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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 10-K**

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**ANNUAL REPORT PURSUANT TO SECTION 13 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

Commission File Number 1-09623

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**IVAX CORPORATION**

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Incorporated under the laws of the  
State of Florida

I.R.S. Employer Identification Number  
16-1003559

4400 Biscayne Boulevard, Miami, Florida 33137  
305-575-6000

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**SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT**

Title of each class	Name of each exchange on which registered
Common Stock, Par Value \$.10	American Stock Exchange London Stock Exchange

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§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.

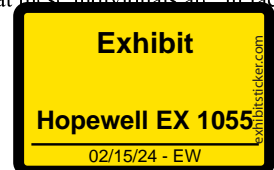
Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

As of February 29, 2004, there were 197,115,277 shares of Common Stock outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2003, was approximately \$2.7 billion, based on the price at which the equity stock was last sold on the American Stock Exchange on such date of \$17.85 per share. Solely for the purpose of this calculation, shares held by directors, executive officers and 10% shareholders of the registrant have been excluded. Such exclusion should not be deemed a determination or an admission by the registrant that these individuals are, in fact, affiliates of the registrant.

**DOCUMENTS INCORPORATED BY REFERENCE:**

<https://www.sec.gov/Archives/edgar/data/772197/000119312504040619/d10k.htm>



Information required by Part III is incorporated by reference to portions of the Registrant's Proxy Statement for the 2004 Annual Meeting of Shareholders which will be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's 2003 year end.

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**for the year ended December 31, 2003**  
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We are a multinational company engaged in the research, development, manufacture and marketing of pharmaceutical products. We were incorporated in Florida in 1993, as successor to a Delaware corporation formed in 1985.

We manufacture and/or market several brand name pharmaceutical products and a wide variety of brand equivalent and over-the-counter pharmaceutical products, primarily in the United States, Europe and Latin America. We also have subsidiaries located throughout the world, some of which are among the leading pharmaceutical companies in their markets. We maintain manufacturing operations in Argentina, Chile, China, the Czech Republic, Germany, Ireland, Italy, Mexico, Puerto Rico, the United Kingdom, the United States, the U.S. Virgin Islands and Venezuela. We conduct our research and development programs in the Czech Republic, Hungary, India, the United Kingdom and the United States. We also have marketing and sales operations in Azerbaijan, Bulgaria, Costa Rica, Croatia, El Salvador, Estonia, Finland, France, Guatemala, Honduras, Hong Kong, Kazakhstan, Latvia, Lithuania, The Netherlands, Nicaragua, Panama, Peru, Poland, Romania, Russia, the Slovak Republic, Sweden, Switzerland, Taiwan, Ukraine, Uruguay and Uzbekistan and market our products through distributors or joint ventures in other foreign markets.

**Growth Strategies**

We expect our future growth to come from:

- discovering and developing and/or acquiring new products;
- developing and marketing selected brand equivalent pharmaceuticals;
- leveraging proprietary technology and development strengths in the respiratory and oncology areas;
- pursuing complementary, accretive or strategic acquisitions; and
- strategically expanding sales and distribution of our proprietary and branded products as well as our brand equivalent pharmaceutical products.

***Discovery and Development and/or Acquisition of New Products***

We expect that new products that we discover, develop and/or acquire will provide a cornerstone for our future growth. In October 1999, we dramatically increased the size and scope of our new product development capability through our acquisition of the Institute for Drug Research (now called IVAX Drug Research Institute), which had approximately 250 employees engaged in drug research and development. We currently have over 800 people involved in our drug research and development programs. In 2003, we spent \$108.3 million for company-sponsored research and development activities compared to \$76.0 million in 2002 and \$88.0 million in 2001.

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Among the proprietary compounds in development that have either entered or that we expect to enter clinical trials in the near future are:

- Xorane™ an oral form of paclitaxel;
- a compound for the treatment of multiple sclerosis and epilepsy;
- a compound for the treatment of inflammation disorders;
- a compound for the treatment of recurrent glioblastoma;
- one or more of the soft steroids that we are developing for asthma, allergic rhinitis, dermatology and gastrointestinal indications both in humans and companion animals;
- a compound for the treatment of benign prostatic hypertrophy; and
- a brain targeted estrogen for the treatment of postmenopausal syndrome, postmenopausal memory disorders and sexual disorders.

Other new compounds in earlier stages of development are being designed to treat cystic fibrosis, HIV infection and neurological disorders.

We believe that our research programs will allow us to develop proprietary and novel compounds and delivery systems.

### ***Developing and Marketing Selected Brand Equivalent Pharmaceuticals***

We develop and market the generic equivalent of brand pharmaceuticals that no longer enjoy patent protection. We seek to develop generic products that have one or more characteristics that we believe will make it difficult for other competitors to develop competing generics. The characteristics of the selected brand equivalent products we pursue may include one or more of the following:

- those requiring specialized manufacturing capabilities;
- those where sourcing the raw material may be difficult;
- those with complex formulation or development characteristics;
- those that must overcome unusual regulatory or legal challenges; or
- those that confront difficult sales and marketing challenges.

We believe that products with some or all of these characteristics may face limited competition and may produce higher profits for a longer period of time than products without these characteristics.

### ***Leverage Proprietary Technology and Development Strengths***

We intend to continue to leverage our proprietary technology and development strengths to develop a portfolio of proprietary pharmaceutical products in the areas of respiratory diseases and oncology. Primary among these strengths are:

- our patented inhalation technology and our expertise in developing and commercializing respiratory products; and
- our experience in the development and commercialization of oncology drugs.

Our technology and capabilities in these areas have also allowed us to pursue new business opportunities in the form of strategic collaborations with pharmaceutical partners desiring to license our technologies and utilize our expertise. In the respiratory area, we were the first company to obtain approvals of our own formulations of certain drugs that did not contain chlorofluorocarbon (CFC).

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### ***Pursue Complementary, Accretive or Strategic Acquisitions***

Acquisitions have in the past helped to build our company, and we expect to use well-timed, carefully selected acquisitions to continue to drive our growth. We intend to pursue primarily acquisitions that will complement our existing businesses and provide new product and market opportunities, as well as leverage our existing assets. In assessing strategic opportunities, we will consider whether we expect the acquisition to:

- be accretive to earnings;
- allow us to leverage our expertise in our areas of therapeutic focus by adding new products or product development capabilities;
- offer geographic expansion opportunities into key strategic markets; and
- allow us to penetrate further our existing markets.

In addition to business acquisitions, we intend to continue to actively pursue strategic product acquisitions and other collaborative arrangements.

### ***Strategically Expand Sales and Distribution of Our Products***

We intend to continue to expand strategically the sales and distribution of our products. We are developing sales capabilities in various European countries to market respiratory products. In 2000, we began marketing proprietary products through our subsidiaries in the United States and in Eastern Europe. In 2003, we purchased 3M's branded respiratory products business, including related marketing and sales people in nine European countries adding over 200 sales professionals to our sales capabilities.

We have completed acquisitions of pharmaceutical companies and facilities in Argentina, Chile, Mexico and Venezuela, which complement our existing operations in Argentina, Peru and Uruguay and continue the expansion of our Latin American operations. Our future plans include the acquisition of additional manufacturing and distribution capabilities in Europe and Latin America.

In Asia, we believe that we can complement the operations of our subsidiaries IVAX Asia Limited, IVAX India PVT Limited and IVAX Pharmaceutical (Beijing) Co. Ltd., and our Kunming Baker Norton joint venture company, by establishing additional joint ventures and selectively establishing distribution channels for our major products.

At the same time, we are attempting to further integrate operations and are continuously seeking to identify and exploit the cross-marketing and distribution opportunities that exist among our various subsidiaries. For example, our Czech Republic subsidiary is a large producer of bulk and final dosage form cyclosporin, a drug used to prevent rejection in organ transplant recipients. Cyclosporin is also used in conjunction with our Xorane™ product.

## **Pharmaceutical Business**

### ***Current Proprietary and Branded Products***

We market a number of proprietary and brand name products treating a variety of conditions through our subsidiaries throughout the world. These products are marketed by our direct sales forces to physicians, pharmacies, hospitals, managed health care organizations and government agencies. These products are sold primarily to wholesalers, retail pharmacies, distributors, hospitals and physicians.

We have substantial expertise in the development, manufacture and marketing of respiratory drugs, primarily for asthma, delivered by metered-dose and dry powder inhalers. Our subsidiary in the

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United Kingdom, Norton Healthcare Limited, trading as IVAX Pharmaceuticals UK, is the third largest respiratory company in that market. At the core of our respiratory franchise are advanced delivery systems, which include a patented breath-activated metered-dose inhaler called Easi-Breathe™ and a patented dry powder inhaler called Airmax™, as well as conventional metered-dose inhalers.

*Easi-Breathe™*. We hold patents on Easi-Breathe™, our breath-activated metered-dose inhaler, which is designed to overcome the difficulty many persons experience with conventional metered-dose inhalers in coordinating inhalation with the emission of the medication. Easi-Breathe™ emits the medication automatically in one step upon inhalation, minimizing coordination problems and ensuring that the medication is delivered to the lungs. We market Easi-Breathe™ through our subsidiaries in France, Ireland, Poland, the United Kingdom, the Czech Republic, the Slovak Republic and Mexico and through distributors in Asia and a distributor in Germany.

We have pioneered the development of aerosol products that do not contain CFC, chemicals believed to be harmful to the environment which are being phased out on a global basis. In November 1997, we received the world's first approval for a CFC-free beclomethasone in Ireland.

In October 2001, we acquired from Elan Corporation the United States rights to the intranasal steroid brand products, Nasarel® and Nasalide®, for the treatment of allergic rhinitis. In March 2002, we also acquired from the Roche Group the same intranasal steroid products, which are marketed under a number of trademarks in Belgium, Canada, the Czech Republic, France, Ireland, The Netherlands, Norway and the United Kingdom.

In April 2002, we entered into an exclusive United States agreement with Minnesota Mining and Manufacturing Company, also known as 3M, related to the QVAR® brand (beclomethasone dipropionate) inhalation aerosol, an inhaled corticosteroid prescribed to treat chronic asthma. QVAR® is a novel metered-dose inhaler that delivers asthma medicine via a non-ozone depleting hydrofluoroalkane (HFA) aerosol rather than conventional CFC propellant. Under the terms of the agreement, we have obtained exclusive United States rights to the QVAR® product as well as a non-exclusive worldwide license to certain 3M patents covering HFA formulations of various asthma drugs. In addition, in 2007, we can exercise an option to obtain ownership of the United States QVAR® trademark, as well as related patents and the New Drug Application, also known as an NDA. QVAR® is currently a registered trademark of 3M through its subsidiary, Riker Laboratories, Inc. 3M manufactures the QVAR® product for us under a long-term contract.

In October 2003, we purchased 3M's branded respiratory products business, including related marketing and sales people in nine European countries. This purchase covers QVAR®, Airomir® in Autohaler® and standard metered dose inhalers, and over 200 professionals to market and sell these products.

### ***New Proprietary and Branded Products Under Development***

We are committed to the cost-effective development of proprietary pharmaceuticals directed primarily towards indications having relatively large patient populations or for which limited or inadequate treatments are available. We seek to accelerate product development and commercialization by in-licensing compounds, especially after clinical testing has begun, and by developing new dosage forms of existing products or new therapeutic indications for existing products. We intend to emphasize the development of drug products in the oncology and respiratory fields and have a variety of proprietary pharmaceuticals in varying stages of development.

*Inhalation Products*. In light of international agreements calling for the eventual phase-out of CFC, we are developing CFC-free inhalation aerosol products, including CFC-free beclomethasone and albuterol, using HFA propellants and dry powder formulations. Beclomethasone and albuterol are two of the most widely prescribed products for asthma.

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We received regulatory approval to market CFC-free beclomethasone in Ireland and France in 1997 in our standard metered-dose inhaler and our Easi-Breathe™ inhaler, the first such approvals for any company anywhere in the world. We received regulatory approval to market CFC-free beclomethasone in our standard metered-dose inhaler in Belgium, Italy, Finland and Portugal in 1999 and in Japan, Germany and Spain in 2000. We received approval in December 2001 through the mutual recognition procedure to market CFC-free beclomethasone in our Easi-Breathe™ inhaler in Belgium, Luxembourg, Spain and Portugal.

In 1998, we also applied for approval to market an albuterol CFC-free formulation in the United Kingdom in our standard metered-dose inhaler and our Easi-Breathe™ inhaler and in April 2000, these products were approved. In October 2001, these approvals were used as the basis for obtaining approvals of these two products in other European countries, including Belgium, Denmark, Germany, Luxembourg, Norway and Spain under the mutual recognition procedure. We also received approval for CFC-free albuterol in our Easi-Breathe™ inhaler in Holland under the same procedure. In the United States, Phase III clinical trials to support marketing approval of an albuterol CFC-free formulation in our standard metered-dose inhaler have been completed and an NDA was submitted for this product (Volare™) in January 2003. At the end of 2003, we received notice from the FDA that this NDA is approvable.

We have also developed a multi-dose dry powder inhaler, which uses no propellant and is believed to have superior dosing accuracy than competing models. In 2001, we received regulatory approval to market formoterol in our multi-dose dry powder inhaler in Denmark and in 2003 we received regulatory approval to market albuterol in our multi-dose dry powder inhaler in the United Kingdom. In November 2003, we also commenced Phase I clinical studies in the United States with etiprednol dicloacetate, an inhaled corticosteroid, in our multi-dose dry powder inhaler.

We are continuing to develop the Easi-Breathe™ inhaler for use with various compounds. During 2003, we completed Phase III clinical trials for Volare™ in Easi-Breathe™ and an NDA was submitted for this product in August 2003. In addition, Phase III clinical trials for QVAR® in Easi-Breathe™ are scheduled to begin in 2004.

In developing CFC-free formulations for metered-dose inhalers, we and many of our competitors have obtained or licensed patents on formulations containing alternative propellants. There are many existing patents covering the use of HFA with pharmaceuticals, and successful product development by us may require that we incur substantial expense in seeking to develop formulations that do not infringe competitors' patents, or that we license or invalidate such patents. We successfully invalidated certain relevant United Kingdom and European patents in the United Kingdom during 1997, 1998 and 1999. In our license agreement with 3M, we have also obtained access to several of 3M's patented HFA based formulations.

*Xorane*™. Presently, paclitaxel, which is one of the leading anti-cancer drugs in the world, is marketed only in injectable form. We are currently marketing paclitaxel injection in the United States under the name Onxol™ and in other countries under the name Paxene®. We are developing an oral formulation of paclitaxel that we believe may provide significant advantages over the injectable dosage form in terms of patient convenience and reduced side effects. We believe that our patented new system will allow patients to obtain effective doses of paclitaxel through oral administration and that this patented system can be applied to other chemotherapeutic agents that are not currently orally available. We have completed Phase II clinical trials with patients with recurrent breast cancer, advanced lung cancer, and advanced stomach cancer and the results showed substantial anti-cancer activity.



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*Cervene™*. In pre-clinical trials of our epidermal growth factor (EGF) receptor-targeted brain cancer therapy, our lead compound, Cervene™, was found to be highly specific and toxic to brain cancer cells. This compound is currently in a Phase II multi-center clinical trial in patients with recurrent glioblastoma.

*Talampanel*. In February 2001, we acquired the rights to develop and market the AMPA receptor antagonist, talampanel, from Eli Lilly & Co. Talampanel was initially discovered at the IVAX Drug Research Institute in Budapest, Hungary. In Phase II studies conducted by Eli Lilly, talampanel was shown to reduce the incidence of seizures in patients with epilepsy, and we have commenced additional Phase II clinical trials in epilepsy patients, involving 25 centers in the United States and Europe. The drug for epilepsy will be marketed under the brand name Ampanel™. In July 2003, we commenced Phase II clinical trials with patients with recurrent glioblastoma and we are planning to commence in 2004 Phase II clinical trials with patients with newly diagnosed glioblastoma. We are also planning to continue Phase II clinical trials with talampanel using patients with Parkinson's disease and planning additional studies using this compound to treat multiple sclerosis and other neurological diseases.

*Estredox™*. In March 2002, we completed a pilot Phase II study in postmenopausal women of our brain targeted estrogen, Estredox™. In this study, luteinizing hormone (LH) levels, normally elevated in postmenopausal women, were suppressed following administration of Estredox™ and plasma levels of estradiol were below normal premenopausal levels. Lower plasma levels should reduce the risks associated with hormone replacement therapy. Early in 2004, we initiated a clinical trial to determine the appropriate dose for the treatment of postmenopausal hot flashes.

*Asthma and Inflammatory Diseases*. In December 1999, we acquired Soft Drugs, Inc., a private company with a significant patent portfolio. This acquisition entered us into a new field of technology and provides us with several new chemical entities to add to our pipeline of proprietary drugs. These chemical entities include a corticosteroid that is rapidly converted to an inactive form after absorption, which reduces the likelihood of side effects normally associated with these types of drugs. Initial applications are expected to treat asthma (as an inhaled product under the mark Respicort™ for BNP-166), allergic rhinitis (under the mark Ethinase™ for BNP-166) and inflammatory diseases of the large intestine (in a special oral formulation under the mark Cronaze™ for BNP-166). One of our soft steroid compounds, BNP-166, has successfully completed Phase Ia and Ib clinical trials for safety for oral administration. After successfully completing regulatory inhalation toxicology, we have started Phase I clinical studies with BNP-166 in the United States towards the development of the compound to treat allergic rhinitis. In November 2003, we initiated Phase I clinical trials with BNP-166 for the indication of bronchial asthma. In August 2003, we acquired the worldwide rights, exclusive of Japan and certain Asian countries, for loteprednol etabonate for allergic rhinitis. In 2003, we completed a Phase II study with loteprednol etabonate for allergic rhinitis. We plan to begin Phase III clinical trials in 2004.

### ***Brand Equivalent Pharmaceutical Products***

Another important part of our pharmaceutical business is the broad line of brand equivalent pharmaceutical products, both prescription and over-the-counter, that our various subsidiaries market as brand equivalent substitutes or under a brand name. Brand equivalent drugs are therapeutically equivalent to their brand name counterparts, but are generally sold at lower prices and as alternatives to the brand name products. In order to remain successful in the brand equivalent pharmaceutical business, we are working to develop new formulations and to obtain marketing authorizations which will enable us to be the first or among the first to launch brand equivalent pharmaceutical products on the market.

In the United States, our subsidiary, IVAX Pharmaceuticals, Inc., manufactures and markets approximately 63 brand equivalent prescription drugs in capsule or tablet forms in an aggregate of approximately 143 dosage strengths. We also distribute in the United States approximately 164 additional brand equivalent prescription and over-the-counter drugs and vitamin supplements, in various dosage forms, dosage strengths and package sizes. Our domestic brand equivalent drug distribution

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network encompasses most trade classes of the pharmaceutical market, including wholesalers, retail drug chains, retail pharmacies, mail order companies, managed care organizations, hospital groups, nursing home providers and government agencies.

In the United Kingdom, we are a leading provider of brand equivalent pharmaceutical products. We market approximately 312 brand equivalent prescription drugs, about half of which we manufacture, in various dosage forms and dosage strengths, constituting an aggregate of approximately 140 molecules. We market such products to wholesalers, retail pharmacies, hospitals, physicians and government agencies. In addition, we manufacture and market various “blow-fill-seal” pharmaceutical products, such as solutions for injection or irrigation, and unit-dose vials for nebulization to treat respiratory disorders.

Brand equivalent products (but not including branded generic products) represented 62% of our revenues in 2003, 56% in 2002 and 57% in 2001.

### ***New Brand Equivalent Products Under Development***

We develop and market the generic equivalent of brand pharmaceuticals that no longer enjoy patent protection. We seek to develop generic products that have one or more characteristics that we believe will make it difficult for other competitors to develop competing generics. The characteristics of the selected brand equivalent products we pursue may include one or more of the following:

- those requiring specialized manufacturing capabilities;
- those where sourcing the raw material may be difficult;
- those with complex formulation or development characteristics;
- those that must overcome unusual regulatory or legal challenges; or
- those that confront difficult sales and marketing challenges.

By emphasizing the development of selected brand equivalent pharmaceutical products, we seek to introduce brand equivalent products that may face limited competition and may produce higher profits for a longer period of time than products without these characteristics. In addition, in evaluating which brand equivalent pharmaceutical product development projects to undertake, we consider whether the new product, once developed, will complement our other products in the same therapeutic family, or will otherwise assist in making our product line more complete. Developing selected brand equivalent pharmaceutical products generally involves more time and resources than developing common brand equivalent pharmaceutical products.

During 2003, we received final United States Food and Drug Administration (FDA) approval of 8 Abbreviated New Drug Applications (ANDAs) for 8 molecules, tentative FDA approval of 4 ANDAs for 4 molecules, approval of 2 ANDAs (the Canadian equivalent of an ANDA) for 2 molecules in Canada, 3 ANDAs for 3 molecules were transferred to us from Schein Pharmaceuticals in Canada, approval of 17 Abridged Marketing Authorization Applications or AMAAs (the European equivalent of an ANDA) for 3 molecules in the United Kingdom, and approval of 31 AMAAs for 7 molecules in the other European Union (EU) countries.

As of January 1, 2004, we had ANDAs or its foreign equivalent pending as follows:

<b>Number Pending</b>	<b>Country</b>
38 (34 molecules)	United States
44 (16 molecules)	United Kingdom
23 (9 molecules)	Other EU Countries

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### *Acquisitions*

The acquisition of strategic and complementary businesses has been a significant component of the expansion of our pharmaceutical business. Some of our recent acquisitions are described below.

*ChemSource Corporation.* In January 2003, we acquired ChemSource, which is based in Puerto Rico. We subsequently changed its name to API Industries, Inc. API Industries develops, manufactures and sells active pharmaceutical ingredients for various pharmaceutical products, including many products which we currently sell or have under development.

*Merck Sharp & Dohme France.* In December 2002, we completed the acquisition of substantially all of the products comprising the generic pharmaceutical business of Merck & Co, Inc.'s Merck Sharp & Dohme subsidiary in France.

*Laboratorio Chile S.A.* Through two tender offers, the first of which commenced on May 31, 2001, we acquired 99.9% of the outstanding shares of Laboratorio Chile S.A. Laboratorio Chile was at the time of purchase and remains the largest Chilean pharmaceutical company in terms of revenue. Through its Argentine subsidiary, Laboratorio Chile was among the major pharmaceutical companies in Argentina. Laboratorio Chile manufactures, markets and sells a broad line of more than 700 branded and brand equivalent products in Chile, Argentina and Peru. Its main products are to treat respiratory and infectious diseases, but it also has strong franchises with cardiovascular, neurological and gynecological products.

*Indiana Protein Technologies, Inc.* In 1999, we acquired 30% of Indiana Protein Technologies, Inc. On April 2, 2001, we acquired the remaining 70% of Indiana Protein Technologies, Inc. that we did not already own. Indiana Protein Technologies specializes in using recombinant technology to develop peptide-based pharmaceutical products. Indiana Protein Technologies had been working with us to develop a number of brand equivalent pharmaceutical products pursuant to a development agreement.

*Laboratorios Fustery, S.A. de C.V.* In February 2001, we acquired Laboratorios Fustery, S.A. de C.V., which is based in Mexico City, Mexico. We subsequently changed its name to IVAX Pharmaceuticals Mexico, S.A. de C.V. IVAX Pharmaceuticals Mexico manufactures, markets and distributes a broad range of prescription pharmaceutical products and is a leading manufacturer of antibiotics and injectable products in Mexico. IVAX Pharmaceuticals Mexico's therapeutic areas of primary emphasis are antibiotics, anti-inflammatories, analgesics, hormone replacement therapy and gastrointestinal products. IVAX Pharmaceuticals Mexico employs approximately 200 medical representatives who promote IVAX Pharmaceuticals Mexico's products.

*Wakefield Pharmaceuticals, Inc.* In September 2000, we acquired Wakefield Pharmaceuticals, Inc., which was merged into IVAX Laboratories, Inc. on October 17, 2001.

*Laboratorios Elmor, S.A.* In June 2000, we acquired Laboratorios Elmor, S.A., which is based in Caracas, Venezuela. Elmor manufactures, markets and distributes a broad range of pharmaceutical products in Venezuela. At the time of purchase, Elmor was the largest Venezuelan pharmaceutical company in terms of units sold, and one of the fastest growing pharmaceutical companies in Venezuela.

*Institute for Drug Research.* In October 1999, we acquired the Institute for Drug Research, which is based in Budapest, Hungary. We subsequently changed its name to IVAX Drug Research Institute, Ltd. IVAX Drug Research Institute employs approximately 250 scientists and support staff and engages in original drug discovery and provides contract research services to other pharmaceutical companies. It was originally founded in 1950 as a government-owned pharmaceutical research and development center for the Hungarian pharmaceutical industry. Through our acquisition of IVAX Drug Research Institute,

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we obtained a research capability that includes drug discovery, screening, synthesis and pre-clinical development. Additionally, IVAX Drug Research Institute has a depository of more than 1,500 microorganisms to produce chemicals of medicinal value through fermentation. As part of the acquisition of the Institute for Drug Research, we also acquired rights to several important compounds, including a patented drug for the treatment of benign prostatic hypertrophy, which successfully completed a Phase II clinical trial. IVAX Drug Research Institute also has a number of other new drug candidates that are in preclinical development, including compounds to prevent metastasis, several peptide analogs with dual anti-thrombin activity and others to treat disseminated intravascular coagulation (DIC) and sepsis.

