the acquisition of EHI by HPI (see Note 2), the Company recorded a $50 million non-interest bearing note payable issued by HPI to the sellers at its estimated present value of $44 million.

The $50 million note provides for installment payments as follows: $10 million on December 8, 2000, $10 million on December 5, 2001, $10 million on September 30, 2002, $10 million on September 30, 2003, and $10 million on December 31, 2003. A payment of $10 million was made to the sellers pursuant to the terms of the note on December 8, 2000 and December 5, 2001. The Note provides for prepayments to be applied against the last installment or installments in the event the Company's earnings before interest, taxes, depreciation and amortization (EBITDA), as defined, exceed $20 million in calendar years 2002 and 2001. If EBITDA exceeds $20 million in either calendar year then a prepayment is required on the Note equal to 50% of the amount in excess of $20 million for such calendar year. In no event shall the aggregate prepayments required by such calculations exceed $20 million. In March 2002, the Company made a payment of $15.2 million. At December 31, 2002, the remaining balance of $4.8 million, net of $0.3 million of unamortized debt discounts is shown in the balance sheet caption "Current portion of note payable." The Company expects to pay the remaining $4.8 million note balance in March 2003.

In connection with the December 2000 acquisition of EHI, the Company borrowed $60 million from Hexal AG, at a fixed rate of 8.75%. In addition, Hexal AG also provides advances to the Company and has allowed interest to accrue. Further, the Company had outstanding borrowings of $16,874 under a $20 million loan agreement with Hexal AG. Interest on advances is calculated at LIBOR (as defined) plus 1.25%. In May 2002, immediately following the closing of the Company's initial public offering, debt of $25,178 due to Hexal AG was converted into 1,678,561 shares of common stock and debt of $66,942 due to Hexal AG was paid with the proceeds of the offering. The payment and stock conversion totaling $92,120 fully paid the balance due at March 31, 2002 which was comprised of the two notes payable of $60,000 and $16,874, plus an additional intercompany payable of $15,246. At December 31, 2002, the Company had approximately $1.6 million payable to Hexal AG, which is included in accrued liabilities.

In December 2000, Hexal AG, HPI and EHI entered into a loan agreement with several lenders, including Bayerische Hypo-Und Vereinsbank AG as agent for the lenders, under which Hexal AG was permitted to borrow up to an aggregate of $40 million. In connection with that loan agreement, HPI and EHI each entered into a guarantee agreement and a pledge and security agreement pursuant to which each of HPI and EHI, each of which was a wholly owned subsidiary of Hexal AG at that time, guaranteed payment when due under the loan agreement. Pursuant to the pledge and security agreement entered into by HPI, HPI pledged all of the capital stock of Eon Labs and EHI, owned by it as collateral for such guarantee. Pursuant to the pledge and security agreement entered into by EHI, EHI pledged all of the capital stock of Eon Labs owned by it as collateral for such guarantee. In June 2002 all outstanding amounts under the loan agreement were repaid and the loan agreement and the pledge and security agreements were terminated.

Unsecured Loan from Hexal AG

On December 6, 2000, the Company entered into an unsecured loan agreement with Hexal AG that provides loans to the Company up to a maximum amount of $8 million. Either party upon three

months notice can terminate the Agreement. Interest on advances is calculated based on the LIBOR rate in effect on December 30 of the preceding year plus 1.75%. On December 8 and December 11, 2000, the Company borrowed $3 million and $4.5 million, respectively, which was paid in 2001. This agreement has been terminated.

9. Accrued Liabilities

Accrued liabilities include the following:

	December 31,	
	2002	2001
Payroll, vacation and related costs	$ 3,065	$ 904
Income taxes payable	375	5,291
Reserve for customer rebates and other allowances	36,960	24,352
Accrued legal costs	1,495	2,110
Other liabilities	6,890	4,644
	$ 48,785	$ 37,301

10. Commitments and Contingencies

Lease Commitments

The Company is obligated under various non-cancelable operating leases for certain machinery, automobiles and office equipment that have terms in excess of one year. Minimum lease payments for years 2003 through 2005 are $34, $17 and $10, respectively. For the years ended December 31, 2002, 2001 and 2000, expense under operating leases was approximately $37, $45 and $30, respectively.

Line of Credit

On February 8, 2002, the Company entered into a three-year $25 million credit agreement, which is collateralized by accounts receivable and inventory. Interest on any borrowing under the line will accrue at the rate of interest equal to either the adjusted LIBOR (as defined) rate plus 1.5%, the prime rate or the fixed rate (as set by the bank). The rate will depend upon the terms of the selected borrowings. The agreement has covenants which require the maintenance of certain financial ratios including leverage, consolidated debt and asset coverage, as defined. At December 31, 2002, there were no outstanding borrowings under the line of credit.