*Galena, a.s.* In 1994, we acquired a 60% interest in Galena, a.s., one of the oldest pharmaceutical companies based in the Czech Republic. We changed its name to IVAX-CR a.s. Through open market purchases made in 1995, 1996, 1999 and 2000, and public tender offers made in 1999 and 2000, we increased our ownership interest in the company to 98%. On December 31, 2002, IVAX-CR a.s. was converted to IVAX Pharmaceuticals s.r.o., a limited liability company, and we increased our ownership in this company to 100%. IVAX Pharmaceuticals s.r.o. develops, manufactures and markets a variety of human pharmaceutical and veterinary products, as well as active ingredients and herbal extracts used in the manufacture of pharmaceuticals, including cyclosporin and ergot alkaloids, in the Czech Republic. IVAX Pharmaceuticals s.r.o. sells its products primarily in Central and Eastern European countries, including Russia.

### ***Collaborative Agreements***

We also seek to enter into collaborative alliances which allow us to exploit our drug discovery and development capabilities or provide us with valuable intellectual property and technologies. Some of these collaborative alliances are described below.

*Mayne Group Limited.* In February 2004, we entered into an agreement with Mayne Group Limited for the marketing and distribution of our injectable paclitaxel product, Paxene<sup>®</sup>, in the European nations of Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Sweden, the United Kingdom and Norway.

*EIS Eczacibasi Ilac Sanayi ve Ticaret A.S.* In May 2003, we entered into an exclusive marketing authorization and supply agreement with EIS Eczacibasi Ilac Sanayi ve Ticaret A.S. for 21 generic products in 15 Central and Eastern European countries.

*Laboratory of Molecular Biology of the National Cancer Institute.* In January 2003, we entered into a collaboration agreement with the Laboratory of Molecular Biology of the National Cancer Institute to develop a recombinant immunotoxin designed to treat HIV infection by selectively destroying HIV infected cells.

*Serono, S.A.* In October 2002, we entered into an exclusive worldwide product development and license agreement with Ares Trading, S.A., an affiliate of Serono, S.A., for the development and commercialization of an oral formulation of IVAX' Cladribine for the treatment of multiple sclerosis. Cladribine is an immunosuppressive agent that has demonstrated encouraging results in Phase II studies.

### ***Licensing***

We have obtained licenses to technology and compounds for the development of new pharmaceutical products from various inventors, universities and the United States government. For example, we are working with compounds licensed from The National Institutes of Health to develop a potential new treatment for brain cancer. We will continue to seek new licenses from third parties, including pharmaceutical companies.

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We also grant licenses to other pharmaceutical companies relating to technologies or compounds under development and, in some cases, finished products.

### **Other Business**

#### ***Diagnostics***

In March 2001, our diagnostics group merged with b2bstores.com forming IVAX Diagnostics, Inc., a publicly traded company which trades on the American Stock Exchange under the symbol IVD and is listed on the Boston Stock Exchange. We own approximately 72% of the equity of IVAX Diagnostics, Inc.

IVAX Diagnostics, Inc. develops, manufactures and markets diagnostic test kits or assays that are used to aid in the detection of disease markers primarily in the area of autoimmune and infectious diseases. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Most of IVAX Diagnostics' tests are based on Enzyme Linked ImmunoSorbent Assay (ELISA) technology, a clinical technology used worldwide. In addition to an extensive line of diagnostic kits, IVAX Diagnostics also designs and manufactures laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. IVAX Diagnostics markets these products to clinical reference laboratories, hospital laboratories, research institutions and other commercial entities in the United States and in Italy through their direct sales force and through independent distributors in various other foreign markets. IVAX Diagnostics also serves as the distribution center for selling these same products to customers located in other European and international markets outside Italy. Some of these sales, such as in Spain and Portugal, are made through distributors while others are made on a direct basis. The sales made on a direct basis occur primarily in the United Kingdom, France and Germany. These sales are supported by IVAX Diagnostics' employees or sales agents based in England, France and Italy.

### **Patents and Proprietary Rights**

We believe that patents and other proprietary rights are important to our business. Our policy is to file patent applications to protect our products, technologies, inventions and improvements that we consider important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We hold approximately 1,026 United States and foreign patents and have filed several hundred United States and foreign patent applications. In addition, we have exclusively licensed several additional United States and foreign patents and patent applications. Our success depends, in part, on our ability to obtain and enforce United States and foreign patent protection for our products, to preserve our trade secrets and proprietary rights and to operate without infringing on the proprietary rights of third parties or having third parties circumvent our rights. Because of the length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the pharmaceutical industry has traditionally placed considerable importance on obtaining patent and trade secret protection for significant new technologies, products and processes.

### **Government Regulation**

Our pharmaceutical and diagnostic operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical and diagnostic products. We devote significant time, effort and expense to addressing the extensive government regulations applicable to our business. In general, the trend is towards more stringent regulation.

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In the United States, the FDA requires extensive testing of new pharmaceutical products to demonstrate that such products are both safe and effective in treating the indications for which FDA approval is sought. Testing in humans may not be commenced until after the FDA grants an Investigational New Drug exemption. An NDA must be submitted to the FDA for new drugs that have not been previously approved by the FDA and for new combinations of, and new indications and new delivery methods for, previously approved drugs. Three phases of clinical trials must be successfully completed before an NDA is approved. Phase I clinical trials involve the administration of the drug to a small number of healthy subjects to determine safety, tolerance, absorption and metabolism characteristics. Phase II clinical trials involve the administration of the drug to a limited number of patients for a specific disease to determine dose response, efficacy and safety. Phase III clinical trials involve the study of the drug to gain confirmatory evidence of efficacy and safety from a wide base of investigators and patients. In the case of a drug that has been previously approved by the FDA, an abbreviated approval process is available for its brand equivalent. For such drugs an ANDA may be submitted to the FDA for approval. For an ANDA to be approved, among other requirements, the drug must be shown to be bioequivalent to the previously approved drug or must be granted a waiver by the FDA of such requirement. The NDA and ANDA development and approval processes generally take a number of years and involve the expenditure of substantial resources. Even so, the time and resources devoted to seeking regulatory approval for new products will not necessarily result in product approvals or earnings.

The NDA applicant, owner of a new drug, is required to list with the FDA all patents which cover the approved drug and its approved uses. A company filing an ANDA and seeking approval to market a product before expiration of all listed patents must certify that such patents are invalid or will not be infringed by the manufacture, use or sale of the applicant's product, and must notify the patent owner and the owner of the approved drug of its filing. If the approved drug owner sues the ANDA filer for patent infringement within 45 days after it receives such notice, then the FDA will not grant final approval of the ANDA until the earlier of 30 months from the date the approved drug owner receives such notice or the date when a court determines that the applicable patents are either invalid or would not be infringed by the applicant's product. As a result, brand equivalent drug manufacturers, including us, are often involved in lengthy, expensive patent litigation against brand name drug companies that have considerably greater resources and that are typically inclined to actively pursue patent litigation in an effort to protect their franchises.

On an ongoing basis, the FDA reviews the safety and efficacy of marketed pharmaceutical products and products considered medical devices and monitors labeling, advertising and other matters related to the promotion of such products. The FDA may cause a recall or withdraw product approvals if regulatory standards are not maintained or if safety or efficacy concerns arise with respect to such products. The FDA also regulates the facilities and procedures used to manufacture pharmaceutical and diagnostic products in the United States or for sale in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with "good manufacturing practices" established by the FDA. Compliance with good manufacturing practices regulations requires the dedication of substantial resources and requires significant costs. The FDA periodically inspects our manufacturing facilities and procedures to assure compliance. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations. In addition, in connection with its review of our applications for new products, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and procedures comply with good manufacturing practices and other FDA regulations. Among

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other things, the FDA may withhold approval of NDAs, ANDAs or other product applications of a facility if deficiencies are found at that facility. Vendors that supply us with finished products or components that we use to manufacture, package or label products are subject to similar regulation and periodic inspections.

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 is generally issued at the conclusion of an FDA inspection and lists conditions the FDA investigators believe may violate good manufacturing practices or other FDA regulations. Failure to comply with FDA or other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, ANDAs or other product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances the FDA also has the authority to revoke previously granted drug approvals.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the severely high level of regulatory oversight result in a continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical and device manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

In connection with our activities outside the United States, we are also subject to regulatory requirements governing the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical and diagnostic products, which requirements vary from country to country. Whether or

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not FDA approval has been obtained for a product, approval of the product by comparable regulatory authorities of foreign countries must be obtained prior to marketing the product in those countries. The approval process may be more or less rigorous from country to country, and the time required for approval may be longer or shorter than that required in the United States. No assurance can be given that clinical studies conducted outside of any country will be accepted by such country, and the approval of any pharmaceutical or diagnostic product in one country does not assure that such product will be approved in another country.

The federal and state governments in the United States, as well as many foreign governments, including the United Kingdom, from time to time explore ways to reduce medical care costs through health care reform. These efforts have resulted in, among other things, government policies that encourage the use of brand equivalent drugs rather than brand name drugs to reduce drug reimbursement costs. Virtually every state in the United States has a brand equivalent substitution law which permits the dispensing pharmacist to substitute a brand equivalent drug for the prescribed brand name product. The debate to reform the United States' health care system is expected to be protracted and intense. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical or diagnostic industries or on our business or operating results.

### **Competition**

The pharmaceutical market is highly competitive and includes many established companies. Some of our major competitors are:

- Astra Zeneca
- Aventis Pharmaceuticals
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Forest Laboratories
- Geneva Pharmaceuticals
- GlaxoSmithKline
- Eli Lilly
- Mylan Pharmaceuticals
- Novartis Pharmaceuticals
- Pfizer Inc.
- Schering-Plough
- Teva Pharmaceuticals
- Watson Pharmaceuticals

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

- significantly greater financial resources;
- larger research and development and marketing staffs;
- larger production facilities; or
- extensive experience in preclinical testing and human clinical trials.

The pharmaceutical market is undergoing, and is expected to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. We intend to compete in the pharmaceutical market by developing or licensing pharmaceutical products that are either patented or proprietary and which are primarily for indications having relatively large patient populations or for which limited or inadequate treatments are available, and, with respect to brand equivalent pharmaceuticals, by developing therapeutic equivalents to previously patented products which we expect to have less intensive competition. Developments by others could make our pharmaceutical products or technologies obsolete or uncompetitive.



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In addition to product development, other competitive factors in the pharmaceutical industry include product quality, price, customer service, and reputation. Price is a key competitive factor in the brand equivalent pharmaceutical business. To compete effectively on the basis of price and remain profitable, a brand equivalent drug manufacturer must manufacture its products in a cost-effective manner.

Revenues and gross profit derived from brand equivalent pharmaceutical products tend to follow a pattern based on regulatory and competitive factors unique to the brand equivalent pharmaceutical industry. As patents for brand name products and related exclusivity periods mandated by regulatory authorities expire, the first brand equivalent manufacturer to apply for regulatory approval for generic equivalents of such products may be entitled to a 180-day period of marketing exclusivity under the Hatch-Waxman Act. During this exclusivity period, the FDA cannot approve any other generic equivalent. If we are not the first brand equivalent applicant, our brand equivalent product will be kept off the market during the 180-day exclusivity period for the first brand equivalent commercial launch of the product. The first brand equivalent product on the market is usually able to achieve relatively high revenues and gross profit. As other brand equivalent manufacturers receive regulatory approvals and enter the market, prices typically decline, and in some cases dramatically. Accordingly, the level of revenues and gross profit attributable to brand equivalent products that we develop and manufacture is dependent, in part, on:

- our ability to maintain a pipeline of products in development;
- our ability to develop and rapidly introduce new products;
- the timing of regulatory approval of such products;
- the number and timing of regulatory approvals of competing products;
- our ability to manufacture such products efficiently; and
- our ability to market such products effectively.

Because of the regulatory and competitive factors discussed above, our revenues and results of operations historically have fluctuated from period to period. We expect this fluctuation to continue as long as a significant part of our revenues are generated from sales of brand equivalent pharmaceuticals.

In addition to competition from other brand equivalent drug manufacturers, we face competition from brand name companies as they increasingly sell their products into the brand equivalent market directly by establishing, acquiring or forming licensing or business arrangements with brand equivalent pharmaceutical companies. No regulatory approvals are required for a brand name manufacturer to sell directly or through a third party to the brand equivalent market, nor do such manufacturers face any other significant barriers to entry into such market.

In addition, many large drug companies are increasingly pursuing strategies to prevent or delay the introduction of brand equivalent competition. These strategies include:

- seeking to establish regulatory obstacles to the ability of brand equivalent product manufacturers to demonstrate that there is no significant difference in the rate and extent to which the active ingredient in the brand equivalent product becomes available at the site of drug action as compared to the brand name counterpart;
- instituting legal actions based on process or other patents that allegedly are infringed by the brand equivalent products that automatically delay approval of brand equivalent products because the approval of the brand equivalent product requires certifications that the brand name drug's patents are invalid or would not be infringed by the brand equivalent;

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- obtaining approvals of patented drugs for a rare disease or condition and, as a result, obtaining seven years of exclusivity for that indication;
- obtaining extensions of patent exclusivity by conducting additional clinical trials of brand name drugs using children;
- persuading the FDA to withdraw the approvals of brand name drugs, the patents for which are about to expire, so that the brand name company can substitute a new patented product; and
- instituting legislative efforts in various states to limit the substitution of brand equivalent versions of certain types of branded pharmaceuticals.

Additionally, in the United States, some companies have lobbied Congress for amendments to the Hatch-Waxman legislation which could give them additional advantages over brand equivalent competitors such as us. For example, although the life of a drug company's drug patent is extended for a period equal to the time that it takes the FDA to approve the drug, some companies have proposed eliminating the maximum five-year period for those patent extensions and extending the patent life by a full year for each year spent in clinical trials, rather than the one-half year that is currently allowed. If proposals like these become effective, our entry into the United States market and our ability to generate revenues associated with these brand equivalent products will be delayed.

Under the Federal Food, Drug, and Cosmetic Act, an additional six months of market exclusivity in the United States may be added for indications of new or currently marketed drugs, if the FDA requests and the applicant completes agreed upon pediatric studies. Brand name companies are utilizing this provision to increase their period of market exclusivity.

A significant amount of our United States brand equivalent pharmaceutical sales are made to a relatively small number of drug wholesalers and retail drug chains, which represent an essential part of the distribution chain of brand equivalent pharmaceutical products in the United States. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation, which has resulted in our customers gaining more purchasing leverage and consequently increasing the pricing pressures facing our United States brand equivalent pharmaceutical business. Further consolidation among our customers may result in even greater pricing pressures and correspondingly reduce our market share, volumes and the gross margins of this business.

Other competitive factors affecting our 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 seek price discounts on pharmaceutical products, and the reimbursement policies of third party payors, such as insurance companies, Medicare and Medicaid. As the influence of these entities continues to grow, we may continue to face increased pricing pressure on the products we market.

### **Backlog Orders**

As of January 30, 2004, the dollar amount of backlog orders for IVAX Pharmaceuticals was \$9.5 million compared to \$36.5 million as of January 30, 2003, and as of January 30, 2004, for IVAX Pharmaceuticals UK it was \$1.1 million compared to \$1.1 million as of January 30, 2003. We expect to fill all of our backlog orders during our current fiscal year.

### **Raw Materials**

Raw materials needed for our business are generally readily available from multiple sources. Certain raw materials and components used in the manufacture of our products are, however, available from limited sources, and in some cases, a single source. Additionally, in many cases we have listed only one supplier in applications with the FDA. A problem with the availability of such approved raw materials

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could cause production or other delays, and, in the case of products for which only one approved raw material supplier exists, could result in a material loss of sales, with consequent adverse effects on our business. In addition, because raw material sources for pharmaceutical products must generally be approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales and customers. We obtain a significant portion of our raw materials from foreign suppliers, and our arrangements with such suppliers are subject to FDA, customs and other government clearances, duties and regulation by the countries of origin.

### **Returns**

Based on industry practice in the United States, brand equivalent manufacturers, including us, have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, the manufacturers give customers credits on the manufacturer's brand equivalent products which the customers hold in inventory after decreases in the market prices of the brand equivalent products. Like our competitors, we also give credits for charge-backs to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers.

### **Seasonality**

While certain of our individual products may have a degree of seasonality, there are no significant seasonal aspects to our business, except that sales of pharmaceutical products indicated for colds and flu symptoms are higher during the fourth quarter as customers supplement inventories in anticipation of the cold and flu season. In addition, revenues that are contingent upon licensees achieving certain sales targets during the year tend to be higher in the second half of the year.

### **Environmental Matters**

We are engaged in a continuing program to comply with federal, state and local environmental laws and regulations. While it is impossible to accurately predict the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not presently expected to have, a material adverse effect on our earnings or competitive position. See "Item 3. Legal Proceedings" for a description of an environmental proceeding involving one of our subsidiaries.

### **Employees**

As of December 31, 2003, we had approximately 8,719 employees worldwide.

### **Available Information**

Our Internet website is: [www.ivax.com](http://www.ivax.com). We make available, free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such documents are electronically filed with or furnished to the Securities and Exchange Commission. Information contained in our website is not part of this report.

### **Risk Factors**

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

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### *Risks Relating to Our Company*

#### **We depend on our development, manufacture and marketing of new products for our future success.**

Our future success is largely dependent upon our ability to develop, manufacture and market commercially successful new pharmaceutical products and brand equivalent versions of pharmaceutical products that are no longer subject to patents. Generally, the commercial marketing of pharmaceutical products depends upon:

- continually developing and testing products;
- proving that new products are safe and effective in clinical trials;
- proving that there is no significant difference in the rate and extent to which the active ingredient in the brand equivalent product becomes available at the site of drug action as compared to the brand name version; and
- receiving requisite regulatory approval for all new products.

Delays in the development, manufacture and marketing of new products will impact our results of operations. Each of the steps in the development, manufacture and marketing of our products, as well as the process taken as a whole, involves significant periods of time and expense. We cannot be sure that:

- any of our products presently under development, if and when fully developed and tested, will perform as we expect;
- we will obtain necessary regulatory approvals in a timely manner, if at all; or
- we can successfully and profitably produce and market any of our products.

#### **Future inability to obtain components and raw materials or products could seriously affect our operations.**

Some components and materials used in our manufactured products, and some products sold by us, are currently available only from one or a limited number of domestic or foreign suppliers. Additionally, in many cases we have listed only one supplier in our applications with the FDA and foreign governmental authorities. This includes products that have historically accounted for a significant portion of our revenues, including paclitaxel. In the event an existing supplier becomes unavailable or loses its regulatory status as an approved source, we will attempt to locate a qualified alternative; however, we may be unable to obtain the required components, raw materials, or products on a timely basis or at commercially reasonable prices. In addition, from time to time, certain of our outside suppliers have experienced regulatory or supply-related difficulties that have adversely impacted their ability to deliver products to us, causing supply delays or interruptions of supply. To the extent such difficulties cannot be resolved within a reasonable time, and at a reasonable cost, or we are required to qualify a new supplier, our revenues, profit margins and market share for the affected product could decrease, as well as delay our development and sales and marketing efforts.

Our arrangements with foreign suppliers are subject to certain additional risks, including the availability of government clearances, export duties, political instability, currency fluctuations and restrictions on the transfer of funds. Arrangements with international raw material suppliers are subject to, among other things, FDA regulation, various import duties and required government clearances. Acts of governments outside the United States may affect the price or availability of raw materials needed for the development or manufacture of our products. In addition, recent changes in patent laws in jurisdictions outside the United States may make it increasingly difficult to obtain raw materials for research and development prior to the expirations of the applicable United States or foreign patents.

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**A relatively small group of products and customers may represent a significant portion of our net revenues or net earnings from time to time. If the volume or pricing of any of these products declines or we lose customers, it could have a material adverse effect on our business, financial condition and results of operations.**

Sales of a limited number of our products often represent a significant portion of our net revenues or net earnings. This has been particularly relevant when a product has enjoyed a period of generic marketing exclusivity under the Hatch-Waxman Act as the first ANDA to be filed containing a paragraph iv certification for the listed patent. If the volume or pricing of our largest selling products declines in the future, our business, financial condition and results of operations could be materially adversely affected.

A significant portion of our net revenues are derived from sales to a limited number of foreign and domestic customers. Any significant reduction or loss of business with one or several of these customers could have a material adverse effect on our business, financial condition and results of operations.

**We depend on our patents and proprietary rights and cannot be certain of their confidentiality and protection.**

Our success with our proprietary products depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to adequately protect our intellectual property, competitors may manufacture and market products similar to ours. We have numerous patents covering our technologies. We have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the United States. The United States Patent and Trademark Office does not publish patent applications or make information about pending applications available to the public until it issues the patent. Since publication of discoveries in the scientific or patent literature tends to follow actual discovery by several months, we cannot be certain that we were the first to file patent applications on our discoveries. We cannot be sure that we will receive patents for any of our patent applications or that any existing or future patents that we receive or license will provide competitive advantages for our products. We also cannot be sure that competitors will not challenge, invalidate or void the application of any existing or future patents that we receive or license. In addition, patent rights may not prevent our competitors from developing, using or selling products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, suppliers, employees and consultants to protect our trade secrets, unpatented proprietary know-how and continuing technological innovation. We cannot assure you that these parties will not breach their agreements with us. We also cannot be certain that we will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, we cannot be sure that our trade secrets and proprietary technology will not otherwise become known or that our competitors will not independently develop our trade secrets and proprietary technology. We also cannot be sure, if we do not receive patents for products arising from research, that we will be able to maintain the confidentiality of information relating to our products.

**Third parties may claim that we infringe their proprietary rights and may prevent us from manufacturing and selling some of our products.**

The manufacture, use and sale of new products that are the subject of conflicting patent rights have been the subject of substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may have to defend against charges that we violated patents or proprietary rights of third parties. This is especially true for the sale of the brand equivalent version of products on which the patent covering the branded product is expiring, an area where

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infringement litigation is prevalent. Our defense against charges that we infringed third party patents or proprietary rights could require us to incur substantial expense and to divert significant effort of our technical and management personnel. If we infringe on the rights of others, we could lose our right to develop or make some products or could be required to pay monetary damages or royalties to license proprietary rights from third parties.

Although the parties to patent and intellectual property disputes in the pharmaceutical industry have often settled their disputes through licensing or similar arrangements, the costs associated with these arrangements may be substantial and could include ongoing royalties. Furthermore, we cannot be certain that the necessary licenses would be available to us on terms we believe to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling a number of our products.

### **Our net revenues and profits will be negatively impacted if we are unable to replace or renew license fees, royalties and development service fees as the existing related agreements expire or are terminated.**

As part of our ongoing business strategy we enter into collaborative alliances and license arrangements, which permit us to reduce our development costs and often involve the receipt of an up-front payment, payment of fees upon completion of certain development milestones and also provide for royalties based upon sales of the products after successful development. We have received significant payments in the past from these arrangements and expect that payments from these arrangements will continue to be an important part of our business. Our future net revenues and profits will depend and will fluctuate from period to period, in part, based upon:

- our ability to continue to enter into collaborative alliances and license agreements, which provide for up-front payments, milestone payments and royalties;
- our ability to replace or renew license fees, royalties and development service fees as the existing related agreements expire or are terminated; and
- our ability to achieve the milestones specified in our license and development agreements.

### **If we are unsuccessful in our collaborations or licensing arrangements our operating results could suffer.**

We have made investments in certain collaborations and licensing arrangements and may use these and other methods to develop or commercialize products in the future. These arrangements typically involve other pharmaceutical companies as partners that may be competitors of ours in certain markets. In many instances, we will not control these collaborations or the commercial exploitation of the licensed products, and cannot assure you that these ventures will be profitable.

### **Our research and development expenditures will negatively impact our earnings in the short term.**

We spent approximately \$108.3 million during 2003 on our research and development efforts. This amount represents a significant increase in the amounts we allocated to research and development in prior periods. We may in the future increase the amounts we expend for research and development. As a result, our research and development expenditures may have an adverse impact on our earnings in the short term. Further, we cannot be sure that our research and development expenditures will, in the long term, result in the discovery or development of products which prove to be commercially successful.

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### **Disruption of production at our principal manufacturing facility could have a material adverse effect on our business, financial condition and results of operations.**

Although we have other facilities, a significant amount of our brand equivalent products are produced at our largest manufacturing facility in Puerto Rico. A significant disruption at that facility, even on a short-term basis, could impair our ability to produce and ship products on a timely basis, which could have a material adverse effect on our business, financial condition and results of operations.

### **Our acquisitions may reduce our earnings, be difficult for us to combine into our operations or require us to obtain additional financing.**

In the ordinary course of our business we evaluate potential business acquisition opportunities, some of which may be material. We seek acquisitions which will provide new product and market opportunities, benefit from and maximize our existing assets, and add critical mass. Acquisitions may expose us to additional risks and may have a material adverse effect on our results of operations. Any acquisitions we make may:

- fail to accomplish our strategic objectives;
- not be successfully combined with our operations;
- not perform as expected; and
- expose us to cross border risks.

In addition, based on current acquisition prices in the pharmaceutical industry, our acquisitions could initially reduce our per share earnings and add significant amortization expense of intangible assets. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in additional leverage, or increased debt obligations as compared to equity, and dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us.

### **We may be unable to manage our growth.**

Over the past five years, our businesses and product offerings have grown substantially. This growth and expansion has placed, and is expected to continue to place, a significant strain on our management, operational and financial resources. To manage our growth, we must continue to (i) expand our operational, customer support and financial control systems and (ii) hire, train and retain qualified personnel. We cannot assure you that we will be able to adequately manage our growth. If we are unable to manage our growth effectively, our business, results of operations and financial condition could be materially adversely affected.

### **A number of internal and external factors have caused and may continue to cause the market price of our stock to be volatile.**

The market prices for securities of companies engaged in pharmaceutical development, including us, have been volatile. Many factors, including many over which we have no control, may have a significant impact on the market price of our common stock, including without limitation:

- our or our competitors' announcement of technological innovations or new commercial products;
- changes in governmental regulation;
- our or our competitors' receipt of regulatory approvals;
- our or our competitors' developments relating to patents or proprietary rights;

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- publicity regarding actual or potential medical results for products that we or our competitors have under development; and
- period-to-period changes in financial results.

### **Sales of our products may be adversely affected by the continuing consolidation of our distribution network and the concentration of our customer base.**

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

### **Political and economic instability and foreign currency fluctuations may adversely affect the revenues generated by our foreign operations.**

Our foreign operations may be affected by the following factors, among others:

- political and/or economic instability in some countries in which we currently do business or may do business in the future through acquisitions or otherwise;
- uncertainty as to the enforceability of, and government control over, commercial rights;
- expropriation by foreign governmental entities;
- limitations on the repatriation of investment income, capital and other assets;
- currency exchange fluctuations and currency restrictions; and
- other adverse regulatory or legislative developments.

We sell products in many countries that are susceptible to significant foreign currency risk. We sell many of these products for United States dollars, which eliminates our direct currency risk but increases our credit risk if the local currency devalues significantly and it becomes more difficult for customers to purchase the United States dollars required to pay us. We sell a growing number of products, particularly in Latin America, for local currency, which results in a direct currency risk to us if the local currency devalues significantly. Additional foreign acquisitions may increase our foreign currency risk and the other risks identified above.

In June 2000, we acquired Laboratorios Elmor S.A., a pharmaceutical company based in Venezuela. In the third quarter of 2001, we acquired 99.9% of Laboratorio Chile S.A., a Chilean pharmaceutical company with operations in Chile, Argentina and Peru. Venezuela was considered a hyperinflationary economic environment through June 30, 2001. Although Venezuela is no longer considered hyperinflationary, this economy continues to experience high inflation rates and devaluation of its currency. The continuing political and economic instability in Venezuela, particularly the labor strikes and other forms of political protest directed against the Hugo Chavez administration, may adversely impact our Venezuelan operations and our consolidated earnings. Approximately 18% of our net revenues for 2003 were attributable to our Latin American operations.



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### **Increased indebtedness may impact our financial condition and results of operations.**

On December 31, 2003, we had approximately \$931.7 million of consolidated indebtedness. As a result of our issuance of 1.5% Convertible Senior Notes on March 3, 2004, our consolidated indebtedness increased by \$400.0 million. We may incur additional indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation:

- we will be required to use a portion of our cash flow from operations for the payment of any principal or interest due on our outstanding indebtedness;
- our outstanding indebtedness and leverage will increase the impact of negative changes in general economic and industry conditions, as well as competitive pressures; and
- the level of our outstanding debt may affect our ability to obtain additional financing for working capital, capital expenditures or general corporate purposes.

General economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control, may affect our future performance. As a result, these and other factors may affect our ability to make principal and interest payments on our indebtedness. We anticipate that approximately \$115.9 million of cash flow from operations will be required during 2004 to discharge our annual obligations on our indebtedness outstanding as of December 31, 2003. This requirement will increase by \$3.0 million as a result of our issuance of \$400.0 million of 1.5% Convertible Senior Notes on March 3, 2004. Our business might not continue to generate cash flow at or above current levels. If we cannot generate sufficient cash flow from operations in the future to service our debt, we may, among other things:

- seek additional financing in the debt or equity markets;
- refinance or restructure all or a portion of our indebtedness;
- sell selected assets;
- reduce or delay planned capital expenditures; or
- reduce or delay planned research and development expenditures.

These measures might not be sufficient to enable us to service our debt. In addition, any financing, refinancing or sale of assets might not be available on economically favorable terms.

### **Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers, may reduce our revenues in future fiscal periods.**

Based on industry practice in the United States, brand equivalent product manufacturers, including us, have liberal return policies and have been willing to give customers post-sale inventory allowances. Under these arrangements, from time to time, we give our customers credits on our brand equivalent products that our customers hold in inventory after we have decreased the market prices of the same brand equivalent products. If new competitors enter the marketplace and significantly lower the prices of any of their competing products, we would likely reduce the price of our product. As a result, we would provide significant credits to our customers who are then holding inventories of such products, which could reduce sales revenue and gross margin for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback is the difference between the price the wholesale customer pays and the price that the wholesale customer's end-customer pays for a product. Although we establish reserves based on our prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances and chargebacks will not exceed our estimates.

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### **Investigations of the calculation of average wholesale prices may adversely affect our business.**

Many government and third party payors, including Medicare, Medicaid, health maintenance organizations and managed care organizations, reimburse doctors and others for the purchase of certain prescription drugs based on a drug's average wholesale price (AWP). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, in which they have suggested that reporting of inflated AWP's have led to excessive payments for prescription drugs. A number of states and counties have sued us and certain of our subsidiaries, as well as numerous other pharmaceutical companies, alleging that certain products were sold at prices lower than the published AWP. Several of the suits also allege that we did not report to the states our best price for certain products under the Medicaid program. Each of these suits alleges, among other things, deceptive trade practices and fraud and seeks monetary and other relief, including civil penalties and treble damages. Although we believe that we have valid defenses to these claims, there can be no assurance as to the outcome of these matters, and a loss in any of these cases, or in similar cases which may be brought in the future, could materially affect future results of operations.

### **There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and results of operations.**

The consolidated and condensed consolidated financial statements included in the periodic reports we file with the Securities and Exchange Commission are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities and related reserves, revenues, expenses and income. This includes, but is not limited to, estimates, judgments and assumptions used in the adoption of the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our financial position and results of operations.

### **The impact of new accounting principles could have a material adverse effect on our financial position or results of operations.**

We account for stock options granted to employees under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. Under this standard, no compensation cost is recorded for stock options granted to employees at fair market value on the date of grant. The Financial Accounting Standards Board is expected to issue a new accounting standard for stock options that would require the cost of stock options granted to employees to be expensed. This and other new accounting principles adopted in the future may have a material adverse effect on our financial position or results of operations.

### **Compliance with governmental regulation is critical to our business.**

Our pharmaceutical and diagnostic operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the testing, approval, manufacture, labeling, marketing and sale of pharmaceutical and diagnostic products. Our inability or delay in receiving, or the loss of any regulatory approval could have a material adverse effect on our results of operations. The evolving and complex nature of regulatory requirements, the broad authority

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and discretion of the FDA and the extremely high level of regulatory oversight result in a continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements.

The FDA may cause a recall or withdraw product approvals if regulatory standards are not maintained. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

We cannot predict the extent to which we may be affected by legislative and regulatory developments. We are dependent on receiving FDA and other governmental or third party approvals to manufacture, market and ship our products. Consequently, there is always a risk that we will not obtain FDA or other necessary approvals, or that the rate, timing and cost of such approvals, will adversely affect our product introduction plans or results of operations. We carry inventories of certain products in anticipation of launch and if such products are not subsequently launched or are not launched when anticipated, we may be required to write-off the related inventory.

### **The concentration of ownership among our executive officers and directors may permit those persons to influence our corporate matters and policies.**

As of February 28, 2004, our executive officers, directors and one additional shareholder had or shared voting control over approximately 24.3% of our issued and outstanding common stock. As a result, these persons may have the ability to significantly influence the election of the members of our board of directors and other corporate decisions.

### **Rising insurance costs could negatively impact profitability.**

The cost of insurance, including director and officer, workers compensation, property, product liability and general liability insurance, have risen significantly in the past year and are expected to continue to increase in 2004. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our results of operations, financial condition and cash flows.

### **We have enacted a shareholder rights plan and charter provisions that may have anti-takeover effects.**

We have in place a shareholder rights plan under which we issued common stock purchase rights. As a result of the plan, each share of our common stock carries with it one common stock purchase right. Each common stock purchase right entitles the registered holder to purchase from us 0.9375 of a share of our common stock at a price of \$12.00 per 0.9375 of a share, subject to adjustment. The common stock purchase rights are intended to cause substantial dilution to a person or group who attempts to acquire us on terms that our board of directors has not approved. The existence of the common stock purchase rights could make it more difficult for a third party to acquire a majority of our common stock. Other provisions of our articles of incorporation and bylaws may also have the effect of discouraging, delaying or preventing a merger, tender offer or proxy contest, which could have an adverse effect on the market price of our common stock.

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### *Risks Related to Our Industry*

#### **Legislative proposals, reimbursement policies of third parties, cost containment measures and health care reform could affect the marketing, pricing and demand for our products.**

Various legislative proposals, including proposals relating to prescription drug benefits, could materially impact the pricing and sale of our products. Further, reimbursement policies of third parties may affect the marketing of our products. Our ability to market our products will depend in part on reimbursement levels for the cost of the products and related treatment established by health care providers, including government authorities, private health insurers and other organizations, such as health maintenance organizations (HMOs) and managed care organizations (MCOs). Insurance companies, HMOs, MCOs, Medicaid and Medicare administrators and others are increasingly challenging the pricing of pharmaceutical products and reviewing their reimbursement practices. In addition, the following factors could significantly influence the purchase of pharmaceutical products, which could result in lower prices and a reduced demand for our products:

- the trend toward managed health care in the United States;
- the growth of organizations such as HMOs and MCOs;
- legislative proposals to reform health care and government insurance programs; and
- price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

These cost containment measures and health care reform proposals could affect our ability to sell our products.

The reimbursement status of a newly approved pharmaceutical product may be uncertain. Reimbursement policies may not include some of our products. Even if reimbursement policies of third parties grant reimbursement status for a product, we cannot be sure that these reimbursement policies will remain in effect. Limits on reimbursement could reduce the demand for our products. The unavailability or inadequacy of third party reimbursement for our products could reduce or possibly eliminate demand for our products. We are unable to predict whether governmental authorities will enact additional legislation or regulation which will affect third party coverage and reimbursement that reduces demand for our products.

#### **Marketed pharmaceutical products are subject to significant regulation in the United States.**

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes.

The federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The majority of states also

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have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

### **If branded pharmaceutical companies are successful in limiting the use of brand equivalent products through their legislative and regulatory efforts, our sales of brand equivalent products may suffer.**

Many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay brand equivalent 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 additional years or otherwise delay the launch of brand equivalent products;
- using the Citizen Petition process to request amendments to FDA standards;
- seeking changes to United States Pharmacopeia, an organization which publishes industry recognized compendia of drug standards;
- attaching patent extension amendments to non-related federal legislation; and
- engaging in state-by-state initiatives to enact legislation that restricts the substitution of some brand equivalent drugs, which could have an impact on products that we are developing.

If branded pharmaceutical companies are successful in limiting the use of brand equivalent products through these or other means, our sales of brand equivalent products may decline. If we experience a material decline in brand equivalent product sales, our results of operations, financial condition and cash flows will suffer.

### **Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995**

This annual report on Form 10-K contains or incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Generally, these statements concern expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts and can be identified by the use of terms such as "estimate," "project," "plan," "intend," "expect," "expect," "believe," "anticipate," "should," "may," "will," and similar expressions. Specifically, this Form 10-K and the documents incorporated into this Form 10-K by reference contain forward-looking statements, including, among others, the following:

- our intention to generate growth through the introductions of new proprietary drugs, the expanded sale and distribution of our current products, the acquisition of new businesses and products and strategic collaborations;
- our intention to generate growth through discovering and developing and/or acquiring new products, developing and marketing selected brand equivalent pharmaceuticals, leveraging proprietary technology and development strengths, acquiring new businesses and products, and expanding sales and distribution of our proprietary and branded products;

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- the ability of our research programs to develop improved forms of drugs, novel compounds and new delivery systems;
- our ability to acquire additional manufacturing, sales and distribution capabilities, including in Europe and Latin America;
- our ability to establish additional joint ventures and sales and distribution channels, including in Asia;
- our ability to integrate operations and exploit opportunities among our subsidiaries;
- our capacity to become a worldwide leader in the asthma market;
- our ability to capitalize on current relationships in the oncology market to market new brand equivalent biotech drugs and our commercialization of Xorane™ and other oncology products;
- our ability to identify, acquire and successfully integrate new acquisitions of companies or products;
- the ability of our new patented oral administration system to provide patients effective doses of paclitaxel with more convenience and reduced side effects and the applicability of this system to other chemotherapeutic agents;
- our ability to develop Easi-Breathe™ for use with various compounds;
- our ability to develop and market Volare™;
- our ability to develop and market Cervene™ for recurrent glioblastoma;
- our ability to develop and market Ampanel™ for epilepsy;
- our ability to further develop CFC-free inhalation aerosol products;
- our ability to develop and market etiprednol dicloacetate, an inhaled corticosteroid, in our multi-dose dry powder inhaler;
- our ability to develop a corticosteroid with minimal side effects to treat asthma and inflammatory diseases of the large intestine;
- our ability to develop new formulations and obtain marketing authorizations which will enable us to be the first, or among the first, to launch brand equivalent products;
- our ability to establish and maintain the bioequivalency and efficacy of our brand equivalent products;
- our ability to develop and market products to treat HIV infection, cystic fibrosis, recurrent glioblastoma, benign prostatic hypertrophy, postmenopausal syndrome, postmenopausal memory disorders and sexual disorders;
- our ability to further develop and market talampanel or other compounds for the treatment of epilepsy, Parkinson's disease, multiple sclerosis, glioblastoma or other neurological diseases;
- our ability to develop and market Estredox™;
- our ability to develop and market Cronaze™ for inflammatory bowel diseases, Respicort™ for asthma and Ethinase™ for allergic rhinitis;
- our ability to develop and market loteprednol etabonate for the treatment of allergic rhinitis and dermatological conditions;
- our ability to supplement our portfolio of brand equivalent products by emphasizing the development of selected brand equivalent products;
- our ability to develop or license proprietary products for indications having large patient populations, or for which limited or inadequate treatments exist;
- our capacity to accelerate product development and commercialization by in-licensing products and by developing new dosage forms or new therapeutic indications for existing products;
- anticipated trends in the pharmaceutical industry and the effect of technological advances on competition;
- our ability to reduce our backlog and manufacture, obtain and maintain a sufficient supply of products to meet market demand, retain our customers and meet contractual deadlines and terms;

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- that our proposed spending on facilities improvement and expansion may not be as projected;
- our ability to obtain and maintain FDA approval of our manufacturing facilities, the failure of which could result in production stoppage or delays;
- our estimates regarding the capacity of our facilities;
- our intention to fund 2004 capital expenditures and research and development from existing cash and internally generated funds;
- uncertainties regarding the outcome of pending investigations and litigation; and
- other matters.

These forward-looking statements involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. The most important factors that could prevent us from achieving our goals, and cause the assumptions underlying forward-looking statements and the actual results to differ materially from those suggested by the forward-looking statements include, but are not limited to, the following:

- difficulties in product development and uncertainties related to the timing or outcome of product development;
- the availability on commercially reasonable terms of raw materials, particularly raw materials for our paclitaxel product, and other third party sourced products;
- our ability to replace or renew license fees, royalties and development service fees as the related agreements expire or are terminated;
- difficulties in complying with governmental regulations;
- difficulties or delays in manufacturing products;
- efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to recalls, withdrawals or declining sales;
- our ability to identify potential acquisitions and to successfully acquire and integrate such operations or products;
- our ability to obtain approval from the FDA to market new pharmaceutical products;
- the acceptance of new products by the medical community as effective as alternative forms of treatment for indicated conditions;
- the outcome of any pending or future litigation (including patent, trademark and copyright litigation and the United Kingdom National Health Service Investigation), and the cost, expenses and possible diversion of management's time and attention arising from such litigation or investigation;
- the impact of new regulations or court decisions or actions by our competitors regarding the protection of patents and the exclusivity period for the marketing of branded drugs;
- the impact of the adoption of certain accounting standards;
- our success in acquiring or licensing proprietary technologies that are necessary for our product development activities;
- the impact of political and economic instability in the countries in which we operate, particularly Venezuela and other Latin American countries;
- our successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions;
- the use of estimates in the preparation of our financial statements;
- our ability to successfully compete in both the branded and brand equivalent pharmaceutical sectors;
- trade buying patterns;
- trends toward managed care and health care cost containment;
- possible United States legislation or regulatory action affecting, among other things, pharmaceutical pricing and reimbursement, including Medicaid and Medicare;

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- interest rate and foreign currency exchange rate fluctuation; and
- other risks and uncertainties detailed herein and from time to time in our Securities and Exchange Commission filings.

Forward-looking statements, therefore, should be considered in light of all of the information included or referred to in this annual report on Form 10-K, including the cautionary information set forth under the heading “Risk Factors” beginning on page 16. We caution you not to place significant reliance on these forward-looking statements, which speak only as of the date of this annual report on Form 10-K or the date of the incorporated document, as applicable, and we undertake no obligation to update or revise these statements.

### **Financial Information about Foreign and Domestic Operations**

Specific financial information with respect to our foreign and domestic operations is provided in Note 13, Business Segment Information, in the Notes to Consolidated Financial Statements.

### **Item 2. Properties**

Our corporate headquarters are located in Miami, Florida. We maintain offices, warehouses, research and development facilities and/or distribution centers in Argentina, Bulgaria, Chile, China, Costa Rica, Croatia, the Czech Republic, El Salvador, Estonia, Finland, France, Germany, Guatemala, Honduras, Hong Kong, Hungary, India, Ireland, Italy, Kazakhstan, Mexico, Latvia, Lithuania, The Netherlands, Nicaragua, Norway, Panama, Peru, Poland, Romania, Russia, the Slovak Republic, Sweden, Switzerland, Taiwan, Ukraine, Uruguay, Uzbekistan, Venezuela and various parts of the United States and the United Kingdom, most of which are held pursuant to leases. None of these leases are material to us.

We operate pharmaceutical manufacturing facilities in Buenos Aires, Argentina; Munro, Argentina; Santiago, Chile; Beijing, China; Opava, Czech Republic; Preston Brook, England; Runcorn, England; Miami, Florida; Falkenhagen, Germany; Budapest, Hungary; Mumbai, India; Waterford, Ireland; Mexico City, Mexico; Ramos Arizpe, Mexico; Northvale, New Jersey; Cidra, Puerto Rico; Guayama, Puerto Rico, St. Croix, the U.S. Virgin Islands; and Guacara, Venezuela. We own our Budapest, Buenos Aires, Cidra, Falkenhagen, Guayama, Guacara, Mexico City, Miami, Munro, Opava and Ramos Arizpe manufacturing facilities, and lease our remaining manufacturing facilities. In connection with the sale of the specialty chemicals business, we retained ownership of our manufacturing facilities in Rock Hill, South Carolina and Marion, Ohio which we are seeking to sell.

We believe our facilities are in satisfactory condition and are suitable for their intended use. We plan to spend between \$100 million and \$120 million in 2004 to improve and expand our pharmaceutical and other related facilities. A portion of our pharmaceutical manufacturing capacity and our research and development activities, as well as our corporate headquarters and other critical business functions are located in areas subject to hurricane and earthquake casualty risks. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm or earthquake.

### **Item 3. Legal Proceedings**

#### Terazosin Litigation

On December 21, 1998, an action purporting to be a class action, styled Louisiana Wholesale Drug Co. vs. Abbott Laboratories, Geneva Pharmaceuticals, Inc. and Zenith Goldline Pharmaceuticals, Inc., was filed against IVAX Pharmaceuticals, Inc. (“IPI”) and others in the United States District Court for the Southern District of Florida, alleging a violation of Section 1 of the Sherman Antitrust Act. Plaintiffs purport to represent a class



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consisting of customers who purchased a certain proprietary drug directly from Abbott Laboratories during the period beginning on October 29, 1998. Plaintiffs allege that, by settling patent-related litigation against Abbott in exchange for quarterly payments, the defendants engaged in an unlawful restraint of trade. The complaint seeks unspecified treble damages and injunctive relief. Eighteen additional class action lawsuits containing allegations similar to those in the Louisiana Wholesale case were filed in various jurisdictions between July 1999 and February 2001, the majority of which have been consolidated with the Louisiana Wholesale case. On December 13, 2000, plaintiffs' motion for summary judgment on the issue of whether the settlement agreement constituted a per se violation of Section 1 of the Sherman Antitrust Act in the Louisiana Wholesale case was granted, but on September 15, 2003, the United States Court of Appeals for the Eleventh Circuit reversed the order. On March 13, 2000 the Federal Trade Commission ("FTC") announced that it had issued complaints against, and negotiated consent decrees with, Abbott Laboratories and Geneva Pharmaceuticals arising out of an investigation of the same subject matter that is involved in these lawsuits. The FTC took no action against IPI. To date, seventeen of the actions naming IPI have either been settled or dismissed.

### Fen-Phen Litigation

IPI has been named in a number of individual and class action lawsuits in both state and federal courts involving the diet drug combination of fenfluramine and phentermine, commonly known as "fen-phen." Generally, these lawsuits seek damages for personal injury, wrongful death and loss of consortium, as well as punitive damages, under a variety of liability theories including strict products liability, breach of warranty and negligence. IPI did not manufacture either fenfluramine or phentermine, but did distribute the brand equivalent version of phentermine manufactured by Eon Labs Manufacturing, Inc. ("Eon") and Camall Company. Although IPI had a very small market share, to date, IPI has been named in approximately 5,542 cases and has been dismissed from approximately 4,966 of these cases, with additional dismissals pending. IPI intends to vigorously defend all of the lawsuits, and while management believes that its defense will succeed, as with any litigation, there can be no assurance of this. Currently Eon is paying for approximately 50% of IPI's costs in defending these suits and is fully indemnifying IPI against any damages IPI may suffer as a result of cases involving product manufactured by Eon. In the event Eon discontinues providing this defense and indemnity, IPI has its own product liability insurance. While IPI's insurance carriers have issued reservations of rights, IPI believes that it has adequate coverage. Although it is impossible to predict with certainty the outcome of litigation, we do not believe this litigation will have a material adverse impact on our financial condition or results of operation.

### Average Wholesale Price Litigation

On July 12, 2002, an action purporting to be a class action styled John Rice v. Abbott Laboratories, Inc., et al. (the "Rice Action") was filed against IPI and others in the Superior Court of the State of California, alleging violations of California's Business & Professional Code §17200 et seq. with respect to the way pharmaceutical companies report their AWP. Plaintiffs allege that each defendant reported an AWP to Medicare and Medicaid which materially misrepresented the actual prices paid to defendants by physicians and pharmacies for prescription drugs. The complaint seeks unspecified damages, including punitive damages, and injunctive relief. Two other class actions, Thompson v. Abbott Laboratories, Inc., et al. (the "Thompson Action") and Turner v. Abbott Laboratories, Inc., et al. (the "Turner Action"), containing similar allegations against IPI and others were filed in California courts in August and September 2002, respectively, as well. All three cases were removed to federal court and transferred to the Pharmaceutical Industry Average Wholesale Price Multi-District Litigation in the United States District Court for the District of Massachusetts. On November 23, 2003, the plaintiff in the Rice Action dismissed his action against IPI and other defendants without prejudice. On January 9, 2004, the court denied the motions filed by the plaintiffs in the Thompson Action and the Turner Action to remand the cases to state court and further ruled that

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the claims in these actions were preempted by ERISA. In February 2004, the plaintiffs in the Thompson Action and the Turner Action also dismissed their actions against IPI and other defendants.

On September 29, 2003, we received a copy of a Summons and Complaint filed by the Commonwealth of Massachusetts against IVAX Corporation, and various other manufacturers of generic pharmaceutical products, alleging that all defendant manufacturers inflated the prices of generic pharmaceutical products paid for by the Massachusetts Medicaid Program through alleged fraudulent promotion, marketing and sales practices, resulting in millions of dollars in overpayments. The Complaint also alleges that the defendant manufacturers reported understated drug pricing to the federal government, which had the effect of reducing rebate payments to the Commonwealth under rebate agreements. The complaint alleges violations of the Massachusetts Medicaid False Claims Act, the Massachusetts False Claims Act and common law fraud, along with claims for unjust enrichment, breach of contract and breach of the duty of good faith and fair dealing. The Commonwealth seeks injunctive relief, restitution, treble damages, civil penalties, attorneys' fees, and investigative and litigation costs. A motion to dismiss this action was filed on January 29, 2004 and is pending. We intend to vigorously defend ourselves in this matter and against these allegations.

On September 15, 2003, IPI and we were served with an Amended Complaint filed in the United States District Court for the District of Massachusetts in the case styled County of Suffolk vs. Abbott Laboratories, Inc., et al. and on August 25, 2003, we were served with a similar complaint filed in the United States District Court for the Southern District of New York in the case styled County of Westchester vs. Abbott Laboratories, Inc. et al. In each of these cases, the plaintiffs allege that the defendants violated the Racketeering Influenced and Corrupt Organizations Act ("RICO"), the Federal Medicaid Statute, New York Social Services Law, New York Department of Health Regulations, and New York General Business Law. The plaintiffs also seek the recovery of damages for unfair trade practices, fraud, breach of contract and under the theory of unjust enrichment. The plaintiffs also seek unspecified damages, including treble and punitive damages, civil penalties, declaratory and injunctive relief and restitution, allegedly suffered by the plaintiffs as a result of the defendants' alleged unlawful scheme to overcharge for prescription medications paid for by Medicaid. The plaintiffs allege that through promotional, discounting, and pricing practices, the defendants reported false and inflated average wholesale prices or wholesale acquisition costs and failed to report their best prices as required by federal and state rebate statutes resulting in the plaintiffs overpaying for certain medications. A motion to dismiss these actions was filed and remains pending. We intend to vigorously defend ourselves in these cases and against these allegations.

IPI, along with numerous other pharmaceutical companies, has received inquiries from and responded to requests for records and information from the Committee on Energy and Commerce of the United States House of Representatives in connection with the Committee's investigation into certain industry and IPI practices regarding average wholesale price. IPI has also received correspondence from the States of Nevada, Kentucky, Florida and Illinois on behalf of itself and 8 other states indicating that the Office of the Attorney General (OAG) for these states are investigating allegations of purportedly improper pricing practices related to the average manufacturer price and best price calculations. We or our subsidiaries have not been named as a defendant in a suit filed by or on behalf of any state, but as a result of the investigation the OAG for the states have advised us that we are required to maintain all records related to the investigation. We are cooperating fully with these requests. The outcome of these investigations could include the imposition of substantial fines, penalties and injunctive or administrative remedies.