Medicaid Rebates

The Omnibus Budget Reconciliation Act of 1990, effective January 1, 1991, requires drug companies to enter into a rebate agreement with the Health Care Financing Administration of the Federal government. The rebate agreement states that drug companies must pay rebates to states for drugs (prescription, non-prescription or biological products) sold to Medicaid recipients. At December 31, 2002 and 2001, $4.1 million and $2.0 million, respectively, are included in accrued liabilities as the estimated liability for Medicaid rebates.

State Medicaid Claims

EHI purchased Major Pharmaceuticals, Inc. ("Major"), a distributor of drug products in 1991 and sold Major in 1995. At the time of the sale, EHI established an escrow account to cover any Medicaid drug rebate liabilities incurred by Major prior to the sale.

As of December 31, 2002, the recorded liability for such claims is $944, which management believes is adequate to resolve such matters. The Company has approximately $808 as of December 31, 2002, in an escrow account to resolve such claims.

Food and Drug Administration "FDA" Regulations

In January 2003, the Company received Inspectional Observations Form FDA 483 (the "FDA 483") at its Laurelton facility following the mislabeling of one lot of product that was distributed. The mislabeled lot was recalled. The Company provided a written response to the FDA 483 discussing the implementation of corrective actions and revisions to procedures that the Company believes addresses the concerns and issues raised by the FDA 483. In February 2003, the FDA issued a Warning Letter and requested that the Company clarify and supplement its responses to the FDA 483. The Company has provided its supplemental responses to the FDA. Based on follow-up discussions with the FDA, the Company has been advised that a Current Good Manufacturing Practices or "GMP" inspection will be conducted by the FDA at the Laurelton facility beginning in April 2003.

11. Employee Benefit Plans

Savings Incentive Plan

The Company has a defined contribution Savings Incentive Plan (the "Savings Plan") which is offered to all eligible employees and is qualified under Section 401(k) of the Internal Revenue Code. Employees are eligible for participation at the start of any calendar quarter providing the employee has attained 21 years of age. The Savings Plan provides an employer matching contribution which will begin at the start of the quarter coincident with or next following the one year anniversary of the participant's hire date in an amount as defined in the Savings Plan. The Savings Plan provides for matching contributions equal to 50% of the participant's contribution, to the extent that the participant's contributions do not exceed 6% of their compensation. The cash contributions to the Savings Plan in 2002, 2001 and 2000 were $173, $145 and $154, respectively.

Stock Appreciation Rights Plan

In June 1996, the Board of Directors adopted the Eon Labs, Inc. Stock Appreciation Rights Plan (the "Plan") which provided for the issuance of up to 75,000 stock appreciation rights ("SARs") to employees, directors and consultants who were in a position to materially contribute to the long-term success of the Company. Upon exercise of any SAR, the grantee was entitled to receive an amount equal to the excess of (i) the fair market value (FMV) of one share of common stock on the last day of the Company's fiscal year immediately prior to such exercise, over (ii) the base value established upon the grant of such SAR.

Fair market value of the common stock on a given date was based, if listed on a national securities exchange or quoted in an interdealer quotation system, the last sales price or, if unavailable, the average of the closing bid and asked prices per share; or, if the common stock was not listed on a national securities exchange or quoted in an interdealer quotation system, the value was determined by the Board in good faith in its sole discretion.

Unless otherwise determined by the Board, the grants vested and became exercisable at the rate of 20% per year subject to the satisfaction of any performance goals with respect to such year provided that the grantee remained an employee, director or consultant through the end of such year. Generally, once vested, SARs remain exercisable until the earlier of the termination of the grantee's employment or the tenth anniversary of the date the SAR is granted. The Company had the right, but not the obligation, to purchase from a grantee any or all shares of common stock acquired by a grantee upon the exercise of SARs at the FMV of such shares. SARs vested at the rate of 20% per year and vesting was not subject to the satisfaction of performance goals.

A summary of the Company's stock appreciation rights is as follows:

	Nine months ended September 30, 2001	Year ended December 31, 2000
	Shares	Shares

	Nine months ended September 30, 2001		Year ended December 31, 2000	
		Weighted Average Exercise Price		Weighted Average Exercise Price
Outstanding at beginning of period	66,875	$ 34.49	73,200	$ 35.52
Granted			900	63.00
Exercised	(1,345)	14.58	(1,805)	34.19
Forfeited	(485)	54.85	(5,420)	50.59
Outstanding at end of period	65,045	$ 34.75	66,875	$ 34.49
Exercisable at end of period	47,433	$ 28.06	35,815	$ 25.04

Stock appreciation rights costs of $9.8 million and $6.2 million were recognized in 2001 and 2000, respectively.