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### United Kingdom Serious Fraud Office Investigation and Related Litigation

In April 2002, we received notice of an investigation by United Kingdom National Health Service officials concerning prices charged by generic drug companies, including Norton Healthcare Limited, trading as IVAX Pharmaceuticals UK, for penicillin-based antibiotics and warfarin sold in the United Kingdom from 1996 to 2000. This is an investigation by the Serious Fraud Office of the United Kingdom involving all pharmaceutical companies that sold these products in the United Kingdom during this period. According to statements by investigating agencies, this is a complex investigation expected to continue for some time and there is no indication from the agencies when or if charges will be made against any of these companies. We are cooperating fully with this investigation.

In December 2002, the Secretary of State for Health, on behalf of itself and others, filed a civil claim for damages and interest against Norton Healthcare, Norton Pharmaceuticals and other defendants alleging that certain of their actions adversely affected competition in the sale and supply of warfarin in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate aggregate amount of 28.6 million Pounds Sterling (approximately \$51.1 million at the December 31, 2003, currency exchange rate), plus interest and costs.

In December, 2003, the Secretary of State for Health, on behalf of itself and others, filed a civil claim for damages and interest against Norton Healthcare, Norton Pharmaceuticals and other defendants alleging that certain of their actions which adversely affected competition in the sale and supply of Penicillin in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate amount of 30.5 million Pounds Sterling (approximately \$54.5 million at the December 31, 2003, currency exchange rate), plus interest and costs.

On April 22, 2003, we received notice that we were named as a defendant along with approximately 25 other pharmaceutical manufacturers in a complaint filed in the US District Court for the Northern District of Texas by an individual who has filed the action purportedly in the name of the United States government, styled United States of America, ex. rel. Paul King v. Alcon Laboratories, Inc., et al. In this suit, the plaintiff seeks to recover damages from the defendants, including us, for allegedly defrauding and conspiring to defraud the United States government by having made sales of drugs to various federal governmental agencies or causing the United States government to reimburse individuals or entities for drug products that did not comply with Current Good Manufacturing Practices and other regulations and laws. The suit seeks the recovery of treble damages from us and the other defendants, jointly and severally, which plaintiff alleges exceeds thirty billion dollars, plus the recovery of attorneys' fees, interest, civil penalties, costs, and other relief. On February 23, 2004, Plaintiff was granted leave to file a Second Amended Complaint, in response to which we intend to move to dismiss the action in its entirety. We intend to vigorously defend ourselves in this action and against these allegations.

On April 22, 2003, GenPharm, Inc. filed a complaint in the United States District Court for the District of Puerto Rico against ChemSource Corporation (currently API Industries, Inc., "API") for damages and equitable relief, including declaratory relief and specific performance, arising out of API's alleged breach of agreements and failure to supply GenPharm with an active pharmaceutical ingredient. The complaint also seeks the recovery of damages for API's alleged negligence in failing to maintain production facilities in accordance with FDA standards. The plaintiff seeks to recover millions of dollars in damages, along with interest, costs and expenses, including attorneys' fees and other fees and costs. The plaintiff also filed a motion for preliminary relief seeking the attachment of approximately 165,000 kilograms of the active pharmaceutical ingredient, which we vigorously opposed. API and Genpharm have agreed in principle to settle the litigation in its entirety, the details of which settlement are being finalized. The complaint has been tendered to the sellers of API for defense and indemnity based on the terms of the agreement by which API was sold to us, but the sellers have denied responsibility for the claim.

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### Environmental Related Proceeding

On January 22, 2003, our subsidiary, API, received an Administrative Compliance Order issued by the United States Environmental Protection Agency dated January 2, 2003, alleging that API was not in compliance with certain conditions of the National Pollutant Discharge Elimination System Permit and certain pretreatment standards. The Order required that API submit particular certified documentation associated with achieving compliance with the given standards. The Order further required that API submit certified information concerning stormwater pollution control matters and costs. API filed its response to the Order and the EPA ordered the matter closed on August 30, 2003.

On April 4, 2003, API received an Order on Consent from The Puerto Rico Aqueduct and Sewer Authority (“PRASA”), which required that API follow a PRASA-approved compliance plan in order to achieve compliance with certain pretreatment standards. This Order also establishes interim limits applicable during the implementation of the compliance plan and attaches stipulated penalties for each day of non-compliance with the prescribed activities and reports schedule. On June 11, 2003, API submitted to PRASA certifications of compliance with two pretreatment standards identified in the Order on Consent. API negotiated with PRASA the final terms of the Order on Consent for the two remaining pretreatment standards, which was signed and finalized on June 30, 2003.

On April 28, 2003, API received an EPA issued Administrative Complaint dated April 15, 2003, which proposes that a civil penalty of approximately \$19,000 be assessed against API for the alleged violation of certain conditions of its NPDES Multi-Sector General Permit. The complaint alleges that API failed to perform certain quarterly visual examinations and conduct an appropriate analysis of parameters during monitoring periods specified in the NPDES general permit. The complaint has been tendered to the sellers of API for defense and indemnity based on the terms of the agreement by which API was sold to us. API responded to the complaint and the parties agreed to settle the matter. A Final Consent Agreement and Final Order was signed by the EPA on November 23, 2003, and the settlement amount of \$8,350 was paid by the sellers of API.

On July 16, 2003, API received an EPA letter requesting API to submit a revised Solid Waste Management Unit (SWMU) Plan, including additional sampling and investigation elements, concerning the alleged presence of isopropyl ether (IPE) in its facility. This matter was tendered to the sellers of API for indemnity based on the terms of the agreement by which API was sold to us, but sellers have denied responsibility for this claim. On November 7, 2003, API filed its response to the EPA’s July 16, 2003, letter and submitted a revised SWMU Plan to cooperate with the agency.

### Other Litigation

We are involved in various other legal proceedings arising in the ordinary course of business, some of which involve substantial amounts. In order to obtain brand equivalent approvals prior to the expiration of patents on branded products, and to benefit from the exclusivity allowed to ANDA applicants that successfully challenge these patents, we frequently become involved in patent infringement litigation brought by branded pharmaceutical companies (see “Governmental Regulation”). Although these lawsuits involve products that are not yet marketed and therefore pose little or no risk of liability for damages, the legal fees and costs incurred in defending such litigation can be substantial. While it is not feasible to predict or determine the outcome or the total cost of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings will not have a material adverse impact on our financial position or results of operations.

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We intend to vigorously defend each of the foregoing lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to us, could have a material adverse effect on our financial position and results of operations. Our ultimate liability with respect to any of the foregoing proceedings is not presently determinable.

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

No matters were submitted to a vote of security holders during the quarter ended December 31, 2003.

### **Executive Officers of the Registrant**

Set forth below are the names, ages, positions held and business experience during the past five years of our executive officers as of March 1, 2004. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of the executive officers, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

#### ***Thomas Beier***

Thomas Beier, age 58, has served as our Senior Vice President - Finance and Chief Financial Officer since October 1997. From December 1996 to October 1997, he served as our Vice President - Finance. Prior to joining us, he served as Executive Vice President and Chief Financial Officer of Intercontinental Bank from 1989 until August 1996.

#### ***Rafick Henein, Ph.D.***

Rafick Henein, age 63, has served as one of our Senior Vice Presidents and as the President and Chief Executive Officer of IVAX Pharmaceuticals, Inc., our principal United States-based brand equivalent pharmaceutical subsidiary, since July 1997. He held various positions in the Novopharm Limited organization (pharmaceuticals) since 1988, rising to the position of President and Chief Executive Officer of Novopharm International in 1996.

#### ***Neil Flanzraich***

Neil Flanzraich, age 60, has served as our Vice Chairman and President since May 1998. He was a shareholder and served as Chairman of the Life Sciences Legal Practices Group of Heller Ehrman White & McAuliffe from 1995 to 1998. From 1981 to 1994, he served in various capacities at Syntex Corporation (pharmaceuticals), most recently as its Senior Vice President, General Counsel and a member of the Corporate Executive Committee. From 1994 to 1995, after Syntex Corporation was acquired by Roche Holding Ltd., he served as Senior Vice President and General Counsel of Syntex (U.S.A.) Inc., a Roche subsidiary. He is a director of IVAX Diagnostics, Inc. (diagnostic reagent kits), a subsidiary of ours, Continucare Corporation (health care) and RAE Systems, Inc. (gas detection and security monitoring systems).

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### ***Phillip Frost, M.D.***

Phillip Frost, age 67, has served as our Chairman of the Board of Directors and Chief Executive Officer since 1987. He served as our President from July 1991 until January 1995. He was the Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach, Florida from 1972 to 1990. Dr. Frost was Chairman of the Board of Directors of Key Pharmaceuticals, Inc. from 1972 to 1986. He is Chairman of the Board of Directors of IVAX Diagnostics, Inc. (diagnostic reagent kits), a subsidiary of ours. He is a director of Continucare Corporation (health care) and Northrop Grumman Corp. (aerospace). He is Chairman of the Board of Trustees of the University of Miami and a member of the Board of Governors of the American Stock Exchange.

### ***Jane Hsiao, Ph.D.***

Jane Hsiao, age 56, has served as our Vice Chairman-Technical Affairs since February 1995, as our Chief Technical Officer since July 1996, and as Chairman, Chief Executive Officer and President of DVM Pharmaceuticals, Inc., our veterinary products subsidiary, since March 1998. From 1992 until February 1995, she served as our Chief Regulatory Officer and Assistant to the Chairman, and as Vice President-Quality Assurance and Compliance of IVAX Research, Inc., our principal proprietary pharmaceutical subsidiary. From 1987 to 1992, Dr. Hsiao was Vice President-Quality Assurance, Quality Control and Regulatory Affairs of IVAX Research, Inc. She is a director of IVAX Diagnostics, Inc. (diagnostic reagent kits), a subsidiary of ours.

## **PART II**

### **Item 5. Market for Registrant's Common Equity and Related Shareholder Matters**

Our common stock is listed on the American Stock Exchange and is traded under the symbol "IVX" and on the London Stock Exchange under the symbol "IVX.L." As of the close of business on February 28, 2004, there were approximately 3,832 holders of record of our common stock. The following table sets forth the high and low sales price of a share of our common stock for each quarter in 2003 and 2002 as reported by the American Stock Exchange:

<b>2003</b>	<b>High</b>	<b>Low</b>
First Quarter	\$13.65	\$10.50
Second Quarter	20.25	12.14
Third Quarter	20.60	16.34
Fourth Quarter	24.69	17.30
<b>2002</b>	<b>High</b>	<b>Low</b>
First Quarter	\$21.07	\$15.40
Second Quarter	15.90	10.53
Third Quarter	14.49	10.05
Fourth Quarter	13.59	10.84

We did not pay cash dividends on our common stock during 2002 or 2003 and we do not intend to pay any cash dividends in the foreseeable future.

Information regarding our stock option programs is set forth under page F-32 of this report.

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**Item 6. Selected Financial Data**

The following table sets forth selected historical financial data as of and for the years ended December 31, 2003, 2002, 2001, 2000 and 1999, that has been derived from, and is qualified by reference to, our audited consolidated financial statements. The information set forth below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the Consolidated Financial Statements and related notes thereto included elsewhere in this report.

	Year Ended December 31,				
	2003(1)	2002	2001(4)	2000(5)	1999
	(in thousands, except per share data)				
<b>OPERATING DATA</b>					
Net revenues	\$1,420,339	\$1,197,244	\$1,215,377	\$ 793,405	\$656,482
Cost of sales	781,383	663,708	583,588	409,903	377,967
Gross profit	638,956	533,536	631,789	383,502	278,515
Selling	212,192	168,952	143,629	92,032	71,131
General and administrative	122,414	118,416	110,477	84,900	85,092
Research and development	108,347	76,041	88,015	65,331	53,403
Amortization	19,719	16,158	19,412	9,042	3,121
Restructuring costs (reversal of accrual)	3,706	4,242	2,367	(4,535)	(612)
Operating income	172,578	149,727	267,889	136,732	66,380
Interest income	3,710	8,090	21,249	13,986	6,142
Interest expense	(43,608)	(48,639)	(41,791)	(14,624)	(5,556)
Other income	11,738	60,321	49,637	15,243	20,106
Income taxes	45,559	51,742	54,065	13,214	14,850
Minority interest	188	838	344	(608)	(2,085)
Income from continuing operations	99,047	118,595	243,263	137,515	70,137
Income from discontinued operations (2)	22,204	—	—	—	585
Cumulative effect of accounting change (3)	—	4,161	—	(6,471)	—
Net income	<u>\$ 121,251</u>	<u>\$ 122,756</u>	<u>\$ 243,263</u>	<u>\$ 131,044</u>	<u>\$ 70,722</u>
Basic earnings per common share:					
Continuing operations	\$ 0.51	\$ 0.61	\$ 1.22	\$ 0.70	\$ 0.35
Discontinued operations (2)	0.11	—	—	—	—
Cumulative effect of accounting change (3)	—	0.02	—	(0.03)	—
Net earnings	<u>\$ 0.62</u>	<u>\$ 0.63</u>	<u>\$ 1.22</u>	<u>\$ 0.67</u>	<u>\$ 0.35</u>
Diluted earnings per common share:					
Continuing operations	\$ 0.50	\$ 0.60	\$ 1.19	\$ 0.67	\$ 0.34
Discontinued operations (2)	0.11	—	—	—	—
Cumulative effect of accounting change (3)	—	0.02	—	(0.03)	—
Net earnings	<u>\$ 0.61</u>	<u>\$ 0.62</u>	<u>\$ 1.19</u>	<u>\$ 0.64</u>	<u>\$ 0.34</u>
Weighted average number of common shares outstanding:					
Basic	195,626	195,037	199,099	196,276	201,885
Diluted	198,900	197,378	204,639	204,058	205,501
Cash dividends per common share	\$ —	\$ —	\$ —	\$ —	\$ —

**BALANCE SHEET DATA**

Working capital	\$ 509,167	\$ 447,154	\$ 597,578	\$ 438,490	\$124,373
Total assets	2,372,934	2,047,759	2,105,449	1,068,186	634,514
Total long-term debt, net of current portion	855,335	872,339	913,486	253,755	93,473
Shareholders' equity	962,311	684,863	718,354	484,120	292,371

- (1) Includes the post-acquisition results of companies acquired, primarily API Industries, Inc. on January 24, 2003, and a branded respiratory business in Europe on October 1, 2003.
- (2) The discontinued operations in 2003 relates to a number of agreements, for certain patent and product rights and settlement of litigation related to a contingent sale price dispute from our 1997 sale of McGaw, Inc. to B. Braun Melsungen AG.
- (3) The cumulative effect of a change in accounting principle relates to adoption of Statement of Financial Accounting Standards No. 142 in 2002 and Securities and Exchange Commission Staff Accounting Bulletin No. 101 in 2000.



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- (4) Includes the post-acquisition results of companies acquired, primarily Laboratorio Chile S.A. on July 5, 2001, IVAX Scandinavia AB on March 13, 2001, and IVAX Pharmaceuticals Mexico, S.A. de C.V. on February 9, 2001, all of which were accounted for under the purchase method of accounting.
- (5) Includes the post-acquisition results of companies acquired, IVAX Laboratories, Inc. on September 7, 2000, and Laboratorios Elmor, S.A. on June 19, 2000, both of which were accounted for under the purchase method of accounting.

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

Except for the historical information contained herein, the following discussion contains forward-looking statements that are subject to known and unknown risks, uncertainties and other factors that may cause our actual results to differ materially from those expressed or implied by such forward-looking statements. We discuss such risks, uncertainties and other factors throughout this report and specifically under the caption "Risk Factors" in Item 1 of this Form 10-K. In addition, the following discussion and analysis should be read in conjunction with the 2003 Consolidated Financial Statements and the related Notes to Consolidated Financial Statements included elsewhere in this report.

#### **Our Business**

We are a multinational company engaged in the research, development, manufacture and marketing of pharmaceutical products. We manufacture and/or market several brand name pharmaceutical products and a wide variety of brand equivalent and over-the-counter pharmaceutical products, primarily in the United States, Europe and Latin America. We also have subsidiaries located throughout the world, some of which are among the leading pharmaceutical companies in their markets.

#### **Results of Operations**

##### **Year ended December 31, 2003 compared to the year ended December 31, 2002**

###### **Overview**

We generated strong revenue growth in 2003 principally due to increased demand and higher prices in all regions. Our revenue growth was also driven by new product launches and the acquisition of businesses. The year ended December 31, 2003, was a year of investment in our future. We invested \$43.2 million, an increase of 26%, more in sales and marketing than in 2002 and \$32.3 million, an increase of 42%, more in research and development than in 2002. Despite these investments, our operating income increased by 15% from \$149.7 million in 2002 to \$172.6 million in 2003. We expect to continue to make significant investments in capital expenditures to increase our manufacturing capacity, in sales and marketing and in research and development.

On October 28, 2003, we received final approval and confirmation of our first to file status from the FDA on Metformin HCl Extended Release and on November 26, 2003, we reached agreement with Alpharma Inc. to share profits on an equal basis on all sales during the 180-day exclusivity period regarding this product. On February 19, 2004, we received final approval and confirmation of our first to file status on glyburide/metformin HCl tablets. Our 180-day exclusivity period will start to run when we launch the product. On March 10, 2004, we received approval from the European Commission for the extension of indication of the existing marketing authorization for Paxene<sup>®</sup> to include treatment of metastatic breast cancer and metastatic ovarian cancer in the 15 member states of the European Union.

As part of our ongoing business strategy, we enter into collaborative alliances, which allow us to exploit our drug discovery and development capabilities or provide us with intellectual property and technologies. Many of these alliances involve licenses to other companies relating to technologies or compounds under development and, in some cases, finished products. These licenses permit us to reduce our development costs and often involve the receipt of an up-front payment and fees upon completion of certain development milestones and also, generally, provide for royalties based on sales of the products. We have received significant payments in the past from these arrangements. We expect that milestone, developmental, royalty and other payments under existing and new collaboration and license agreements with other parties will continue to be an important part of our business. For example, we expect to receive a milestone payment of up to \$26.0 million under a collaboration agreement, which will be recognized as other revenue in the first or second quarter of 2004, based on satisfaction of certain conditions. Our future net revenues and profits will depend and will fluctuate from period to period, in part, based upon our ability to replace or

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renew license fees, royalties and development service fees as the related agreements expire or are terminated. We expect that our future net revenues and profits will also depend upon:

- our ability to obtain and maintain FDA approval of our manufacturing facilities;
- our ability to maintain a pipeline of products in development;
- our ability to achieve the milestones specified in our license and development agreements;
- our ability to manufacture, obtain and maintain a sufficient supply of products to meet market demand, retain our customers and meet contractual deadlines and terms;
- our ability to develop and rapidly introduce new products and to introduce existing products into new territories;
- the timing of regulatory approval of such products;
- the availability and cost of raw materials required to manufacture such products;
- our ability to manufacture such products efficiently;
- the number and timing of regulatory approvals of competing products;
- the outcome and timing of legal proceedings, particularly those related to Hatch-Waxman exclusivity and patent infringement cases;
- our ability to forecast inventory levels and trends at our customers and their end-customers; and
- our and our competitors' pricing and chargeback policies.

### Net Revenues and Gross Profit

The composition of the change in net revenues by region is as follows (in millions):

	2003	2002	Change	% Change
North America	\$ 650.6	\$ 508.6	\$142.0	28%
Europe	532.4	454.4	78.0	17%
Latin America	251.9	229.1	22.8	10%
Corporate and other	(14.6)	5.1	(19.7)	N.M.*
Total net revenues	<u>\$1,420.3</u>	<u>\$1,197.2</u>	<u>\$223.1</u>	19%

\* Not meaningful

The increase in North American net revenues was due to the impacts of price increases of \$55.9 million (including the impact of the change in estimates discussed below) and volume increases of \$94.3 million including the launch of new generic products, partially offset by a decrease in other revenues of \$8.2 million, primarily product collaboration and development fees. North American subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$566.4 million in 2003 and \$576.2 million in 2002.

The increase in European net revenues was primarily due to favorable effects of currency exchange rates of \$55.1 million and the impact of volume increases of \$56.2 million, partially offset by the impact of price decreases of \$11.0 million and a decrease, net of currency effects, in other revenues of \$22.3 million. The decrease in other revenues was primarily due to reduced product collaboration and development fees of \$22.1 million and a decrease in various other revenues of \$6.2 million, partially offset by a \$6.0 million milestone payment received in the second quarter under a license and development agreement. European subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$41.1 million in 2003 and \$51.2 million in 2002.

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The increase in Latin American net revenues was primarily due to the impacts of price increases of \$18.3 million and volume increases of \$26.2 million, partially offset by the unfavorable effects of currency devaluations of \$21.4 million and a decrease, net of currency effects, in other revenues of \$0.3 million. Latin American subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$36.3 million in 2003 and \$33.8 million in 2002.

The composition of the change in our net revenues and gross profit is as follows (in millions):

	<u>2003</u>	<u>2002</u>	<u>Change</u>	<u>% Change</u>
Net revenues	\$1,420.3	\$1,197.2	\$223.1	19%
Cost of sales	781.4	663.7	117.7	18%
Gross profit	<u>\$ 638.9</u>	<u>\$ 533.5</u>	<u>\$105.4</u>	20%
% of net revenues	45.0%	44.6%		

As a result of our recent return, customer inventory experience, analysis of allowance for doubtful accounts and tax reserves, our estimates of product returns and other sales allowances, inventory obsolescence, allowance for doubtful accounts and income tax exposures decreased and, accordingly, we recognized increased net revenues, reduced cost of sales, reduced bad debt expense and reduced income tax provision during 2003. During the year ended December 31, 2003, these changes increased net revenues by \$13.7 million, reduced cost of sales by \$0.8 million, reduced bad debt expense by \$3.7 million, reduced the income tax provision by \$2.7 million, increased net income by \$14.0 million and increased diluted earnings per share by \$0.07.

### **Operating Expenses**

The composition of the change in operating expenses is as follows (in millions):

	<u>2003</u>	<u>2002</u>	<u>Change</u>	<u>% Change</u>
Selling	\$212.2	\$169.0	\$ 43.2	26%
% of net revenues	14.9%	14.1%		
General and administrative	122.4	118.4	4.0	3%
% of net revenues	8.6%	9.9%		
Research and development	108.3	76.0	32.3	43%
% of net revenues	7.6%	6.4%		
Amortization	19.8	16.2	3.6	22%
Restructuring	3.7	4.2	(0.5)	(13)%
Total operating expenses	<u>\$466.4</u>	<u>\$383.8</u>	<u>\$ 82.6</u>	22%

The increase in selling expenses was primarily attributable to higher expenses associated with the expansion of our United States proprietary respiratory sales force and an increase in the European sales force from the acquisition of a branded respiratory business on October 1, 2003.

The increase in general and administrative expenses is primarily attributable to general and administrative expenses from the operations of API Industries, Inc. ("API," formerly ChemSource Corporation), which we acquired on January 24, 2003, and of the branded respiratory business in Europe, which was acquired on October 1, 2003, and a \$1.5 million severance payment to an executive officer who retired during the year, partially offset by \$5.4 million of net legal settlements we received during 2003 and changes in our allowance for doubtful accounts.

The increase in research and development expenses is primarily attributable to an increase in various research and development projects, bio-study costs and work force in North America and Europe. Our future level of research and development expenditures will depend on, among other things, the outcome of clinical testing of products under development, the timing and impact of patent challenges and litigation, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions, collaborative alliances and liquidity.

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During 2003, we incurred \$3.7 million of restructuring costs in Europe and Chile, consisting primarily of employee termination benefits. During 2002, we incurred \$4.2 million of restructuring costs, which were substantially paid out during the second quarter, at two subsidiaries, consisting primarily of employee termination benefits.

### **Other Income (Expense)**

The composition of the change in other income (expense) is as follows (in millions):

	<u>2003</u>	<u>2002</u>	<u>Change</u>	<u>% Change</u>
Interest income	\$ 3.7	\$ 8.1	\$ (4.4)	(54)%
Interest expense	(43.6)	(48.6)	5.0	(10)%
Other income, net	11.7	60.3	(48.6)	(81)%
Total other income (expense)	<u>\$ (28.2)</u>	<u>\$ 19.8</u>	<u>\$ (48.0)</u>	<u>(242)%</u>

The decrease in interest income and interest expense compared to 2002 is primarily due to the early extinguishment of debt.

Other income, net decreased \$48.6 million for the year ended December 31, 2003, compared to the prior year. During 2003, we realized gains of \$2.3 million on the repurchase of subordinated notes compared to \$17.3 million in 2002. We incurred \$10.0 million of net foreign currency losses in 2003 compared to \$1.1 million in 2002. During 2002, we realized a gain of \$6.3 million on the sale of certain intangible assets in the Czech Republic. We earned \$12.8 million in 2003 of royalty and other payments recorded as additional consideration for the 1997 sale of Elmiron® to ALZA Corporation compared to \$35.2 million in 2002.

During the fourth quarter of 2002, we received \$20.0 million in connection with certain amendments to the contract for the 1997 sale of Elmiron® with Ortho-McNeil Pharmaceutical, Inc. (“OMP”), a subsidiary of Johnson & Johnson, which acquired ALZA Corporation in 2002. We originally entered into an agreement to sell to ALZA Corporation certain rights in Elmiron® in 1997. This agreement provided, in part, for the payment of milestones and royalties on sales of Elmiron®. Upon acquisition of ALZA by OMP, representatives of OMP made it clear to us that they believed that the existing royalty structure, which provided for escalating royalties at certain sales levels, created a disincentive towards the continued growth of and their investment in the product. In order to address these issues, in exchange for minimum guaranteed royalties through 2006, we agreed to forego our rights to receive increased royalty payments upon sales of Elmiron® by OMP beyond certain sales levels and reduced the royalty rates we would receive at other sales levels. We also provided for the orderly transition of the manufacture of Elmiron® to OMP. As the \$20.0 million payment was nonrefundable and since we have no other obligations under the agreement other than those related to the manufacture of Elmiron® on fair market terms, we determined that the \$20.0 million up-front payment is the culmination of a separate earnings process and recorded the payment as additional proceeds from the 1997 sale of Elmiron® to OMP. We will continue to receive payments from OMP over the next several years based upon sales of Elmiron® by OMP.

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### Income

The composition of the change in our income is as follows (in millions, except per share data):

	2003	2002	Change	% Change
Income from continuing operations	\$ 99.1	\$ 118.6	\$(19.5)	(17)%
Income from discontinued operations	22.2	—	22.2	
Cumulative effect of accounting change	—	4.2	(4.2)	
Net income	<u>\$ 121.3</u>	<u>\$ 122.8</u>	<u>\$ (1.5)</u>	<u>(1)%</u>

	Basic		Diluted	
	2003	2002	2003	2002
Earnings per common share:				
Continuing operations	\$ 0.51	\$ 0.61	\$ 0.50	\$ 0.60
Discontinued operations	0.11	—	0.11	—
Cumulative effect of accounting change	—	0.02	—	0.02
Net earnings	<u>\$ 0.62</u>	<u>\$ 0.63</u>	<u>\$ 0.61</u>	<u>\$ 0.62</u>

During the second quarter of 2003, we recorded income from discontinued operations in the amount of \$22.2 million, net of tax of \$12.8 million, or \$0.11 per diluted share, resulting from a number of agreements, for certain patent and product rights and the settlement of litigation related to a contingent sale price dispute from our 1997 sale of McGaw, Inc. to B. Braun Melsungen AG. Under these agreements, we received \$13.9 million of cash, net of related expenses incurred in 2003, and recorded a current tax payable of \$5.1 million. In addition, the agreements provide for additional payments totaling \$25.5 million due in five approximately equal annual installments, which were recorded as a receivable discounted at 4%. We also accrued \$1.6 million of additional fees related to the settlement and a deferred tax liability of \$7.7 million. As of January 1, 2002, we recorded a cumulative change in accounting principle credit in the amount of \$4.2 million, or \$0.02 per diluted share, in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 141, *Business Combinations*.

### Year ended December 31, 2002 compared to the year ended December 31, 2001

Net income for the year ended December 31, 2002, was \$122.8 million, or \$0.62 per diluted share, compared to \$243.3 million, or \$1.19 per diluted share, in 2001. Income from continuing operations was \$118.6 million, or \$0.60 per diluted share, for the year ended December 31, 2002, compared to \$243.3 million, or \$1.19 per diluted share, in 2001. As of January 1, 2002, we recorded a cumulative change in accounting principle credit in the amount of \$4.2 million, or \$0.02 per diluted share, in accordance with SFAS No. 141, *Business Combinations*.

### Net Revenues and Gross Profit

Net revenues for the year ended December 31, 2002, totaled \$1.2 billion consistent with the \$1.2 billion reported in 2001. The net revenues decrease in North American subsidiaries was offset by increases from European subsidiaries, Latin American subsidiaries and other operations. As a result of exchange rate differences, net revenues decreased by \$45.2 million in 2002 as compared to 2001.

North American subsidiaries generated net revenues of \$508.6 million in 2002 compared to \$595.0 million in 2001. The \$86.4 million, or 15%, decrease in net revenues was primarily attributable to decreased volume and lower prices of our paclitaxel product and higher sales returns and allowances, partially offset by increased volume and prices of certain other brand equivalent pharmaceutical products, increased sales of proprietary respiratory products and the receipt of increased product development fees. North American subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$576.2 million in 2002 and \$370.0 million in 2001. The increase of \$206.2 million, or 56%, was primarily due to price changes on certain brand equivalent pharmaceutical products and changes in sales volume and product mix.

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European subsidiaries generated net revenues of \$454.4 million in 2002 compared to \$419.1 million in 2001. The \$35.3 million, or 8%, increase in net revenues was primarily due to higher sales volumes and favorable effects of currency exchange rates and \$5.8 million of other revenues from a previously deferred up-front payment received under a license agreement that was terminated during the third quarter of 2002, partially offset by reduced product development fees and lower prices for certain brand equivalent products. European subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$51.2 million in 2002 and \$34.7 million in 2001. The increase of \$16.5 million, or 47%, was primarily due to reduced prices on certain brand equivalent pharmaceutical products and increased financial discounts.

Latin American subsidiaries generated net revenues of \$229.1 million in 2002 compared to \$224.1 million in 2001. The \$5.0 million, or 2%, increase was primarily due to revenue generated by Laboratorio Chile S.A. ("Lab Chile"), which we acquired on July 5, 2001, partially offset by unfavorable effects of currency exchange rates. Latin American subsidiaries recorded provisions for sales returns and allowances that reduced gross sales by \$33.8 million in 2002 and \$25.7 million in 2001. The increase of \$8.1 million, or 32%, was primarily due to the inclusion of the operations of Lab Chile for the full year in 2002 as compared to only a partial period in 2001.

Gross profit for the year ended December 31, 2002, decreased \$98.3 million, or 16%, to \$533.5 million (44.6% of net revenues) from \$631.8 million (52.0% of net revenues) in 2001. The decrease in gross profit percentage was primarily attributable to reduced volume and pricing of our paclitaxel product. We continued to experience increased competition for paclitaxel as well as our brand equivalent albuterol products and the resulting pricing and volume pressures had negatively impacted our revenues and gross profits. Our results for 2002 were also adversely impacted by significant currency devaluations in Argentina and Venezuela, reductions in government purchases of our products in Mexico and continued pricing pressures in the United States and the United Kingdom. Revenues from the sale of our paclitaxel product did not contribute significantly to our revenues and gross profits during 2002 and, because of the continuing price erosion and competition, are not likely to contribute significantly in the near future to our North American results.

### **Operating Expenses**

Selling expenses increased \$25.3 million, or 18%, to \$169.0 million (14% of net revenues) in 2002 compared to \$143.6 million (12% of net revenues) in 2001. The increase was due to higher expenses associated with the operations of Lab Chile, which we acquired on July 5, 2001, and IVAX Pharmaceuticals Mexico, S.A. de C.V. ("IVAX Mexico"), which we acquired on February 9, 2001, and increased sales and promotional expenses at IVAX Laboratories, Inc. ("Laboratories"), our United States proprietary respiratory subsidiary, and our European subsidiaries, partially offset by reduced sales and promotional expenses at Elvetium Argentina, which merged into IVAX Argentina, S.A. during 2002, and favorable effects of foreign currency rates.

General and administrative expenses increased \$7.9 million, or 7%, to \$118.4 million (10% of net revenues) in 2002 compared to \$110.5 million (9% of net revenues) in 2001. The increase was primarily attributable to additional general and administrative expenses from the operations of Lab Chile and IVAX Mexico and increased expenses at Laboratories and our European subsidiaries, partially offset by reduced expenses at Elvetium Argentina, favorable effects of foreign currency rates and lower professional fees at our corporate level. In June 2002, we received \$2.2 million in partial settlement of a vitamin price-fixing class action lawsuit. In addition, we paid \$2.1 million to settle the Louisiana Wholesale Drug Co. v. Abbott Laboratories and Valley Drug Co. v. Abbott Laboratories et al. cases.

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Research and development expenses decreased \$12.0 million, or 14%, to a total of \$76.0 million (6% of net revenues) in 2002 compared to \$88.0 million (7% of net revenues) in 2001. The decrease was primarily due to lower legal fees paid during 2002 related to patent challenges. Our future level of research and development expenditures will depend on, among other things, the outcome of clinical testing of products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions, collaborative alliances and liquidity.

During 2002, we incurred \$4.2 million of restructuring costs, which were substantially paid out during the second quarter, at two subsidiaries, consisting primarily of employee termination benefits.

### **Other Income (Expense)**

During 2002, interest income decreased \$13.2 million and interest expense increased \$6.8 million compared to 2001 primarily due to the cash purchases of Lab Chile on July 5, 2001, and Nasarel<sup>®</sup> and Nasalide<sup>®</sup> on October 16, 2001, and the issuance of \$725.0 million of 4.5% Convertible Senior Subordinated Notes in 2001.

Other income, net increased \$10.7 million for the year ended December 31, 2002, compared to the prior year. During 2002, we realized gains of \$17.3 million on the repurchase of subordinated notes compared to \$11.3 million in 2001. We incurred \$1.1 million of net foreign currency losses in 2002 compared to net foreign currency gains of \$2.7 million in 2001. During 2002, we realized a gain of \$6.3 million on the sale of certain intangible assets in the Czech Republic. During 2001, we recorded a gain of \$10.3 million on the partial sale of IVAX Diagnostics, Inc. ("IVAX Diagnostics") in connection with IVAX Diagnostics' March 2001 merger with b2bstores.com. During 2001, we recorded a gain of \$21.7 million on derivative contracts due to the devaluation of the Argentine peso, partially offset by a \$19.0 million loss on bank debt and other liabilities denominated in currencies foreign to the Argentine operations. During 2002, we earned \$35.2 million of royalty and other payments compared to \$13.8 million in 2001, which are recorded as additional consideration under the contract for the 1997 sale of Elmiron<sup>®</sup> with OMP.

### **Recently Issued Accounting Standards**

In June 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 143, *Accounting for Asset Retirement Obligations*, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) normal operation of a long-lived asset, except for certain obligations of lessees. It requires that the fair value of an asset retirement obligation be recognized as a liability in the period in which it is incurred if a reasonable estimate can be made and that the associated retirement costs be capitalized as part of the carrying amount of the long-lived asset. It is effective for fiscal years beginning after June 15, 2002. The impact of adoption of this statement was not significant.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. It supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, and certain provisions of APB No. 30, *Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, for the disposal of a segment of a business. It also amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*. It establishes a single accounting model for the accounting for a segment of a business accounted for as a discontinued operation that was not addressed by SFAS No. 121 and resolves other implementation issues related to SFAS No. 121. It is effective for fiscal periods beginning after December 15, 2001. The impact of adoption of this statement was not significant.

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Effective January 1, 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Assets*. Intangible assets that have indefinite lives and goodwill are no longer amortized. This increased net income by approximately \$1.8 million per quarter, or \$7.0 million per year. The life of one product intangible asset with a net book value of \$6.5 million as of January 1, 2002, was extended based on a review of the expected remaining estimated useful life. During 2002, intangible assets with indefinite lives were tested for impairment resulting in the write-down of one intangible asset by \$0.2 million. The initial test for impairment of goodwill as of January 1, 2002, was completed during the second quarter of 2002 and no impairments were indicated. During 2003, impairment testing of goodwill and intangible assets with indefinite lives was performed and no impairments were indicated.

During the second quarter of 2002, we elected to early adopt SFAS No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. The impact of adoption was the reclassification into income from continuing operations of an extraordinary gain from the early retirement of subordinated notes of \$7.1 million, net of taxes of \$4.2 million, during the third quarter of 2001, an extraordinary gain of \$3.4 million, net of taxes of \$2.0 million, during the first quarter of 2002 and an extraordinary gain of \$2.7 million, net of taxes of \$1.5 million, during the second quarter of 2002.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which addresses financial accounting and reporting for costs associated with exit or disposal activities. This statement 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)*. It requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred (rather than when the exit or disposal decision is made). It also establishes fair value as the objective for the initial measurement of the liability. It is effective for fiscal years beginning after December 31, 2002. The impact of adoption of this statement was not significant.

In November 2002, the EITF reached a consensus on Issue No. 00-21, *Revenue Arrangement with Multiple Deliverables*, which is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. It addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities and how arrangement considerations should be measured and allocated to the separate units of accounting in the arrangement. Reclassification of prior period amounts was required. The impact of adoption was not significant.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities an interpretation of ARB No. 51*, which addresses consolidation by business enterprises of variable interest entities (“VIE’s”). During December 2003, the FASB revised FASB Interpretation No. 46, deferring the effective date of application for public companies to the first reporting period ending after March 15, 2004, except for disclosure requirements and VIE’s that are special purpose entities. As part of the acquisition of Lab Chile, we acquired a note receivable secured by an option to acquire all of the outstanding shares of common stock of a company that owns 50.1% of a Latin American pharmacy chain, which had net revenues of \$42.2 million during the year ended December 31, 2003. As a result of the adoption of the interpretation, we may be required to consolidate the pharmacy chain as of March 31, 2004. We expect that our maximum exposure to loss is the recorded value of the note receivable, which was \$1.7 million at December 31, 2003.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, which amends and clarifies accounting for derivative instruments under SFAS No. 133. It is effective for contracts entered into after June 30, 2003. The impact of adoption of this statement was not significant.



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In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The impact of adoption of this statement was not significant.

In December 2003, the FASB issued SFAS No. 132, *Employers' Disclosures about Pensions and Other Postretirement Benefits – an amendment of FASB Statements No. 87, 88 and 106 (revised 2003)*, that revised employers' disclosures about pension plans and other postretirement benefits plans. It does not change the measurement or recognition of those plans required by SFAS No. 87, 88 and 106. This statement retains the disclosure requirements in the original SFAS No. 132 and requires additional information on changes in the benefits obligations and fair values of plan assets. It requires additional disclosures including information describing the types of plan assets, investment strategy, measurement date(s), plan obligations, cash flows, and components of net periodic benefit cost recognized during interim periods. It is effective for financial statements with fiscal years ending after December 15, 2003. The interim period disclosure requirements are effective for interim periods beginning after December 15, 2003. Disclosure information about foreign plans required by paragraphs 5(d), 5(e), 5(g), and 5(k) of this statement is effective for fiscal years ending after June 15, 2004. The impact of adoption of this statement was not significant.

In December 2003, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 104, *Revenue Recognition*, which revises the existing revenue recognition SAB in Topic 13, *Revenue Recognition*, in order for the interpretive guidance to be consistent with current accounting guidance, primarily EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The impact of adoption was not significant.

### **Liquidity and Capital Resources**

At December 31, 2003, working capital was \$509.2 million compared to \$447.1 million at December 31, 2002, and \$597.6 million at December 31, 2001. Cash and cash equivalents were \$146.9 million at December 31, 2003, compared to \$155.4 million at December 31, 2002, and \$178.3 million at December 31, 2001. Short-term marketable securities were \$10.5 million at December 31, 2003, compared to \$28.9 million at December 31, 2002, and \$154.8 million at December 31, 2001.

Net cash of \$82.6 million was provided by operating activities during 2003 compared to \$151.1 million in 2002 and \$199.0 million in 2001. The decrease in cash provided by operating activities during 2003 was primarily due to an increase in inventory from managements' desire to maintain higher levels of inventory and accounts receivable from increased sales and a decrease in income from continuing operations and payments of accounts payable. The decrease in cash provided by operating activities during 2002 was primarily the result of reduced operating earnings and increases in inventories, partially offset by increased collections of accounts receivable.

Net cash of \$75.7 million was used for investing activities during 2003 compared to \$28.3 million provided by investing activities in 2002 and \$705.3 million used for investing activities in 2001. During the fourth quarter of 2002, we received \$20.0 million in connection with certain amendments to the contract for the 1997 sale of Elmiron<sup>®</sup> with OMP. We will continue to receive payments from OMP over the next several years based upon sales of Elmiron<sup>®</sup> by OMP, with specified minimum royalty payments

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due for the period 2003 through 2006. During 2003, our capital expenditures were \$95.4 million compared to \$98.7 million in 2002 and \$73.5 million in 2001. The increase in 2002 as compared to 2001 was due to improvement and expansion of certain facilities. During 2003, we received \$2.0 million in proceeds from the sale of assets as compared to \$1.6 million in 2002 and \$41.7 million in 2001. During 2003, we spent \$7.8 million to acquire intangible assets as compared to \$38.3 million in 2002 and \$133.9 million in 2001. During 2003, \$23.5 million was used to acquire businesses and increase our ownership interest in affiliates as compared to no activity in 2002 and \$480.2 million spent in 2001. During 2003, we received \$27.2 million in net proceeds from the sale of marketable securities as compared to \$128.6 million received in 2002 and \$73.2 million used for the purchase of marketable securities in 2001. During December 2002, we purchased for \$2.2 million the remaining outstanding minority interest shares of IVAX Pharmaceuticals s.r.o., our subsidiary in the Czech Republic.

During the second quarter of 2003, we recorded income from discontinued operations in the amount of \$22.2 million, net of tax of \$12.8 million, resulting from a number of agreements, for certain patent and product rights and the settlement of litigation related to a contingent sale price dispute from our 1997 sale of McGaw, Inc. to B. Braun Melsungen AG. Under these agreements, we received \$13.9 million of cash, net of related expenses incurred in 2003, and recorded a current tax payable of \$5.1 million. In addition, the agreements provide for additional payments totaling \$25.5 million due in five approximately equal annual installments, which were recorded as a receivable discounted at 4%. We also accrued \$1.6 million of additional fees related to the settlement and a deferred tax liability of \$7.7 million.

On January 24, 2003, we acquired API in Puerto Rico from Chemo Iberica S.A. and Quimica Sintetica S.A. for 1.0 million shares of our common stock, valued at \$12.4 million, and \$0.1 million in cash. API develops, manufactures and sells active pharmaceutical ingredients for various pharmaceutical products, including many products that we sell or have under development. We acquired API to further our objective of complementing existing businesses and to provide new products and marketing opportunities.

On May 27, 2003, we entered into an agreement to acquire Advanced Tobacco Products, Inc. ("ATP"), for 0.2 million shares of our common stock, valued at \$4.1 million. During the third quarter of 2003, the transaction to acquire ATP was approved by the shareholders of ATP and the transaction was completed. ATP is an inhalation technology company that developed a patent for nicotine impermeable copolymer technology marketed for smoking cessation, that it sold to Pharmacia in 1987. ATP receives payments from Pharmacia on the sales of those products. ATP also has an exclusive license to certain dry powder inhaler technology from Duke University. We acquired ATP because of the complementary nature of ATP's technology to our product line and because of the anticipated payments from sales of Pharmacia's products incorporating the patented nicotine technology sold by ATP to Pharmacia.

On October 1, 2003, we completed an agreement with 3M Pharmaceutical Division, 3M Innovative Properties Company and Riker Laboratories, Inc., to acquire exclusive rights to branded respiratory products, together with related marketing and sales people in nine European countries: United Kingdom, Ireland, France, Germany, Netherlands, Finland, Norway, Denmark and Sweden. The agreement covers the products QVAR<sup>®</sup> (CFC-free beclomethasone dipropionate), Airomir<sup>®</sup> (CFC-free salbutamol, known in the United States as albuterol) in Autohaler<sup>®</sup> and MDI devices, and over 200 professionals to market and sell these products. The total consideration due from us under the agreement, including minimum annual royalty payments, is \$77.0 million, of which we paid \$26.0 million on closing, \$24.0 million is due on the first and second anniversaries of the closing date and \$3.0 million is due on the third anniversary. We are also required to make additional royalty payments on achieving certain annual sales levels up to a maximum of \$1.3 million per year, or \$6.6 million in total.

Net cash of \$29.5 million was used by financing activities during 2003 compared to \$179.3 million used in 2002 and \$492.9 million provided by financing activities in 2001. During 2003, we made

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\$28.6 million of new borrowings, repaid \$41.9 million of long-term debt, repurchased \$28.3 million of our convertible debentures for \$25.4 million, and reduced our repurchases of common stock by \$50.4 million compared to 2002.

On April 22, 2002, we acquired an exclusive United States license to the patent rights to market QVAR<sup>®</sup> (beclomethasone dipropionate HFA), an aerosol inhaler prescribed to treat asthma. In addition, we have an option to obtain ownership of the United States QVAR<sup>®</sup> trademark, as well as related patents and the New Drug Application on April 21, 2007. The total consideration due from us under the contract, including options and extensions, is \$105.0 million, of which \$21.0 million was paid on the effective date and \$20.0 million was paid on the first anniversary. We are entitled to reduce the purchase price by \$4.0 million for required pediatric trials. The remaining payments due from us are: \$30.0 million on the second anniversary, \$25.0 million on the third anniversary and \$5.0 million on the fifth anniversary upon exercise of the option, subject to reimbursement of all or a portion of the \$4.0 million in the event we do not continue the pediatric trials.

On August 22, 2003, we executed a mortgage note and borrowed \$15.0 million from a financial institution. The note matures on August 21, 2008, and bears interest at an annual rate of 4.3% through August 21, 2005. Thereafter, through the maturity date, the interest rate is adjusted annually based on a variable rate of twenty-five basis points over the prime rate. The note requires monthly principal payments of \$0.04 million plus interest, with a balloon payment of \$12.9 million due August 21, 2008. The mortgage covers the land and building at our corporate headquarters in Miami.

Between August 2000 and March 2002, our Board of Directors increased its authorization of share repurchases under the share repurchase program by 22.5 million shares. We repurchased (including shares repurchased via the physical settlement method disclosed below) 0.7 million shares of our common stock in 2003 at a total cost, including commissions, of \$9.0 million, 3.9 million shares in 2002 for \$59.4 million and 6.8 million shares in 2001 for \$155.1 million. At December 31, 2003, we had the authority to purchase a remaining 13.2 million shares of our common stock or a like-valued amount of our convertible debentures under the March 2002 authorization. During 2001, in connection with our share repurchase program, we received \$4.7 million in premiums on the issuance of eight freestanding put options for 1.9 million shares of our common stock, which was credited to "Capital in excess of par value," of which one put option for 0.2 million shares expired unexercised prior to December 31, 2001. We also received \$0.2 million upon renewal/rollforward of three put options for 0.9 million shares into two put options for 0.9 million shares. Five put options for 1.6 million shares were exercised by the holders at strike prices ranging from \$27.68 to \$31.50 during 2001. We elected the physical settlement method upon exercise of one put option for 0.3 million shares and paid \$7.8 million in exchange for the underlying shares. We elected the net share settlement method upon exercise of the remaining four put options for 1.4 million shares and issued 0.3 million shares of our common stock in settlement of the obligation. In the event the put options were exercised, we had the right to elect to settle by one of three methods: physical settlement by payment in exchange for our shares, net cash settlement or net share settlement. During 2002, five put options were exercised for 1.2 million shares by the holders at strike prices ranging from \$19.00 to \$32.28. We elected the physical settlement method upon the exercise of two put options for 0.5 million shares and paid \$12.7 million in exchange for the underlying shares. We elected the net share settlement method for the exercises of the remaining three put options for 0.7 million shares and issued 1.0 million shares of our common stock in settlement of the obligation.

On March 3, 2004, we issued \$400.0 million of our 1.5% Convertible Senior Notes due 2024. Under certain circumstances, the 1.5% Notes are convertible, unless previously redeemed, into 33.4874 shares of our common stock per \$1,000 of principal amount of the 1.5% Notes. This ratio results in a conversion price of approximately \$29.86 per share. We may redeem the 1.5% Notes on or after March 1, 2011. Beginning with the six-month period commencing on March 1, 2011, we will pay contingent interest on the 1.5% Notes during a six-month interest period if the average trading price of the 1.5% Notes is above a specified level. In addition, holders of the 1.5% Notes may require us to repurchase the notes on each of March 1, 2011, 2014, and 2019 and upon certain events.

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Net proceeds from the offering of the 1.5% Notes of approximately \$390.5 million are expected to be used to redeem our outstanding 5.5% Convertible Senior Subordinated Notes and for general corporate purposes, including potential acquisitions of, and investments in, products, technologies and companies, capital expenditures and working capital. At December 31, 2003, we had approximately \$249.0 million of our 5.5% Notes outstanding. The 5.5% Notes are, unless previously redeemed, convertible into 33.6 shares of our common stock per \$1,000 principal amount. In the event the 5.5% Notes are redeemed between May 16, 2004 and May 16, 2005, we expect that approximately \$254.9 million in cash will be used to redeem the notes, and that a one-time financial charge of approximately \$8.6 million will be incurred in connection with the redemption.

We plan to spend between \$120 million and \$140 million in 2004 to continue the research and development of pharmaceutical products. Research and development expenses may fluctuate from quarter to quarter and from year to year based on the timing of clinical studies, regulatory filings and litigation. Accordingly, we cannot assure that our level of research and development spending will be at these levels. In addition, we plan to spend between \$100 million and \$120 million in 2004 to improve and expand our pharmaceutical and other related facilities.

### Contractual Obligations

Additional long-term cash obligations are presented, by period due, in tabular format below (in thousands):

<u>Obligation</u>	<u>Total</u>	<u>Due in Less Than 1 Year</u>	<u>Due in 1-3 Years</u>	<u>Due in 4-5 Years</u>	<u>Due After 5 Years</u>
Long-term debt	\$ 913,942	\$ 58,608	\$54,739	\$ 799,195	\$ 1,400
Loans payable	17,804	17,804	—	—	—
Capital lease obligations	3,478	1,908	1,570	—	—
Operating leases	19,856	6,183	5,847	3,041	4,785
Unconditional purchase obligations	442	442	—	—	—
Other long-term obligations	27,660	2,372	15,744	3,739	5,805
Total cash obligations	\$ 983,182	\$ 87,317	\$77,900	\$ 805,975	\$11,990

Our principal sources of short-term liquidity are existing cash and internally generated funds, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over the short term. For the long term, we intend to principally utilize internally generated funds, which are anticipated to be derived primarily from the sale of existing pharmaceutical products, pharmaceutical products currently under development and pharmaceutical products we license or acquire. There can be no assurance that we will successfully complete products under development, that we will be able to obtain regulatory approval for any such products, or that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed or that we will acquire any such products. We may consider issuing debt or equity securities in the future to fund potential acquisitions and growth.