Stock Option Plan

Effective September 30, 2001, the Company converted its SAR plan to a stock option plan pursuant to provisions for such conversion in the SAR plan. In connection with the conversion, each outstanding SAR was converted into an option to purchase one share of common stock at an exercise price equal to the original base value of the SAR at date of grant.

The stock option plan provides for the granting of up to 3,000,000 options to purchase common stock of which 551,500 are available for future grants at December 31, 2002. Stock options granted under the plan are exercisable for up to ten years following the date of grant. Vesting provisions are determined by the Compensation Committee of the Board of Directors on a case-by-case basis. As of the conversion date, the Company has classified deferred compensation of $18,957 as additional paid-in capital. For option awards not fully vested as of September 30, 2001, the remaining unrecorded

deferred compensation expense of $2,134 will be recognized over the remaining vesting period. The Company has amortized an additional $1,154 and $348 of deferred compensation into expense for the years ended December 31, 2002 and 2001, respectively.

A summary of the Company's stock options granted is as follows:

	Year ended December 31, 2002		Year ended December 31, 2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Balance at beginning of year	1,951,350	$ 1.16		$
SARs converted to options on October 1, 2001			65,045	34.75
Effect of stock split			1,886,305	1.16
Exercised	(517,380)	.74		
Forfeited or cancelled	(15,000)	18.25		
Granted	512,150	18.78		
Outstanding at end of period	1,931,120	$ 5.81	1,951,350	$ 1.16

	Year ended December 31, 2002		Year ended December 31, 2001	
Exercisable at end of period	1,200,030	$ 1.16	1,449,390	$ .93

The following table summarizes options outstanding and exercisable at December 31, 2002:

Exercise Prices	Number Outstanding	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.23	304,750	8.75	$ 0.23	304,750	$ 0.23
$ 1.20	629,250	8.75	$ 1.20	627,150	$ 1.20
$ 2.10	499,970	8.75	$ 2.10	268,130	$ 2.10
$18.25	385,150	9.50	$ 18.25		$
$20.67	112,000	9.82	$ 20.67		$
	1,931,120		$ 5.81	1,200,030	$ 1.16

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations in accounting for its stock-based compensation. In addition, the Company provides pro forma disclosure of stock-based compensation, as measured under the fair value requirements of SFAS No. 123, "Accounting for Stock-Based Compensation" and determined through the use of the Black-Scholes option pricing model. These pro forma disclosures are provided as required under SFAS No. 148, "Accounting for Stock-Based Compensation Transition and Disclosure."

The fair value of the options was determined using the Black-Scholes option pricing model with the following assumptions:

	2002	2001
Dividend yield	0%	0%
Volatility	45%	0%
Risk-free interest rate	3.0% to 4.0%	2.3% to 3.7%
Expected life	1 to 5 years	1 to 4 years

A reconciliation of the Company's net earnings to pro forma net earnings and the related pro forma earnings per share amounts, for the years ended December 31, 2002 and 2001, is provided below. There were no stock options outstanding in 2000. For purposes of pro forma disclosure, stock-based compensation expense is recognized in accordance with the provisions of SFAS No. 123.

	2002	2001
Net income, as reported	$ 43,263	$ 15,791
Adjustment to net income for pro forma stock-based compensation expense, net of related tax effect	(225)	(4)
Pro forma net income	$ 43,038	$ 15,787
As reported and pro forma net earnings per share:		
Basic	$ 1.62	$
Diluted	$ 1.06	$ 0.49

12. Equity

Stock Splits

In May 2002, the Company effected a 30-for-1 stock split of the Company's preferred stock and the Company's non-voting common stock with no change in par value. Additional paid-in capital, preferred stock, common stock, per share and shares outstanding data in the Consolidated Financial Statements and Notes to the Consolidated Financial Statements have been retroactively restated to reflect this stock split.

Also, in May 2002, the outstanding 30,000,000 preferred shares were converted to common stock. In addition, the Company changed the number of shares of authorized preferred stock to 5,000,000, increased the number of shares of authorized voting common stock to 70,000,000 and converted shares of non-voting common stock to shares of a single class of common stock.

Initial Public Offering and Shareholders' Equity

In June 2002, the Company completed its initial public offering of common stock, which resulted in net proceeds of $139,236 and the issuance of 10,200,813 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 30,000,000 shares of common stock and warrants were exercised resulting in the issuance of 1,680,528 shares of common stock. Immediately following the

closing of the Company's initial public offering, debt of $25,178 due to Hexal AG was converted into 1,678,561 shares of common stock and debt of $66,942 due to Hexal AG was paid with the proceeds of the offering.