We filed a shelf registration statement on Form S-4, which was declared effective in March 2001, registering up to a total of 18.8 million shares of common stock that can be issued in connection with the acquisition of businesses, assets or securities. During 2003, we issued an aggregate of 1.0 million shares under the shelf registration statement in connection with the acquisition of API. In conjunction with the availability under our previous shelf registration statement on Form S-4, as of the date of this report, we have the ability to issue up to 39.3 million shares of our common stock under our shelf registration statements in connection with the acquisition of businesses, assets or securities.

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We filed a universal shelf registration statement on Form S-3, which was declared effective in March 2001, registering the sale of up to \$400.0 million of any combination of debt securities or common stock. During 2001, we issued an aggregate of 0.3 million shares under the universal shelf registration statement in connection with the net settlement of the put options discussed above. Under this registration statement, as of the date of this report, we have the ability to issue any combination of debt securities or common stock in an aggregate amount of \$382.5 million.

### **Income Taxes**

We recognized a \$45.6 million tax provision for 2003 compared to \$51.7 million in 2002 and \$54.1 million in 2001. Our effective tax rate was 32% for 2003, 31% for 2002 and 18% for 2001. In 2003 and 2002, the effective tax rate was less than the statutory rate primarily due to low tax rates applicable to our Puerto Rico and Waterford, Ireland manufacturing operations and our Swiss and Chilean operations. In 2001, the effective tax rate was lower than the United States statutory income tax rate, principally due to net operating loss and tax credit carryforwards and tax incentives in certain jurisdictions where our manufacturing facilities are located. The domestic current provision was favorably impacted by \$29.6 million during 2001 from utilization of previously reserved net operating loss and tax credit carryforwards. The 2001 domestic current provision was also favorably impacted by the non-taxable gain on the partial sale of IVAX Diagnostics. Payment of the current tax provision will be reduced by \$1.9 million for our domestic operations and \$2.3 million for our foreign operations for the year ended December 31, 2003, were reduced by \$1.4 million for our domestic operations and \$0.4 million for our foreign operations for the year ended December 31, 2002, and were reduced by \$8.0 million for our domestic operations and \$2.6 million for our foreign operations for the year ended December 31, 2001, representing the incremental impact of compensation expense deductions associated with non-qualified stock option exercises during those years. In addition, during 2001 we recorded \$7.4 million of tax effect of prior years' stock option exercises. These amounts were credited to "Capital in excess of par value" in the accompanying consolidated balance sheet. We recognized \$20.0 million in 2001 of United States taxable income on the intercompany assignment of a contract. For financial reporting purposes this transaction was eliminated in consolidation.

Valuation allowances previously recorded against the foreign and domestic net deferred tax assets of \$2.6 million in 2003, \$3.6 million in 2002 and \$11.2 million in 2001 were reversed due to management's expectation of increased domestic taxable income in the coming year. The domestic net deferred tax asset was \$79.2 million at December 31, 2003, and \$108.7 million at December 31, 2002, and the aggregate net deferred tax asset in foreign countries was \$14.9 million at December 31, 2003, and \$7.5 million at December 31, 2002. As of December 2003 and 2002, the domestic deferred tax asset was not reserved. As of December 31, 2003, the aggregate foreign net deferred tax asset was approximately 66% reserved. Realization of the net deferred tax assets is dependent upon generating sufficient future domestic and foreign taxable income. Although realization is not assured, management believes it is more likely than not that the net deferred tax assets will be realized. Our estimates of future taxable income are subject to revision due to, among other things, regulatory and competitive factors affecting the pharmaceutical industries in the markets in which we operate.

Our future effective tax rate will depend on the mix between foreign and domestic taxable income or losses and the statutory tax rates of the related tax jurisdictions. The mix between our foreign and domestic taxable income may be significantly affected by the jurisdiction in which new products are developed and manufactured.

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Income from IVAX Pharmaceuticals' Puerto Rico manufacturing operations is subject to certain tax exemptions under the terms of a grant from the Puerto Rican government, which will expire on January 1, 2021. The grant reduced tax expense by approximately \$6.2 million in 2003, \$3.5 million in 2002 and \$4.5 million in 2001. Under the terms of the grant, IVAX Pharmaceuticals is required to maintain certain employment levels. We have historically received a United States tax credit under Section 936 of the Internal Revenue Code for certain income generated by our Puerto Rico and Virgin Islands operations. These credits were approximately \$6.1 million in 2003, \$3.9 million for 2002 and \$6.3 million for 2001 and offset the United States tax liability of such operations. In 2002, the Section 936 tax credit began to be phased out over four years.

### **Risk of Product Liability Claims**

Testing, manufacturing and marketing pharmaceutical products subject us to the risk of product liability claims. We are a defendant in a number of product liability cases, none of which we believe will have a material adverse effect on our business, results of operations or financial condition. We believe that we maintain an adequate amount of product liability insurance, but there can be no assurance that our insurance will cover all existing and future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. There can be no assurance that claims arising under any pending or future product liability cases, whether or not covered by insurance, will not have a material adverse effect on our business, results of operations or financial condition (See Note 14, Commitments and Contingencies, in the Notes to Consolidated Financial Statements).

### **Critical Accounting Policies**

The consolidated financial statements include the accounts of IVAX Corporation and all majority-owned subsidiaries. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect amounts reported in the accompanying consolidated financial statements and related footnotes. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. We base our estimates and judgments on historical experience and other assumptions that we believe are reasonable. However, application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ materially from these estimates. We periodically evaluate estimates and assumptions used in the preparation of the financial statements and make changes on a prospective basis when adjustments are necessary. Significant estimates include amounts for accounts receivable exposures, deferred tax asset allowances, inventory reserves, environmental reserves, litigation and sales returns and allowances, including, but not limited to, chargebacks, rebates, returns and shelf-stock adjustments, and the useful lives of intangible assets. As a result of our recent return, customer inventory experience, analysis of allowance for doubtful accounts and tax reserves, our estimates of product returns and other sales allowances, inventory obsolescence, allowance for doubtful accounts and income tax exposures decreased and, accordingly, we recognized increased net revenues, reduced cost of sales, reduced bad debt expense and reduced income tax provision during 2003. During the year ended December 31, 2003, these changes increased net revenues by \$13.7 million, reduced cost of sales by \$0.8 million, reduced bad debt expense by \$3.7 million, reduced the income tax provision by \$2.7 million, increased net income by \$14.0 million and increased diluted earnings per share by \$0.07.

**Revenue Recognition, Sales Returns and Allowances** – Revenues and the related cost of sales are recognized at the time title to our products and the risks and rewards of ownership passes to our customers. Our pharmaceutical revenues are affected by the level of provisions for estimated returns, inventory credits, discounts, promotional allowances, rebates, chargebacks, reimbursements relating to Medicaid and Medicare and other allowances. The custom in the United States pharmaceutical industry is

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generally to grant customers the right to return purchased goods. In the generic pharmaceutical industry, this custom has resulted in a practice of suppliers issuing inventory credits (also known as shelf-stock adjustments) to customers based on the customers' existing inventory following decreases in the market price of the related generic pharmaceutical product. We have contractual agreements with many of our customers, which require that we grant these customers inventory credit following a price decrease. In other cases, the determination to grant a credit to a customer following a price decrease is at our discretion. These credits allow customers with established inventories to compete with those buying product at the current market price, and allow us to maintain shelf space, market share and customer loyalty.

Provisions for estimated returns, inventory credits and chargebacks, as well as other sales allowances, are established by us concurrently with the recognition of revenue. The provisions are established in accordance with accounting principles generally accepted in the United States based upon consideration of a variety of factors, including actual return and inventory credit experience for products during the past several years, the number and timing of regulatory approvals for the product by our competitors (both historical and projected), the market for the product, expected sell-through levels by our wholesale customers to customers with contractual pricing arrangements with us, estimated customer inventory levels and projected economic conditions. Actual product returns and inventory credits incurred are, however, dependent upon future events, including remaining shelf-life and price competition and the level of customer inventories at the time of any price decreases. We continually monitor the factors that influence the pricing of our products and customer inventory levels and make adjustments to these provisions when we believe that actual product returns, inventory credits and other allowances may differ from established reserves.

Royalty and license fee income are recognized when obligations associated with earning the royalty or licensing fee have been satisfied and are included in "Net revenues" in the accompanying consolidated statements of operations. In accordance with EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, our accounting policy is to review each contract to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenue is recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. Up-front payments are deferred, if appropriate, and recognized into revenues over the obligation period.

Gain on Sale of Product Rights – During 1997, we entered into an agreement to sell to OMP certain rights in Elmiron<sup>®</sup>. The agreement required an up-front payment, as well as milestones and royalties on sales of Elmiron<sup>®</sup>. A portion of the up-front and milestone payments that we have received and included in other income in prior years, \$34.0 million as of January 1, 2004, is refundable through December 31, 2004, and then ratably decreases through 2009, if our patent rights are found to be invalid and a brand equivalent of Elmiron<sup>®</sup> is introduced by another company.

We believe that the probability of occurrence of our patent rights being found invalid and a brand equivalent of Elmiron<sup>®</sup> being introduced by another company is remote, because substantially all agreements for the sale and licensing of a product contain representations and warranties by the seller that the underlying patent is valid. Elmiron<sup>®</sup> possesses strong patent protection and exclusive use legal protections and Elmiron<sup>®</sup>'s current and expected future market size makes it uneconomical for another company to incur the substantial cost to develop a generic equivalent, perform the long FDA clinical trials and litigate with OMP and us to obtain generic status. If the patent were to be challenged, then we, as the owner of the patent rights, would be entitled to a 30-month statutory delay, during which we would maintain exclusive right to sell Elmiron<sup>®</sup>. The active ingredient for Elmiron<sup>®</sup> is manufactured by only one source in the world and is subject to a "know-how" license held by us and because of the unique aspects of Elmiron<sup>®</sup>, we believe that there is no reliable means for a competitor to demonstrate the bio-equivalence that would be required for approval of a potential generic. The potential refund represents a warranty provision, which is not inconsistent with representations and warranties (typically without

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quantification of damages) that are present in most sales and licensing agreements. When conducting our analysis of the amount to record of the warranty obligation, we first assessed the chance of an adverse outcome under the warranty arrangement. Since we determined the chance of an adverse outcome to be remote, no provision for the warranty was recorded.

During the fourth quarter of 2002, we received \$20.0 million in connection with certain amendments to the contract. Upon acquisition of ALZA by OMP, representatives of OMP made it clear to us that they believed that the existing royalty structure, which provided for escalating royalties at certain sales levels, created a disincentive towards the continued growth of and their investment in the product. In order to address these issues, in exchange for minimum guaranteed royalties through 2006, we agreed to forego our rights to receive increased royalty payments upon sales of Elmiron® by OMP beyond certain sales levels and reduced the royalty rates we would receive at other sales levels. We also provided for the orderly transition of the manufacture of Elmiron® to OMP. As the \$20.0 million payment was nonrefundable and since we have no other obligations under the agreement other than those related to the manufacture of Elmiron® on fair market terms, we determined that the \$20.0 million up-front payment is the culmination of a separate earnings process and recorded the payment as additional proceeds from the 1997 sale of Elmiron® to OMP. We will continue to receive payments from OMP over the next several years based upon sales of Elmiron® by OMP.

Royalty and milestone payments from the 1997 sale of rights in Elmiron® and certain other urology products in the United States and Canada to OMP totaled \$12.8 million in 2003, \$35.2 million in 2002 and \$13.8 million in 2001 and are included in other income as additional gain on the sale of product rights. Royalties and milestone payments receivable from OMP included in "Other current assets" in the accompanying consolidated balance sheets totaled \$8.3 million at December 31, 2003, \$12.3 million at December 31, 2002, and \$11.1 million at December 31, 2001.

Inventory - Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life of the inventory and current market price of the inventory. We have made, are in the process of making and/or will scale-up and make commercial quantities of certain of our product candidates prior to the date we anticipate that such products will receive final FDA or foreign governmental marketing approval and/or satisfactory resolution of patent infringement litigation involving them (i.e., pre-launch inventory). The scale-up and commercial production of pre-launch inventories involves the risk that such products may not be approved for marketing by the governmental agencies on a timely basis, or ever, and/or that the outcome of related litigation may not be satisfactory. This risk notwithstanding, we plan to continue to scale-up and build pre-launch inventories of certain products that have not yet received final governmental approval and/or satisfactory resolution of patent infringement litigation when we believe that such action is appropriate in relation to the commercial value of the product launch opportunity. As of December 31, 2003, we had approximately \$24.8 million of inventories related to certain products pending final approval and/or satisfactory resolution of litigation.

Impairment of Long-Lived Assets – We continually evaluate whether events and circumstances have occurred that indicate that the remaining estimated useful life of long-lived assets may require revision or that the remaining net book value may not be recoverable. When factors indicate that an asset may be impaired, we use various methods to estimate the asset's 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 based on the excess of the carrying amount over the estimated fair value of the asset. Any impairment amount is charged to operations.



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**Intangible Assets** – Intangible assets with definite lives are amortized and carried at cost less accumulated amortization. Goodwill and intangible assets with indefinite lives are carried at cost, are not amortized and are tested for impairment annually. No impairments were identified during 2003.

**Sale of Subsidiary Stock** – During 2001, we elected income statement recognition as our accounting policy for sales of subsidiary stock and recorded a gain of \$10.3 million related to the merger of IVAX Diagnostics with b2bstores.com, which is included in “Other income, net” in the consolidated statements of operations.

**Legal Costs** – Legal charges are recorded for the costs anticipated to be incurred in connection with litigation and claims against us when we can reasonably estimate these costs. We intend to vigorously defend each of the lawsuits described in Note 14, Commitments and Contingencies, in the Notes to Consolidated Financial Statements, but their respective outcomes cannot be predicted. Any of such lawsuits or investigations, if determined adversely to us, could have a material adverse effect on our financial position and results of operations. Our ultimate liability with respect to any of these proceedings is not presently determinable.

We are involved in various other legal proceedings arising in the ordinary course of business, some of which involve substantial amounts. In order to obtain brand equivalent approvals prior to the expiration of patents on branded products, and to benefit from the exclusivity allowed to Abbreviated New Drug Application applicants that successfully challenge these patents, we frequently become involved in patent infringement litigation brought by branded pharmaceutical companies. Although these lawsuits involve products that are not yet marketed and therefore pose little or no risk of liability for damages, the legal fees and costs incurred in defending such litigation can be substantial. While it is not feasible to predict or determine the outcome or the total cost of these proceedings, in our opinion, based on a review with legal counsel, any losses resulting from such legal proceedings will not have a material adverse impact on our financial position or results of operations.

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

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows. We, in the normal course of doing business, are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

**Foreign Currency Exchange Rate Risk** – We have subsidiaries in more than 20 countries worldwide. During 2003, sales outside the United States accounted for approximately 51% of our worldwide sales. The majority of these sales were denominated in currencies of the local country. As such, our reported profits and cash flows are exposed to changing exchange rates. If the United States dollar weakens relative to the foreign currency, the earnings generated in the foreign currency will, in effect, increase when converted into United States dollars and vice versa. Although we do not speculate in the foreign exchange market, we do from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. As a result of exchange rate differences, net revenues increased by \$34.8 million in 2003 as compared to 2002 and decreased by \$45.2 million in 2002 compared to 2001. The effects of inflation on consolidated net revenues and operating income were not significant. Certain firmly committed transactions are hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated at current spot rates, with gains and losses included in earnings.

Our derivative activities, which primarily consist of foreign exchange forward contracts, are initiated primarily to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign

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exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We enter into these contracts with counterparties that we believe to be creditworthy and do not enter into any leveraged derivative transactions. We had \$16.2 million at December 31, 2003, and \$19.6 million at December 31, 2002, in foreign exchange forward contracts outstanding, primarily to hedge Euro-based operating cash flows against Pounds Sterling. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the consolidated statement of operations at maturity, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. As of December 31, 2001, we had \$68.7 million in foreign exchange forward contracts outstanding, of which \$55.0 million related to United States dollar denominated bank loans of \$48.0 million of our Argentine based subsidiary, IVAX Argentina. The \$48.0 million of bank loans were repaid in January 2002 resulting in a pretax loss of \$2.8 million.

Interest Rate Risk – Our only material debt obligations relate to the 1.5%, 4.5% and 5.5% Convertible Notes, which bear fixed rates of interest, and the amounts we owe for the purchase of QVAR<sup>®</sup> and other respiratory products, which carry no stated interest rate. We believe that our exposure to market risk relating to interest rate risk is not material.

### **Item 8. Financial Statements and Supplementary Data**

Our Financial Statements and supplementary data are on pages F-1 through F-43.

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

The disclosure required by this item has been previously reported in our current report on Form 8-K dated May 22, 2002, as amended on a Form 8-K/A dated May 24, 2002, and in our annual report on Form 10-K for the year ended December 31, 2002.

### **Item 9A. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

We have evaluated the design and operation of our disclosure controls and procedures to determine whether they are effective in ensuring that the disclosure of required information is timely made in accordance with the Exchange Act and the rules and forms of the Securities and Exchange Commission. This evaluation was made under the supervision and with the participation of management, including our principal executive officer and principal financial officer as of the end of the period covered by this Annual Report on Form 10-K. The principal executive officer and principal financial officer have concluded, based on their review and subject to the limitations noted below, that our disclosure controls and procedures, as defined at Exchange Act Rules 13a-14(c) and 15d-14(c), are effective to ensure that information required to be disclosed by us in reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

#### ***Changes in Internal Controls***

No significant changes were made to our internal controls or other factors that could significantly affect these controls subsequent to the date of their evaluation.

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### ***Limitations on the Effectiveness of Controls***

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and internal controls will prevent all error and fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

### ***Information Contained in Certifications***

Exhibits 31.1 and 31.2 to this annual report on Form 10-K are Certifications of our Chief Executive Officer and Chief Financial Officer which are required under the Sarbanes-Oxley Act of 2002. This item 9A, Controls and Procedures, is information concerning the evaluation referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

## **PART III**

### **Item 10. Directors and Executive Officers of the Registrant**

The information required by item 10 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of our 2003 year end. However, the information concerning executive officers required by item 10 is contained in the discussion entitled “Executive Officers of the Registrant” in Part I hereof.

### **Item 11. Executive Compensation**

The information required by item 11 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of our 2003 year end.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

The information required by item 12 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of our 2003 year end.

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### **Item 13. Certain Relationships and Related Transactions**

The information required by item 13 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of our 2003 year end.

### **Item 14. Principal Accountant Fees and Services**

The information required by item 14 is incorporated by reference to our Proxy Statement for our 2004 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission within 120 days after the close of our 2003 year end.

## **PART IV**

### **Item 15. Exhibits, Financial Statement Schedule and Reports on Form 8-K**

#### **(a)(1) Financial Statements**

See Item 8. "Financial Statements and Supplementary Data" for Financial Statements included with this Annual Report on Form 10-K.

#### **(a)(2) Financial Statement Schedule**

The following financial statement schedule is filed as a part of this report:

Schedule II Valuation and Qualifying Accounts for the three years ended December 31, 2003

All other schedules have been omitted because the required information is not applicable or the information is included in the consolidated financial statements or the notes thereto.

The independent auditors' report with respect to Schedule II is also filed as part of this report.

#### **(a)(3) Exhibits**

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Articles of Incorporation.	Incorporated by reference to our Form 8-B dated July 28, 1993.
3.2	Amended and Restated Bylaws.	Incorporated by reference to our Form 10-Q for the quarter ended June 30, 2002.
3.3	Articles of Amendment to Articles of Incorporation of IVAX Corporation.	Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2001.

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4.1	Indenture dated May 12, 2000, between IVAX Corporation and U.S. Bank Trust National Association, as Trustee, with respect to IVAX Corporation's 5 1/2% Convertible Subordinated Notes due May 15, 2007.	Incorporated by reference to our Form S-3 dated August 7, 2000.
4.2	Form of 5 1/2% Convertible Subordinated Notes due May 15, 2007 in Global Form.	Incorporated by reference to our Form S-3 dated August 7, 2000.
4.3	Rights Agreement, dated December 29, 1997, between IVAX Corporation and ChaseMellon Shareholder Services, L.L.C., with respect to the IVAX Corporation Shareholder Rights Plan.	Incorporated by reference to our Form 8-K dated December 19, 1997.
4.4	Indenture, dated as of May 4, 2001, between IVAX Corporation and U.S. Bank Trust National Association, as Trustee, with respect to the \$725,000,000 4 1/2% Convertible Senior Subordinated Notes due 2008.	Incorporated by reference to our Form S-3 dated July 31, 2001.
4.5	Form of 4 1/2% Convertible Senior Subordinated Notes due 2008.	Incorporated by reference to our Form S-3 dated July 31, 2001.
4.6	Indenture, dated as of March 3, 2004, between IVAX Corporation and U.S. Bank Trust National Association, as Trustee, with respect to the \$400,000,000 1 1/2% Convertible Senior Notes due 2024.	Filed herewith.
4.7	Form of 1 1/2% Convertible Senior Notes due 2024.	Filed herewith.
10.1	IVAX Corporation 1985 Stock Option Plan.	Incorporated by reference to our Form 10-K for the year ended December 31, 1997.
10.2	IVAX Corporation 1994 Stock Option Plan.	Incorporated by reference to our Form 10-K for the year ended December 31, 1997.
10.3	Form of Indemnification Agreement for Directors.	Incorporated by reference to our Form 8-B dated July 28, 1993.
10.4	Form of Indemnification Agreement for Officers.	Incorporated by reference to our Form 8-B dated July 28, 1993.
10.5	Agreement Containing Consent Order, dated December 6, 1994, between IVAX Corporation and the United States Federal Trade Commission.	Incorporated by reference to our Form 10-K for the year ended December 31, 1994.
10.6	Employment Agreement, dated November 28, 1997, between IVAX Corporation and Phillip Frost, M.D.	Incorporated by reference to our Form 10-K for the year ended December 31, 1997.

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10.7	Employment Agreement, dated November 28, 1997, between IVAX Corporation and Isaac Kaye.	Incorporated by reference to our Form 10-K for the year ended December 31, 1997.
10.8	Employment Agreement, dated January 19, 1998, between IVAX Corporation and Jane Hsiao, Ph.D.	Incorporated by reference to our Form 10-K for the year ended December 31, 1997.
10.9	Employment Agreement, dated July 28, 1997, between IVAX Corporation and Rafick G. Henein, Ph.D.	Incorporated by reference to our Form 10-Q for the quarter ended June 30, 1997.
10.10	Employment Agreement, dated as of May 26, 1998, between IVAX Corporation and Neil Flanzraich.	Incorporated by reference to our Form 10-Q for the quarter ended September 30, 1998.
10.11	Form of Employment Agreement (Change in Control) between IVAX Corporation and certain of its executive officers.	Incorporated by reference to our Form 10-K for the year ended December 31, 1998.
10.12	IVAX Corporation 1999 Employee Stock Purchase Plan.	Incorporated by reference to our Form 10-K for the year ended December 31, 1999.
10.13	IVAX Corporation 1997 Stock Option Plan.	Incorporated by reference to our Form S-8 dated December 22, 1997.
10.14	Warrant to Purchase Shares of Common Stock of IVAX Corporation dated November 18, 1999 between IVAX Corporation and Frost-Nevada Limited Partnership.	Incorporated by reference to our Form 10-K for the year ended December 31, 2000.
10.15	Registration Rights Agreement dated May 12, 2000 by and between IVAX Corporation, UBS Warburg LLC and ING Baring L.L.C.	Incorporated by reference to our Form S-3 dated August 7, 2000.
10.16	Form of Registration Rights Agreement between the Company and UBS AG.	Incorporated by reference to our Form S-3 dated April 10, 2001.
10.17	Registration Rights Agreement, dated May 4, 2001, between IVAX Corporation and UBS Warburg LLC, as the Initial Purchaser, with respect to the \$725,000,000 4 1/2% Convertible Senior Subordinated Notes due 2008.	Incorporated by reference to our Form S-3 dated July 31, 2001.

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10.18	Registration Rights Agreement, dated March 3, 2004, between IVAX Corporation and UBS Securities LLC, as the Initial Purchaser and as agent for the other Initial Purchasers, with respect to the \$400,000,000 1 1/2% Convertible Senior Notes due 2024.	Filed herewith.
10.19	Agreement to Tender dated as of May 18, 2001, among IVAX Corporation, Comercial e Inversiones Portfolio Limitada and Inversiones Portfolio S.A.	Incorporated by reference to our Form 8-K dated May 18, 2001.
10.20	Termination Agreement dated March 20, 1998 by and among NaPro BioTherapeutics, Inc., IVAX Corporation, Baker Norton Pharmaceuticals, Inc. and D & N Holding Company (Confidential Treatment Requested).	Incorporated by reference to our Form 10-K for the year ended December 31, 2001.
10.21	Retirement Agreement, dated as of May 8, 2003, between IVAX Corporation and Isaac Kaye.	Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2003.
10.22	Amendment dated June 12, 2003, to Employment Agreement between IVAX Corporation and Rafick G. Henein, Ph.D.	Incorporated by reference to our Form 10-Q for the quarter ended June 30, 2003.
21	Subsidiaries of IVAX Corporation.	Filed herewith.
23.1	Consent of Ernst & Young LLP.	Filed herewith.
23.2	Information Regarding Consent of Arthur Andersen LLP.	Filed herewith.
31.1	Certificate of the Chief Executive Officer of IVAX Corporation pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a).	Filed herewith.
31.2	Certificate of the Chief Financial Officer of IVAX Corporation pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a).	Filed herewith.
32.1	Certificate of the Chief Executive Officer of IVAX Corporation pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32.2	Certificate of the Chief Financial Officer of IVAX Corporation pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

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On October 30, 2003, we furnished a current report on Form 8-K to provide our earnings release for the third quarter of 2003. Such information shall not be deemed “filed” for purpose of Section 18 of the Exchange Act.