13. Litigation

Product Liability Litigation

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 and distributors 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 Food and Drug Administration ("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 United States 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 substantially curb their testimony 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 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 United States

District Court for the Eastern District of Pennsylvania, which supervises discovery of all federal fen-phen cases in a consolidated multidistrict litigation (the "Fen-Phen MDL"), certified a nationwide settlement class and approved the proposed settlement, which became final in January 2002. This settlement has reduced the number of cases in which the Company and its distributors have been named as defendants.

As of December 31, 2002, the Company had been named and served in approximately 6,400 fen-phen product liability cases. More than 96% of these cases have been dismissed, and fewer than 190 remained open. 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 case, the Company and all the phentermine defendants, including other phentermine manufacturers and distributors, were 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, 2002, 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 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, 2002 only one such claim remained pending. A second case was served on the Company in February 2003.

One of the remaining cases is currently pending in a consolidated federal fen-phen multidistrict litigation pending in the United States District Court for the Eastern District of Pennsylvania. The second was removed to the United States District Court for the Central District of Florida, and may be transferred to the federal multidistrict litigation.

Additionally, the Company has been named as a defendant in one state court case alleging injury from the use of Company phentermine in combination with phenylpropanolamine (PPA) made by another company.

Because discovery has not been completed in these pending cases, predicting the ultimate outcome of these actions is not possible, and no provision for any liability has been reflected in the Company's financial statements. The Company believes it has substantial defenses to these claims.

Gross sales of phentermine by the Company for the years 2002, 2001 and 2000 were $32 million, $51 million and $21 million, respectively.

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 the fen-phen, phentermine-only and phentermine-PPA product liability lawsuits. Additionally, the Company has reached agreements under which the Company will 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/indemnity agreements with several retailers, and is negotiating the resolution of several additional claims with other retailers. Fen-phen and phentermine litigation defense costs, and the costs of related defense agreements, are being expensed as incurred.

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, 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, 2002, all but one PPA case against the Company had been dismissed or discontinued. In early 2003, the Company was named in another lawsuit alleging injury from PPA. Discovery in these two lawsuits has yet to begin. The first lawsuit, which was served on the Company in December 2002, has been removed to federal court, and has been identified to the federal Joint Panel on Multidistrict Litigation as a potential "tag-along" case for transfer to the consolidated federal phenylpropanolamine multidistrict litigation ("PPA MDL") pending in the United States District Court for the Western District of Washington. Plaintiff has filed a motion seeking remand of this case to state court in New York, which motion is pending. The second lawsuit was filed in the United States District Court for the District of Maryland and served upon the Company in January 2003. It is likely to be transferred to the PPA MDL. Because these two lawsuits were only recently filed, and discovery in them has yet to begin, predicting the ultimate outcome of these actions is not possible, no provision for any liability has been reflected in the Company's financial statements.

Patent Infringement Litigation

On August 30, 2000, Novartis Pharmaceuticals Corporation filed a complaint in the United States District Court for the District of Delaware alleging among other things that our generic cyclosporine product infringes a patent owned by Novartis. An adverse outcome in patent litigation with Novartis involving cyclosporine capsules could result in the Company being unable to market this product which would materially harm its profits and cash flows and could result in the Company paying damages, cost, expenses, and fees that could have a material adverse impact on its financial performance. Our potential liability and expenses in this matter are not covered by insurance. In December 2002, the United States District Court for the District of Delaware granted the Company's motion for summary judgment of non-infringement of the patent. Novartis has appealed the judgment. The ultimate outcome of this lawsuit cannot be determined at this time.

In January 2001, Apotex, Inc. filed an action in the United States District Court for the Eastern District of New York alleging that by manufacturing, selling and offering to sell cyclosporine capsules the Company is infringing a patent of which Apotex alleges it is the exclusive licensee. Apotex seeks injunctive relief as well as an unspecified amount of damages and has also asserted a claim that the alleged infringement was willful, that the case is therefore exceptional and that Apotex should therefore be awarded the attorney fees it has incurred in the action. The Company's potential liability and expenses in this matter are not covered by insurance. 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 impact on the Company's financial performance.

The Company has denied that it has infringed any valid patent claims asserted by Apotex, has alleged affirmatively, among other things, that the patent is invalid and that it is not infringed by the Company's manufacture, sale or offer to sell its cyclosporine capsules.