[Table of Contents](#)**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.

## IVAX CORPORATION

Dated: March 12, 2004

/s/ Phillip Frost, M.D.

By: \_\_\_\_\_

Phillip Frost, M.D.  
Chairman of the Board  
and Chief Executive Officer

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

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Phillip Frost, M.D.</u> Phillip Frost, M.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 12, 2004
<u>/s/ Thomas E. Beier</u> Thomas E. Beier	Chief Financial Officer (Principal Financial Officer)	March 12, 2004
<u>/s/ Thomas E. McClary</u> Thomas E. McClary	Vice President – Accounting (Principal Accounting Officer)	March 12, 2004
<u>/s/ Betty G. Amos</u> Betty G. Amos	Director	March 12, 2004
<u>/s/ Mark Andrews</u> Mark Andrews	Director	March 12, 2004
<u>/s/ Ernst Biekert, Ph.D.</u> Ernst Biekert, Ph.D.	Director	March 12, 2004
<u>/s/ Paul L. Cejas</u> Paul L. Cejas	Director	March 12, 2004

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<u>/s/ Jack Fishman, Ph.D.</u>	Director	March 12, 2004
Jack Fishman, Ph.D.		
<u>/s/ Neil Flanzraich</u>	Director, President and Vice Chairman	March 12, 2004
Neil Flanzraich		
<u>/s/ Bruce W. Greer</u>	Director	March 12, 2004
Bruce W. Greer		
<u>/s/ Jane Hsiao, Ph.D.</u>	Director and Vice Chairman- Technical and Regulatory Affairs	March 12, 2004
Jane Hsiao, Ph.D.		
<u>/s/ David A. Lieberman</u>	Director	March 12, 2004
David A. Lieberman		
<u>/s/ Modesto A. Maidique, Ph.D.</u>	Director	March 12, 2004
Modesto A. Maidique, Ph.D.		
<u>/s/ Richard C. Pfenniger, Jr.</u>	Director	March 12, 2004
Richard C. Pfenniger, Jr.		
<u>/s/Bertram Pitt, M.D.</u>	Director	March 12, 2004
Bertram Pitt, M.D.		

[Table of Contents](#)**REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS**

To the Board of Directors and Shareholders  
of IVAX Corporation:

We have audited the accompanying consolidated balance sheets of IVAX Corporation and subsidiaries as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity and cash flows for the years then ended. 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. The consolidated financial statements of IVAX Corporation and subsidiaries for the year ended December 31, 2001, were audited by other auditors who have ceased operations and whose report dated February 12, 2002, expressed an unqualified opinion on those statements prior to the revision described in Note 2.

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

In our opinion, the 2003 and 2002 financial statements referred to above present fairly, in all material respects, the consolidated financial position of IVAX Corporation and subsidiaries at December 31, 2003 and 2002, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for business combinations and goodwill and its method of reporting gains and losses on the extinguishment of debt during the year ended December 31, 2002.

As discussed above, the financial statements of IVAX Corporation and subsidiaries as of December 31, 2001 and for the year then ended, were audited by other auditors who have ceased operations. As described in Note 2, these financial statements have been revised to include the transitional disclosures required by Statement of Financial Accounting Standards (Statement) No. 142, *Goodwill and Other Intangible Assets*, which was adopted by the Company as of January 1, 2002. Our audit procedures with respect to the disclosures in Note 2 with respect to 2001 include (a) agreeing the previously reported net income to the previously issued financial statements and the adjustments to reported net income representing amortization expense (including any related tax effects) recognized in those periods related to goodwill, intangible assets that are no longer being amortized, and changes in amortization periods for intangible assets that will continue to be amortized as a result of initially applying Statement No. 142 (including any related tax effects) to the Company's underlying records obtained from management and (b) testing the mathematical accuracy of the reconciliation of adjusted net income to reported net income, and the related earnings-per-share amounts. In our opinion, the disclosures for 2001 in Note 2 described above are appropriate. However, we were not engaged to audit, review, or apply any procedures to the 2001 financial statements of the Company other than with respect to such disclosures and, accordingly, we do not express an opinion or any other form of assurance on the 2001 financial statements taken as a whole.

/s/ Ernst & Young LLP

Miami, Florida  
February 18, 2004, except for Note 17, as  
to which the date is March 3, 2004

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[Table of Contents](#)**REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS**

*To the Board of Directors and Shareholders  
of IVAX Corporation:*

We have audited the accompanying consolidated balance sheets of IVAX Corporation (a Florida corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IVAX Corporation and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

As explained in Note 2 to the financial statements, effective January 1, 2000, IVAX Corporation changed its method of accounting for up-front licensing fees to comply with Securities and Exchange Commission Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements.

As explained in Note 2 to the financial statements, effective January 1, 2001, IVAX Corporation changed its method of accounting for derivative instruments to comply with Statement of Financial Accounting Standard No. 133, Accounting for Derivative Instruments and Hedging Activities.

As explained in Note 2 to the financial statements, effective January 1, 2001, IVAX Corporation changed its method of accounting for equity derivative contracts to comply with Emerging Issues Task Force No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In, a Company's Own Stock.

ARTHUR ANDERSEN LLP

Miami, Florida,

February 12, 2002 (except with respect to  
the matters discussed in Note 16, as to  
which the date is March 15, 2002).

This is a copy of the audit report previously issued by Arthur Andersen LLP in connection with IVAX Corporation's filing on Form 10-K for the year ended December 31, 2001. This audit report has not been reissued by Arthur Andersen LLP in connection with this filing on Form 10-K. See Exhibit 23.2 for further discussion.

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except per share data)

	December 31,	
	2003	2002
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 146,870	\$ 155,408
Marketable securities	10,470	28,873
Accounts receivable, net of allowances for doubtful accounts of \$17,675 in 2003 and \$21,719 in 2002	264,317	224,768
Inventories	413,872	309,655
Other current assets	160,187	162,513
	995,716	881,217
Property, plant and equipment, net	502,942	420,246
Goodwill, net	489,665	407,403
Intangible assets, net	314,361	283,298
Other assets	70,250	55,595
	\$2,372,934	\$2,047,759
	\$2,372,934	\$2,047,759
<b><u>LIABILITIES AND SHAREHOLDERS' EQUITY</u></b>		
Current liabilities:		
Accounts payable	\$ 139,990	\$ 111,590
Current portion of long-term debt	58,607	28,617
Loans payable	17,804	14,935
Accrued income taxes payable	27,990	50,555
Accrued expenses and other current liabilities	242,158	228,366
	486,549	434,063
Long-term debt, net of current portion	855,335	872,339
Other long-term liabilities	56,208	46,115
Minority interest	12,531	10,379
Commitments and contingencies – see Note 14		
Shareholders' equity:		
Common stock, \$0.10 par value, authorized 437,500 shares, issued and outstanding 196,708 shares in 2003 and 194,372 in 2002	19,671	19,437
Capital in excess of par value	341,231	311,367
Retained earnings	690,476	569,225
Accumulated other comprehensive loss	(89,067)	(215,166)
	962,311	684,863
Total liabilities and shareholders' equity	\$2,372,934	\$2,047,759
	\$2,372,934	\$2,047,759

*The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.*

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

	Year Ended December 31,		
	2003	2002	2001
Net revenues	\$1,420,339	\$1,197,244	\$1,215,377
Cost of sales	781,383	663,708	583,588
Gross profit	638,956	533,536	631,789
Operating expenses:			
Selling	212,192	168,952	143,629
General and administrative	122,414	118,416	110,477
Research and development	108,347	76,041	88,015
Amortization of intangible assets	19,719	16,158	19,412
Restructuring costs	3,706	4,242	2,367
Total operating expenses	466,378	383,809	363,900
Operating income	172,578	149,727	267,889
Other income (expense):			
Interest income	3,710	8,090	21,249
Interest expense	(43,608)	(48,639)	(41,791)
Other income, net	11,738	60,321	49,637
Total other income (expense)	(28,160)	19,772	29,095
Income before income taxes and minority interest	144,418	169,499	296,984
Provision for income taxes	45,559	51,742	54,065
Income before minority interest	98,859	117,757	242,919
Minority interest	188	838	344
Income from continuing operations	99,047	118,595	243,263
Income from discontinued operations, net of tax of \$12,763	22,204	—	—
Cumulative effect of accounting change	—	4,161	—
Net income	\$ 121,251	\$ 122,756	\$ 243,263
Basic earnings per common share:			
Continuing operations	\$ 0.51	\$ 0.61	\$ 1.22
Discontinued operations	0.11	—	—
Cumulative effect of accounting change	—	0.02	—
Net income	\$ 0.62	\$ 0.63	\$ 1.22
Diluted earnings per common share:			
Continuing operations	\$ 0.50	\$ 0.60	\$ 1.19
Discontinued operations	0.11	—	—
Cumulative effect of accounting change	—	0.02	—
Net income	\$ 0.61	\$ 0.62	\$ 1.19

Weighted average number of common shares outstanding:

Basic	195,626	195,037	199,099
Diluted	198,900	197,378	204,639

*The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.*

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
(In thousands)

	Common Stock		Capital in Excess of Par Value	Put Options	Retained Earnings	Accumulated Other Comprehensive Loss	Total
	Number of Shares	Amount					
<b>BALANCE</b> , January 1, 2001	198,546	\$ 19,855	\$ 315,039	\$ —	\$ 203,206	\$ (53,980)	\$ 484,120
Comprehensive income:							
Net income	—	—	—	—	243,263	—	243,263
Translation adjustment	—	—	—	—	—	(57,613)	(57,613)
Unrealized net gain on available-for-sale equity securities and derivatives, net of tax	—	—	—	—	—	1,081	1,081
Comprehensive income							186,731
Exercise of stock options	1,531	153	13,870	—	—	—	14,023
Tax benefit of option exercises	—	—	18,001	—	—	—	18,001
Employee stock purchases	38	4	823	—	—	—	827
Repurchase of common stock	(6,779)	(678)	(146,634)	(7,785)	—	—	(155,097)
Shares issued in acquisitions	2,873	287	79,963	—	—	—	80,250
Reclassification of put options from temporary equity	—	—	—	84,503	—	—	84,503
Put options issued – net of premium received	—	—	(74,202)	79,025	—	—	4,823
Expired put options	—	—	80,608	(80,608)	—	—	—
Shares issued to settle put options	314	31	40,454	(40,485)	—	—	—
Value of stock options issued to non-employees	—	—	173	—	—	—	173
<b>BALANCE</b> , December 31, 2001	196,523	19,652	328,095	34,650	446,469	(110,512)	718,354
Comprehensive income:							
Net income	—	—	—	—	122,756	—	122,756
Translation adjustment	—	—	—	—	—	(104,816)	(104,816)
Unrealized net gain on available-for-sale equity securities and derivatives, net of tax	—	—	—	—	—	162	162
Comprehensive income							18,102
Exercise of stock options	681	68	5,188	—	—	—	5,256
Tax benefit of option exercises	—	—	1,467	—	—	—	1,467
Employee stock purchases	79	8	920	—	—	—	928
Repurchase of common stock	(3,882)	(388)	(46,315)	(12,725)	—	—	(59,428)



Shares issued to settle put options	971	97	21,828	(21,925)	—	—	—
Value of stock options issued to non-employees	—	—	184	—	—	—	184
<b>BALANCE, December 31, 2002</b>	<u>194,372</u>	<u>\$19,437</u>	<u>\$ 311,367</u>	<u>\$ —</u>	<u>\$569,225</u>	<u>\$ (215,166)</u>	<u>\$ 684,863</u>

(Continued)

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

(In thousands)

(Continuation)

	Common Stock		Capital in Excess of Par Value	Put Options	Retained Earnings	Accumulated Other Comprehensive Loss	Total
	Number of Shares	Amount					
<b>BALANCE, December 31, 2002</b>	194,372	\$19,437	\$311,367	\$ —	\$ 569,225	\$ (215,166)	\$684,863
Comprehensive income:							
Net income	—	—	—	—	121,251	—	121,251
Translation adjustment	—	—	—	—	—	125,651	125,651
Unrealized net gain on available-for-sale equity securities and derivatives, net of tax	—	—	—	—	—	448	448
Comprehensive income							247,350
Exercise of stock options	1,710	171	17,004	—	—	—	17,175
Tax benefit of option exercises	—	—	4,278	—	—	—	4,278
Employee stock purchases	89	9	1,029	—	—	—	1,038
Repurchase of common stock	(700)	(70)	(8,927)	—	—	—	(8,997)
Shares issued in acquisitions	1,237	124	16,366	—	—	—	16,490
Value of stock options issued to non-employees	—	—	114	—	—	—	114
<b>BALANCE, December 31, 2003</b>	196,708	\$19,671	\$341,231	\$ —	\$ 690,476	\$ (89,067)	\$962,311

*The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.*

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2003	2002	2001
Cash flows from operating activities:			
Net income	\$ 121,251	\$ 122,756	\$ 243,263
Adjustments to reconcile net income to net cash flows from operating activities:			
Restructuring accrual	3,706	4,242	2,367
Depreciation and amortization	76,808	59,877	52,158
Deferred tax provision (benefit)	17,099	(8,110)	(43,645)
Tax benefit of stock option exercises	4,278	1,467	18,001
Value of stock options issued to non-employees	114	184	173
Provision for (reversal of) doubtful accounts	(1,948)	4,239	1,143
Provision for inventory obsolescence	31,017	15,446	25,397
Interest accretion on notes receivable and payable, net	2,378	1,935	—
Minority interest in earnings	(188)	(838)	(344)
Equity in earnings of unconsolidated affiliates	(1,645)	(877)	(1,070)
Gains (loss) on sale of marketable securities	1,106	(4)	(3,807)
Gains on sale of product rights	(12,835)	(35,150)	(13,792)
Losses (gain) on sale of assets, net	119	2,930	(12,328)
Gains on extinguishment of debt	(2,323)	(17,346)	(11,302)
Income from discontinued operations	(22,204)	—	—
Cumulative effect of accounting change	—	(4,161)	—
Changes in operating assets and liabilities:			
Accounts receivable	(18,465)	12,493	(37,643)
Inventories	(111,953)	(68,591)	(45,920)
Other current assets	671	(293)	(34,680)
Other assets	753	5,800	3,059
Accounts payable, accrued expenses and other current liabilities	(3,880)	48,318	62,547
Other long-term liabilities	(1,261)	6,821	(4,540)
Net cash flows from operating activities	82,598	151,138	199,037
Cash flows from investing activities:			
Proceeds from sale of product rights	12,835	35,150	13,792
Capital expenditures	(95,358)	(98,670)	(73,484)
Proceeds from sales of assets	2,025	1,602	41,668
Acquisitions of intangible assets	(7,798)	(38,274)	(133,864)
Acquisitions of businesses, net of cash acquired	(27,110)	3,629	(466,153)
Investment in affiliates	3,658	(3,677)	(14,052)
Purchases of marketable securities	(36,095)	(445,864)	(378,176)
Proceeds from sales of marketable securities	63,296	574,429	304,955
Net proceeds from discontinued operations	8,824	—	—
Net cash flows from investing activities	(75,723)	28,325	(705,314)
Cash flows from financing activities:			
Borrowings on long-term debt and loans payable	28,598	12,745	723,818
Payments on long-term debt and loans payable	(67,298)	(138,812)	(95,533)
Exercise of stock options and employee stock purchases	18,213	6,184	14,850
Repurchase of common stock, net of put option premium	(8,997)	(59,428)	(150,274)

Net cash flows from financing activities	(29,484)	(179,311)	492,861
Effect of exchange rate changes on cash and cash equivalents	14,071	(23,008)	16,886
Net (decrease) increase in cash and cash equivalents	(8,538)	(22,856)	3,470
Cash and cash equivalents at the beginning of the year	155,408	178,264	174,794
Cash and cash equivalents at the end of the year	\$ 146,870	\$ 155,408	\$ 178,264

(Continued)

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**IVAX CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

(Continuation)

	Year Ended December 31,		
	2003	2002	2001
Supplemental disclosures:			
Interest paid, net of capitalized interest	\$39,619	\$44,671	\$ 12,563
	\$51,907	\$46,585	\$ 50,890
Income tax payments			
Supplemental schedule of non-cash investing and financing activities:			
Purchase of intangible assets through the issuance of debt		\$80,054	
		\$80,054	
Information with respect to acquisitions accounted for under the purchase method of accounting is summarized as follows:			
Fair value of assets acquired	\$55,890		\$ 238,862
Liabilities assumed	(4,874)		(180,834)
	51,016		58,028
Net assets acquired			
Purchase price:			
Cash, net of cash acquired	25,592		459,788
Acquisition costs	1,518		6,365
Present value of future minimum royalty payments	48,638		—
Fair market value of stock and options issued	16,490		79,750
	92,238		545,903
Total			
Goodwill	\$41,222		\$ 487,875
	\$41,222		\$ 487,875

*The accompanying Notes to Consolidated Financial Statements are an integral part of these financial statements.*

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**IVAX CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

(In thousands, except per share data)

**(1) Organization:**

IVAX Corporation is a multinational company engaged in the research, development, manufacture and marketing of pharmaceutical products. These products are sold primarily to customers within the United States, Europe and Latin America. All references to “IVAX,” “our,” “us” or “we” mean IVAX Corporation and its subsidiaries unless otherwise required by the context.

**(2) Summary of Significant Accounting Policies:**

Principles of Consolidation – The accompanying consolidated financial statements include the accounts of IVAX Corporation and its subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation. Investments in affiliates representing 20% to 50% ownership interests are recorded under the equity method of accounting. Investments in affiliates representing less than 20% ownership interests are recorded at cost. The minority interest held by third parties in majority owned subsidiaries is separately stated. For purposes of these financial statements, North America includes the United States and Canada. Mexico is included within Latin America. Certain amounts presented in the accompanying consolidated financial statements for prior periods have been reclassified to conform to the current year presentation.

Use of Estimates – The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions in certain circumstances that affect the reported amounts of assets and liabilities and the reported amounts of revenues and expenses during the reporting period. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. We base our estimates and judgments on historical experience and other assumptions that we believe are reasonable. However, application of these accounting policies involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, actual results could differ materially from these estimates. We periodically evaluate estimates and assumptions used in the preparation of the financial statements and make changes on a prospective basis when adjustments are necessary. Significant estimates include amounts for accounts receivable exposures, deferred tax asset allowances, inventory reserves, environmental reserves, litigation and sales returns and allowances, including, but not limited to, chargebacks, rebates, returns and shelf-stock adjustments, and the useful lives of intangible assets.

As a result of our recent return, customer inventory experience, analysis of allowance for doubtful accounts and tax reserves, our estimates of product returns and other sales allowances, inventory obsolescence, allowance for doubtful accounts and income tax exposures decreased and, accordingly, we recognized increased net revenues, reduced cost of sales, reduced bad debt expense and reduced income tax provision during 2003. During the year ended December 31, 2003, these changes increased net revenues by \$13,733, reduced cost of sales by \$824, reduced bad debt expense by \$3,673, reduced the income tax provision by \$2,700, increased net income by \$14,029 and increased diluted earnings per share by \$0.07.

Cash and Cash Equivalents – We consider all investments with a maturity of three months or less as of the date of purchase to be cash equivalents.

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**Marketable Securities** – Short-term investments in marketable debt securities generally mature between three months and three years from date of purchase or are auction rate securities with final maturities longer than three years, but with interest rate auctions occurring every 28 or 35 days. These short-term marketable securities consist primarily of taxable municipal bonds, corporate bonds, government agency securities and commercial paper. It is our intent to maintain a liquid portfolio to take advantage of investment opportunities; therefore, most securities are deemed short-term, are classified as available for sale securities and are recorded at market value using the specific identification method. Unrealized gains and losses, net of tax, are reflected in “Accumulated other comprehensive loss” in the accompanying consolidated balance sheets. Realized gains and losses are included in “Other income” in the accompanying consolidated statements of operations using the specific identification method.

Investments in marketable securities consist of the following:

	December 31, 2003			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Mutual funds	\$ 8,776	\$ —	\$ —	\$ 8,776
Auction rate securities	1,660	—	—	1,660
Equity securities	1,016	434	—	1,450
Total marketable securities	11,452	434	—	11,886
Less: Short-term marketable securities	10,470	—	—	10,470
Long-term marketable securities	\$ 982	\$ 434	\$ —	\$ 1,416
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
	December 31, 2002			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Market Value
Mutual funds	\$ 2,667	\$ 19	\$ —	\$ 2,686
Auction rate securities	21,150	—	—	21,150
Corporate bonds	5,084	—	(47)	5,037
Equity securities	9,264	88	(51)	9,301
Total marketable securities	38,165	107	(98)	38,174
Less: Short-term marketable securities	28,901	19	(47)	28,873
Long-term marketable securities	\$ 9,264	\$ 88	\$ (51)	\$ 9,301
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

**Long-Term Investments** – We have investments in three marketable securities that are deemed long-term, available for sale, which are marked to market value using the specific identification method. Unrealized gains and losses, net of tax, are reflected in “Accumulated other comprehensive loss” in the accompanying consolidated balance sheets. Realized gains and losses are included in “Other income” in the accompanying consolidated statements of operations using the specific identification method. In addition, we have one investment in a limited investment partnership. In accordance with Emerging Issues Task Force (“EITF”) Topic D-46, *Accounting for Limited Partnership Investments*, investments in limited investment partnerships representing greater than 5% ownership interests are considered to be more than minor and are accounted for under the equity method; otherwise, they are carried at cost. These investments are included in “Other assets” in the accompanying consolidated balance sheets.

**Inventories** – Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. In evaluating whether inventory is stated at the lower of cost or market, we consider such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life of the inventory and current market price of the inventory.

Inventories consist of the following:

	December 31,	
	2003	2002
Raw materials	\$155,159	\$117,485
Work-in-process	65,194	50,678
Finished goods	193,519	141,492
Total inventories	<u>\$413,872</u>	<u>\$309,655</u>

As of December 31, 2003, we had approximately \$24,778 in inventories relating to products pending launch while we await receipt of final FDA or foreign governmental marketing approval and/or satisfactory resolution of patent infringement litigation.

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Property, Plant and Equipment – Property, plant and equipment are carried at cost less accumulated depreciation and amortization and consist of the following:

	December 31,	
	2003	2002
Land	\$ 24,758	\$ 21,881
Buildings and improvements	255,863	202,894
Machinery and equipment	323,210	246,397
Furniture and computer equipment	92,875	78,576
Construction in process	84,428	77,862
	<hr/>	<hr/>
Total cost	781,134	627,610
Less: Accumulated depreciation and amortization	278,192	207,364
	<hr/>	<hr/>
Property, plant and equipment, net	\$502,942	\$420,246
	<hr/> <hr/>	<hr/> <hr/>

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows: buildings and improvements (10 - 40 years), machinery and equipment (3 - 20 years) and furniture and computer equipment (2 - 10 years). Leasehold improvements are amortized on a straight-line basis over the shorter of the term of the lease or their estimated useful lives. Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs that do not extend the life of the assets are expensed. Upon sale or disposition of property, plant and equipment, the cost and related accumulated depreciation or amortization are eliminated from the accounts and any resulting gain or loss is credited or charged to operations. Depreciation expense was \$56,387 in 2003, \$42,848 in 2002 and \$32,062 in 2001.

Capitalization of Software Development Costs – Costs associated with software developed or obtained for internal use are capitalized when (1) the preliminary project stage is completed and (2) management has authorized further funding for the project, it is probable that the project will be completed and the software will be used for the intended purpose. Costs capitalized include (1) external direct costs of materials and services consumed, (2) payroll and payroll-related costs for employees directly associated with or who devote time to the project and (3) interest costs incurred while developing the software. Upgrades and enhancements that add functionality are capitalized. Costs of training, maintenance, data conversion and nonspecific upgrades and enhancements are expensed.

Capitalization of Interest – Interest capitalized on certain construction projects was \$2,109 in 2003 and \$430 in 2002.

Intangible Assets – Effective July 1, 2001, we adopted the provisions of Statement of Financial Accounting Standards (“SFAS”) No. 142, *Goodwill and Other Intangible Assets*, relating to the amortization of goodwill. Goodwill of companies acquired prior to June 30, 2001, was amortized through December 31, 2001. Amortization of goodwill of companies acquired after June 30, 2001, is no longer allowed. Effective January 1, 2002, all goodwill amortization ceased and goodwill is evaluated for impairment annually. No goodwill impairments were identified during 2003 or 2002.

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Intangible assets with definite lives are amortized and carried at cost less accumulated amortization. Intangible assets with indefinite lives are carried at cost, are not amortized and are tested for impairment annually. Intangible assets consist of the following:

	December 31,			
	2003		2002	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Amortized intangible assets:				
Patents and related licenses	\$ 75,642	\$ 48,468	\$ 71,716	\$ 40,989
Trademarks	131,688	13,855	113,160	7,518
Licenses and other intangibles	161,548	17,473	132,457	7,205
Total	<u>\$368,878</u>	<u>\$ 79,796</u>	<u>\$317,333</u>	<u>\$ 55,712</u>
Unamortized intangible assets:				
Trademarks and product registrations	<u>\$ 25,279</u>		<u>\$ 21,677</u>	

Patents, trademarks, licenses and other intangible assets with finite lives are amortized using the straight-line method over their respective estimated lives (ranging from 1 - 20 years), while those with indefinite lives are not amortized. On an annual basis by region, we evaluate the recoverability of intangible assets and evaluate events or circumstances that have occurred that warrant revising estimates of useful lives or that indicate that an impairment exists. The weighted average life of patents, trademarks, licenses and other intangibles was 15.6 years at December 31, 2003, and 13.0 years at December 31, 2002. Amortization expense was \$20,421 in 2003, \$17,029 in 2002 and \$20,096 in 2001.