In addition, the Company has been named in several other patent infringement actions alleging that the Company has infringed patents by filing an application with the FDA for approval to market products before the plaintiffs' patents expire. In general, plaintiffs seek judgments precluding the FDA from approving the Company's application to market the product before their patent expires and have asserted claims that the alleged infringement was willful, that the action is therefore exceptional and that plaintiffs should therefore be awarded the attorney fees they have incurred in the action.

The Company and its outside counsel believe that the Company has substantial defenses and counterclaims to these above patent infringement actions, though the ultimate outcome cannot be determined.

Because predicting the ultimate outcome of these actions is not possible, no provision for any liability has been reflected in the Company's financial statements.

Other Litigation

The Company is in other litigation incidental to its business activities. The ultimate disposition of such lawsuits will not materially affect the Company's financial statements.

14. Transactions Between the Company and Related Parties

The following is a summary of related party transactions with profit/loss implications:

	2002	2001	2000
Net sales to subsidiaries of Hexal AG	$ 113	$ 365	$ 46
Reimbursement of other expenses		126	
Transfers of products and supplies to subsidiaries of Hexal AG		15	104
Purchase of products and supplies from subsidiaries of Hexal AG	(849)	(617)	(131)
Cyclosporine agreements with Hexal AG(a)	(4,026)	(3,923)	(1,099)
Reimbursements to Hexal AG for shared bioequivalency studies		(140)	(425)
Interest on intercompany loans from Hexal AG	(2,463)	(6,674)	(1,616)
Fees incurred for rights to product development files of Hexal AG	(100)		(225)

(a) Under agreements with Hexal AG, the Company pays Hexal AG based on sales of a specific product, which were developed using Hexal AG's patented technology.

In 2002, 2001 and 2000, HPI was a party to certain research and development contracts with third parties for which Hexal AG loaned $0.7 million, $1.6 million, and $1.3 million, respectively, to HPI for the payment of its obligations. During 2002, the research and development contracts which were unrelated to the Company's business were transferred to an entity, unrelated to the Company.

15. Selling, General and Administrative Expenses

Included in selling, general and administrative expenses were legal defense costs for phentermine litigation of approximately $3.4 million, $6.1 million and $8.1 million (net of insurance reimbursement of $3.75 million) for the years 2002, 2001 and 2000, respectively.

Included in selling, general and administrative expenses for the years ended December 31, 2002, 2001 and 2000 were approximately $6.3 million, $4.9 million and $1.8 million, respectively, of legal costs incurred in connection with patent challenges involving drugs manufactured and sold by other companies.

Allowance for doubtful accounts were $1.0 million in each year presented. In 2002 and 2001, the Company neither made any additional provision nor wrote-off any bad debts. The Company's allowance for doubtful accounts was impacted by additional allowances of $80, and write-off of bad debts of $124 in 2000.

16. Other Supplemental Cash Flow Information

Other supplemental cash flow information is as follows:

	2002
Non-cash financing activities	
Unrealized gain on investments	$ 44

	2002
Non-cash financing activities:	
Conversion of preferred stock	300
Exercise of warrants	17
Issuance of common stock to repay loans and advances to Hexal AG	25,178

In 2000, HPI acquired EHI and allocated the purchase price as follows:

Purchase price:	
Cash	$ 60,000
Seller note, net of discount	43,687
Warrants	4,892
	$ 108,579

The purchase price was allocated to the assets and liabilities acquired, based on their estimated fair values, as follows:

Inventory	$ 2,365
In-process research and development	2,450
Property, plant and equipment	2,615
Value of existing products	37,600
Intangibles workforce	1,450
Goodwill	47,514
Deferred income taxes	(13,577)
Book value of acquired equity	28,162
Purchase price	$ 108,579

17. Unaudited Quarterly Financial Data

2002	First Quarter(1)	Second Quarter	Third Quarter	Fourth Quarter
Net sales	$ 48,198	$ 52,000	$ 75,351	$ 68,720
Gross profit	$ 23,213	$ 28,303	$ 40,270	$ 33,892
Net income	$ 6,346	$ 9,504	$ 14,183	$ 13,230
Earnings per share(1)				
Basic	$	$ 0.51	$ 0.33	$ 0.30
Diluted	$ 0.19	$ 0.25	$ 0.31	$ 0.29
2001				
Net sales	$ 39,096	$ 42,586	$ 42,545	$ 41,216
Gross profit	$ 20,708	$ 26,207	$ 23,655	$ 21,561
Net income	$ 2,680	$ 5,368	$ 3,643	$ 4,100
Earnings per share(1)				
Basic	$	$	$	$
Diluted	$ 0.08	$ 0.17	$ 0.11	$ 0.12

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

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