Estimated intangible assets amortization expense for the next five years is approximately \$23,117 in 2004, \$22,640 in 2005, \$21,360 in 2006, \$23,147 in 2007, and \$21,177 in 2008.

On July 1, 2002, in connection with the termination of a license granted by us to specified products in our proprietary dry powder inhaler device ("MDPI"), we entered into an agreement to acquire the technical files, trademark and related rights invented or produced by the licensee in connection with the commercialization of products under the license. The total consideration due was 5,000 Pounds Sterling (\$7,665 at the July 1, 2002, currency exchange rate), of which 1,400 Pounds Sterling (\$2,232 at the January 2, 2003, currency exchange rate) was paid in 2003. The purchase price was allocated to other intangible assets and is being amortized over its estimated useful life of ten years. An additional payment of between 250 to 1,100 Pounds Sterling will be paid to the licensee upon the receipt of marketing approval and launch of a specified product using the acquired rights and data.

On April 22, 2002, we acquired an exclusive United States license to the patent rights to market QVAR<sup>®</sup> (beclomethasone dipropionate HFA), an aerosol inhaler prescribed to treat asthma. In addition, we have an option to obtain ownership of the United States QVAR<sup>®</sup> trademark, as well as related patents and the New Drug Application on April 21, 2007. 3M Drug Delivery Systems will manufacture the QVAR<sup>®</sup> product for us under a long-term contract. We also acquired a non-exclusive worldwide license to certain 3M patents covering HFA formulations of various asthma drugs. The purchase price was allocated to the fair values of the assets acquired resulting in a value of \$27,140 for the license agreement, which is being amortized over its five-year life, and \$67,141 for the option, which is not being amortized. If the option is exercised, the value of the option will be allocated to the underlying assets acquired by the exercise and appropriate lives determined. The total consideration due from us under the contract, including options and extensions, is \$105,000, of which \$21,000 was paid on the effective date and \$20,000 was paid on the first anniversary. We are entitled to reduce the purchase price by \$4,000 for required pediatric trials. The remaining payments due from us are: \$30,000 on the second anniversary, \$25,000 on the third anniversary and \$5,000 on the fifth anniversary upon exercise of the option, subject to reimbursement of all or a portion of the \$4,000 in the event we do not continue the pediatric trials. The present value of the payments due are recorded as long-term debt.

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On April 2, 2002, we entered into an agreement to acquire the technical files and French marketing authorizations to substantially all of the products comprising the generic pharmaceutical business of Merck & Co., Inc.'s subsidiary in France. The total consideration due was 5,641 Euros (\$4,917 at the March 31, 2002, currency exchange rate), one-half of which was paid upon signing and the remainder in four months. The purchase price was recorded as other intangible assets, which is being amortized over its estimated useful life of ten years. On July 19, 2002, the agreement was amended reducing the second payment to 2,565 Euros (\$2,531 as of the August 2, 2002, payment date).

On March 1, 2002, we acquired from Syntex Pharmaceuticals International Ltd. the non-United States rights to pharmaceutical products containing flunisolide hemihydrate, sold under the trademarks Syntaris™, Nasalide®, Rhinalar™, Locasyn™ and Lokilan™, for 10,156 Swiss francs (\$5,986 at the February 28, 2002, currency exchange rate). As of December 31, 2003, the final allocation of the intangible assets, net of accumulated amortization, is \$3,970 of trademarks, \$562 of patents and related licenses and \$504 of licenses and other intangibles. These intangible assets are amortized over their fourteen-year weighted average life.

Impairment of Long-Lived Assets – We continually evaluate whether events and circumstances have occurred that indicate the remaining estimated useful life of long-lived assets may require revision or the remaining net book value may not be recoverable. When factors indicate that an asset may be impaired, we use various methods to estimate the asset's 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 based on the excess of the carrying amount over the estimated fair value of the asset. Any impairment amount is charged to operations.

Foreign Currencies – Our operations include subsidiaries which are located outside of the United States. Assets and liabilities as stated in local currencies are translated at the rate of exchange prevailing at the balance sheet date. The gains or losses that result from this process are shown in "Accumulated other comprehensive loss" in the accompanying consolidated balance sheets. Amounts in the statements of operations are translated at the average rates for the period. Foreign currency transaction gains and losses arising from cash transactions are credited to or charged against current earnings. Laboratorios Elmor, S.A. is located in Venezuela, which was considered a hyperinflationary economic environment through June 30, 2001. Prior to July 1, 2001, its local currency financial statements were remeasured into the United States dollar by translating monetary assets and liabilities at the current exchange rate, non-monetary assets and expenses related to non-monetary assets at the historical rates, and revenues and expenses at the average exchange rate in effect during the year. The resulting translation adjustment was included in the results of operations.

Financial Instruments – The carrying amounts of cash and cash equivalents, accounts receivable, loans payable and accounts payable approximate fair value due to the short maturity of the instruments and reserves for potential losses, as applicable. The disclosed fair value of marketable securities, other assets and long-term debt is estimated using quoted market prices, whenever available, or an appropriate valuation method (See Note 7, Investments In and Advances to Unconsolidated Affiliates, and Note 8, Debt).

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We do not speculate in the foreign exchange market. We may, however, from time to time, manage exposures that arise in the normal course of business related to fluctuations in foreign currency rates by entering into foreign exchange forward contracts. We enter into these contracts with counterparties that we believe to be creditworthy and do not enter into any leveraged derivative transactions. These foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity date. As the exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are generally recognized in the consolidated statements of operations at maturity. Costs associated with entering into these contracts are amortized over the contracts' lives, which typically are less than one year. We held foreign exchange forward contracts with notional principal amounts of \$16,188 at December 31, 2003, which mature in January 2004 through July 2004, and \$19,586 at December 31, 2002, which matured from January 2003 through August 2003, primarily to hedge Euro-based operating cash flows against Pounds Sterling.

Prior to its acquisition by us, Laboratorio Chile S.A. ("Lab Chile") engaged in a partial hedge of its then \$63,000 United States dollar denominated loans against a possible devaluation of the Argentine peso, by entering into forward contracts in early 2001 to purchase \$55,000 United States dollars at contract prices ranging from 1.0405 pesos to 1.0412 pesos with expiration dates in January 2002. If the contracts expired unexercised, a fee of \$2,247 would have been paid. Due to the lack of liquidity in the currency forwards market in Argentina on July 5, 2001, (the date we acquired Lab Chile), the most reliable indicator of fair value was the amortized amount of the original contract fee. Accordingly, these contracts were recorded as an asset and a liability at the original contract fee amount and the asset was amortized over the life of the contracts. Due to the devaluation of the Argentine peso and the Argentine government halting foreign exchange transactions from mid-December 2001 through approximately January 11, 2002, the contracts were valued at December 31, 2001, at the negotiated amounts at which the contracts were settled during January 2002 resulting in a pretax gain of \$21,655 recorded at December 31, 2001, which was recorded in other income.

In addition, we have short-term balances that are denominated in foreign currencies. A portion of these balances are hedged, from time to time, using foreign exchange forward contracts, and gains and losses on these contracts are included in the consolidated statements of operations as they arise. We incurred net foreign exchange transaction losses of \$10,013 in 2003 and \$1,056 in 2002, and net foreign exchange transaction gains of \$2,728 in 2001, which are included in "Other income, net" in the accompanying consolidated statements of operations.

Concentration of Credit Risk – We sell a significant amount of United States brand equivalent pharmaceutical products to a relatively small number of retail drug chains and drug wholesalers, which represents an essential part of the distribution chain of pharmaceutical products in the United States. Credit is extended based on an evaluation of the customer's financial condition and collateral is generally not required. We monitor the credit worthiness of our customers and review outstanding receivable balances for collectibility on a regular basis and record allowances for doubtful accounts as necessary.

We follow an investment policy that limits investments in individual issuers that meet certain minimum credit rating and size requirements, generally, to the lesser of \$10,000 or 10% of program size.

Revenue Recognition – Revenues and the related cost of sales are recognized at the time title to our products and the risks and rewards of ownership passes to customers. Net revenues are comprised of gross revenues less provisions for expected customer returns, inventory credits, discounts, promotional allowances, rebates, chargebacks, reimbursements relating to Medicaid and Medicare and other

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allowances. These sales provisions totaled \$647,264 in 2003, \$664,565 in 2002 and \$433,653 in 2001. The reserve balances related to these provisions are included in the following balance sheet accounts:

	December 31,	
	2003	2002
Accounts receivable	\$136,475	\$147,580
Accrued expenses	110,079	94,937
 Total sales returns and allowances reserves	 \$246,554	 \$242,517

The custom in the United States pharmaceutical industry is generally to grant customers the right to return purchased goods. In the generic pharmaceutical industry, this custom has resulted in a practice of suppliers issuing inventory credits (also known as shelf-stock adjustments) to customers based on the customers' existing inventory following decreases in the market price of the related generic pharmaceutical product. Contractual agreements with many customers require that we grant these customers inventory credit following a price decrease. In other cases, the determination to grant a credit to a customer following a price decrease is at our discretion. These credits allow customers with established inventories to compete with those buying product at the current market price, and allow us to maintain shelf space, market share and customer loyalty.

We establish provisions for estimated returns, inventory credits and chargebacks, as well as other sales allowances, concurrently with the recognition of revenue. The provisions are established in accordance with accounting principles generally accepted in the United States based upon consideration of a variety of factors, including actual return and inventory credit experience for products during the past several years, the number and timing of regulatory approvals for the product by our competitors (both historical and projected), the market for the product, expected sell-through levels by our wholesale customers to customers with contractual pricing arrangements with us, estimated customer inventory levels and projected economic conditions. Actual product returns and inventory credits incurred are, however, dependent upon future events, including remaining shelf-life, price competition and the level of customer inventories at the time of any price decreases. We continually monitor the factors that influence the pricing of our products and customer inventory levels and make adjustments to these provisions when we believe that actual product returns, inventory credits and other allowances may differ from established reserves.

Royalty and license fee income are recognized when obligations associated with earning the royalty or licensing fee have been satisfied and are included in "Net revenues" in the accompanying consolidated statements of operations. Royalties earned under license agreements were \$1,837 in 2003, \$745 in 2002 and \$879 in 2001. In accordance with EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, our accounting policy is to review each contract to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenue is recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. Up-front payments are deferred, if appropriate, and recognized into revenues over the obligation period. Other revenues included \$318 in 2002 and \$879 in 2001 of amortization of revenue deferred in accordance with SAB No. 101. Upon termination of a license agreement, during 2002, the remaining \$5,981 of deferred revenue was recognized in income.

Shipping and handling fees billed to customers are recognized in net revenues. Shipping and handling costs are included in cost of sales.

Legal Costs – Legal charges are recorded for the costs anticipated to be incurred in connection with litigation and claims against us when we can reasonably estimate these costs.

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Research and Development Costs – Research and developments costs related to future products are expensed currently.

Sale of Subsidiary Stock – We elected income statement recognition as our accounting policy for sales of subsidiary stock. Accordingly, gains and losses on sales are recorded in “Other income” in the consolidated statement of operations.

Income Taxes – The provision for income taxes is based on the consolidated United States entities’ and individual foreign companies’ estimated tax rates for the applicable year. Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax basis of assets and liabilities under the applicable tax laws. Deferred income tax provisions and benefits are based on the changes in the deferred tax asset or tax liability from period to period (See Note 10, Income Taxes).

Earnings Per Common Share – A reconciliation of the denominator of the basic and diluted earnings per share computation for income from continuing operations is as follows:

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Basic weighted average number of shares outstanding	195,626	195,037	199,099
Effect of dilutive securities – stock options and warrants	3,274	2,341	5,540
Diluted weighted average number of shares outstanding	<u>198,900</u>	<u>197,378</u>	<u>204,639</u>
Not included in the calculation of diluted earnings per share because their impact is antidilutive:			
Stock options outstanding	9,017	13,669	2,784
Convertible debt	21,895	23,643	24,891

Accumulated Other Comprehensive Loss – Other comprehensive loss refers to revenues, expenses, gains and losses that under accounting principles generally accepted in the United States are excluded from net income as these amounts are recorded directly as an adjustment to shareholders’ equity. Accumulated other comprehensive loss is comprised of the cumulative effects of foreign currency translation and unrealized gains and losses on available for sale equity securities and derivatives.

Stock-Based Compensation Plans – As permissible under SFAS No. 123, *Accounting for Stock-Based Compensation*, we account for all stock-based compensation arrangements using the intrinsic value method prescribed by Accounting Principles Board Opinion (“APB”) No. 25, *Accounting for Stock Issued to Employees*, as interpreted by Financial Accounting Standards Board (“FASB”) Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, and disclose pro forma net earnings and earnings per share amounts as if the fair value method had been adopted. Accordingly, no compensation cost is recognized for stock option awards granted to employees at or above fair market value.

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Our pro forma net income, pro forma net income per common share and pro forma weighted average fair value of options granted, with related assumptions, assuming we had adopted the fair value method of accounting for all stock-based compensation arrangements consistent with the provisions of SFAS No. 123, using the Black-Scholes option pricing model for all options granted after January 1, 1995, are indicated below:

	Year Ended December 31,		
	2003	2002	2001
Net income as reported	\$121,251	\$122,756	\$243,263
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	20,702	19,034	20,139
Pro forma net income	\$100,549	\$103,722	\$223,124
Basic net income per share as reported	0.62	0.63	1.22
Pro forma basic net income per share	0.51	0.53	1.12
Diluted net income per share as reported	0.61	0.62	1.19
Pro forma diluted net income per share	0.51	0.53	1.09
Pro forma weighted average fair value of options granted	\$ 16.60	\$ 7.99	\$ 12.03
Expected life (years)	4.8	5.3	5.6
Risk-free interest rate	2.7-4.0%	3.4-4.8%	3.9-5.2%
Expected volatility	26%	27%	30%
Dividend yield	0%	0%	0%

As the SFAS No. 123 method of accounting has not been applied to options granted prior to January 1, 1995, the resulting pro forma compensation cost may not be representative of that to be expected in future years. In addition, valuations are based on highly subjective assumptions about the future, including stock price volatility and exercise patterns.

**Recently Issued Accounting Standards** – In June 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) normal operation of a long-lived asset, except for certain obligations of lessees. It requires that the fair value of an asset retirement obligation be recognized as a liability in the period in which it is incurred if a reasonable estimate can be made and that the associated retirement costs be capitalized as part of the carrying amount of the long-lived asset. It is effective for fiscal years beginning after June 15, 2002. The impact of adoption of this statement was not significant.

In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. It supersedes SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of*, and certain provisions of APB No. 30, *Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, for the disposal of a segment of a business. It also amends Accounting Research Bulletin No. 51, *Consolidated Financial Statements*. It establishes a single accounting model for the accounting for a segment of a business accounted for as a discontinued operation that was not addressed by SFAS No. 121 and resolves other implementation issues related to SFAS No. 121. It is effective for fiscal periods beginning after December 15, 2001. The impact of adoption of this statement was not significant.

Effective January 1, 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Assets*. Intangible assets that have indefinite lives and goodwill are no longer amortized. This increased net income by approximately \$1,750 per quarter, or \$7,000 per year. The life of one product intangible asset with a net book value of \$6,519 as of January 1, 2002, was extended based on a review of the expected remaining estimated useful life. During 2002, intangible assets with indefinite lives were tested for

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impairment resulting in the write-down of one intangible asset by \$177. The initial test for impairment of goodwill as of January 1, 2002, was completed during the second quarter and no impairments were indicated. During 2003, impairment testing of goodwill and intangible assets with indefinite lives was performed and no impairments were indicated.

### Goodwill and Other Intangible Assets – Adoption of SFAS No. 142:

	Year Ended December 31,		
	2003	2002	2001
Reported net income	\$ 121,251	\$ 122,756	\$ 243,263
Addback: Goodwill amortization	—	—	5,209
Addback: Workforce in place amortization	—	—	216
Adjust: Product intangible amortization	—	—	3,611
Adjusted net income	\$ 121,251	\$ 122,756	\$ 252,299
Basic earnings per common share:			
Reported net income	\$ 0.62	\$ 0.63	\$ 1.22
Goodwill amortization	—	—	0.03
Product intangible amortization	—	—	0.02
Adjusted net income	\$ 0.62	\$ 0.63	\$ 1.27
Diluted earnings per common share:			
Reported net income	\$ 0.61	\$ 0.62	\$ 1.19
Goodwill amortization	—	—	0.03
Product intangible amortization	—	—	0.02
Adjusted net income, diluted	\$ 0.61	\$ 0.62	\$ 1.24

The following table displays the changes in the carrying amounts of goodwill, net, by geographic segment:

	North America	Europe	Latin America	Corporate and Other	Consolidated Goodwill, Net
January 1, 2002	\$ 3,972	\$24,200	\$ 427,157	\$ 46,748	\$ 502,077
Foreign exchange and other	—	8,639	(104,020)	707	(94,674)
December 31, 2002	\$ 3,972	\$32,839	\$ 323,137	\$ 47,455	\$ 407,403
Acquisitions	—	41,222	—	—	41,222
Foreign exchange and other	(2,500)	7,792	35,859	(111)	41,040
December 31, 2003	\$ 1,472	\$81,853	\$ 358,996	\$ 47,344	\$ 489,665

During the second quarter of 2002, we elected to early adopt SFAS No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. The impact of adoption was the reclassification into income from continuing operations of an extraordinary gain from the early retirement of subordinated notes of \$7,120, net of taxes of \$4,182, during the third quarter of 2001, an extraordinary gain of \$3,413, net of taxes of \$1,962, during the first quarter of 2002 and an extraordinary gain of \$2,664, net of taxes of \$1,531, during the second quarter of 2002.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which addresses financial accounting and reporting for costs associated with exit or disposal activities. This statement nullifies EITF Issue No. 94-3, *Liability Recognition for Certain*



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*Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. It requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred (rather than when the exit or disposal decision is made). It also establishes fair value as the objective for the initial measurement of the liability. It is effective for fiscal years beginning after December 31, 2002. The impact of adoption of this statement was not significant.

In November 2002, the EITF reached a consensus on Issue No. 00-21, *Revenue Arrangement with Multiple Deliverables*, which is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. It addresses certain aspects of the accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities and how arrangement considerations should be measured and allocated to the separate units of accounting in the arrangement. Reclassification of prior period amounts was required. The impact of adoption was not significant.

In January 2003, the FASB issued FASB Interpretation No. 46, *Consolidation of Variable Interest Entities an interpretation of ARB No. 51*, which addresses consolidation by business enterprises of variable interest entities (“VIE’s”). During December 2003, the FASB revised FASB Interpretation No. 46, deferring the effective date of application for public companies to the first reporting period ending after March 15, 2004, except for disclosure requirements and VIE’s that are special purpose entities. As part of the acquisition of Lab Chile, we acquired a note receivable secured by an option to acquire all of the outstanding shares of common stock of a company that owns 50.1% of a Latin American pharmacy chain, which had net revenues of \$42,249 during the year ended December 31, 2003. As a result of the adoption on the interpretation, we may be required to consolidate the pharmacy chain as of March 31, 2004. We expect that our maximum exposure to loss is the recorded value of the note receivable, which was \$1,728 at December 31, 2003.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, which amends and clarifies accounting for derivative instruments under SFAS No. 133. It is effective for contracts entered into after June 30, 2003. The impact of adoption of this statement was not significant.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The impact of adoption of this statement was not significant.

In December 2003, the FASB issued SFAS No. 132, *Employers’ Disclosures about Pensions and Other Postretirement Benefits – an amendment of FASB Statements No. 87, 88 and 106 (revised 2003)*, that revised employers’ disclosures about pension plans and other postretirement benefits plans. It does not change the measurement or recognition of those plans required by SFAS No. 87, 88 and 106. This statement retains the disclosure requirements in the original SFAS No. 132 and requires additional information on changes in the benefits obligations and fair values of plan assets. It requires additional disclosures including information describing the types of plan assets, investment strategy, measurement date(s), plan obligations, cash flows, and components of net periodic benefit cost recognized during interim periods. It is effective for financial statements with fiscal years ending after December 15, 2003. The interim period disclosure requirements are effective for interim periods beginning after December 15, 2003. Disclosure information about foreign plans required by paragraphs 5(d), 5(e), 5(g), and 5(k) of this statement is effective for fiscal years ending after June 15, 2004. The impact of adoption of this statement was not significant.

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In December 2003, the Securities and Exchange Commission issued Staff Accounting Bulletin (“SAB”) No. 104, *Revenue Recognition*, which revises the existing revenue recognition SAB in Topic 13, *Revenue Recognition*, in order for the interpretive guidance to be consistent with current accounting guidance, primarily EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. The impact of adoption was not significant.

### **(3) Mergers and Acquisitions:**

On January 24, 2003, we acquired ChemSource Corporation in Puerto Rico from Chemo Iberica S.A. and Quimica Sintetica S.A. for 1,000 shares of our common stock, valued at \$12,393, and \$100 in cash. ChemSource Corporation was subsequently renamed API Industries, Inc. (“API”). The total purchase price, including acquisition costs of \$315, less cash acquired of \$358, was \$12,450. API develops, manufactures and sells active pharmaceutical ingredients for various pharmaceutical products, including many products that we sell or have under development. We acquired API to further our objective of complementing existing businesses and to provide new products and marketing opportunities. The operating results of API are included in the consolidated financial statements subsequent to the January 24, 2003, acquisition date.

On May 27, 2003, we entered into an agreement to acquire Advanced Tobacco Products, Inc. (“ATP”), for 237 shares of our common stock, valued at \$4,097. On September 23, 2003, the transaction to acquire ATP was approved by the shareholders of ATP and the transaction was completed. The total purchase price, including acquisition costs of \$254, less cash acquired of \$332, was \$4,183. ATP is an inhalation technology company that developed a patent for nicotine impermeable copolymer technology marketed for smoking cessation, that it sold to Pharmacia in 1987. ATP receives payments from Pharmacia on the sales of those products. ATP also has an exclusive license to certain dry powder inhaler technology from Duke University. We acquired ATP because of the complementary nature of ATP’s technology to our product line and because of the anticipated payments from sales of Pharmacia’s products incorporating the patented nicotine technology sold by ATP to Pharmacia. The operating results of ATP are included in the consolidated financial statements subsequent to the consummation of the acquisition on September 23, 2003.

On October 1, 2003, we acquired a branded respiratory business including license rights to certain branded respiratory products and the related marketing and sales forces in nine European countries. This acquisition was treated for accounting purposes as the acquisition of a business, rather than the acquisition of assets, since it meets the definition of a business under EITF Issue No. 98-3, *Determining Whether a Nonmonetary Transaction Involves the Receipt of Productive Assets or of a Business*. The total consideration due from us under the agreement, including minimum annual royalty payments, is \$77,000, of which we paid \$26,000 on closing, \$24,000 is due on the first and second anniversaries of the closing date and \$3,000 is due on the third anniversary. We are also required to make additional royalty payments on achieving certain annual sales levels up to a maximum of \$1,265 per year, or \$6,575 in total. The total purchase price, including acquisition costs of \$949, plus the present value of future minimum royalty payments, which is treated as part of the purchase price, is \$75,605. The present value of the payments due are recorded as long-term debt. As part of the acquisition, we assumed certain defined benefit obligations, which were recorded as long-term liabilities in the amount of the estimated projected benefit obligation. In addition, a receivable from the sellers was recorded for the amount of the estimated projected benefit obligation pending resolution of the amount that will be funded by the sellers into the pension plan or to us. The preliminary allocation of the purchase price is subject to adjustment based on receipt of final information on the fair value of assets acquired and liabilities assumed. The operating results of the acquired business are included in the consolidated financial statements subsequent to the consummation of the acquisition on October 1, 2003.

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The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the dates of acquisition, the purchase price paid and resulting goodwill.

Current assets, excluding cash acquired	\$ 7,446
Property, plant and equipment	11,599
Intangible assets	33,730
Other assets	3,115
	<hr/>
Total assets acquired	55,890
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Current liabilities	2,413
Long-term debt	2,461
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Total liabilities assumed	4,874
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Net assets acquired	\$51,016
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Purchase price:	
Cash, net of cash acquired	\$25,592
Acquisition costs	1,518
Present value of future minimum royalty payments	48,638
Fair market value of stock issued	16,490
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Total	\$92,238
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Goodwill	\$41,222
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The results of operations prior to the acquisitions were not significant in relation to our results of operations.

During 2002, IVAX Pharmaceuticals s.r.o., our subsidiary in the Czech Republic, acquired the remaining outstanding shares owned by minority interests for \$2,151, resulting in IVAX Pharmaceuticals s.r.o. becoming wholly-owned.

On August 30, 2002, we acquired for \$6,000 in cash Glaxo Wellcome S.A. (subsequently renamed "IVAX Manufacturing Argentina S.A."), an Argentine manufacturing pharmaceutical company consisting primarily of a manufacturing facility, in order to consolidate manufacturing operations in Argentina. The operating results of this company are included in the consolidated financial statements subsequent to its acquisition date.

#### **(4) Partial Sale of IVAX Diagnostics, Inc.:**

On March 14, 2001, our wholly-owned subsidiary, IVAX Diagnostics, Inc. ("IVAX Diagnostics"), merged with b2bstores.com, a non-operating company with approximately \$22,285 of cash, resulting in our owning approximately 70% of the newly merged public company. We received 20,000 shares of b2bstores.com common stock in exchange for all of the outstanding shares of IVAX Diagnostics and b2bstores.com's name was changed to IVAX Diagnostics. For accounting purposes, this transaction is treated as a partial sale of IVAX Diagnostics in exchange for cash of b2bstores.com. We elected income statement recognition as our accounting policy for sales of subsidiary stock and recorded a gain of \$10,278, which is included in "Other income, net" in the consolidated statements of operations. Deferred taxes have not been recorded related to the gain as it represents an outside basis difference and we expect we can recover our investment in IVAX Diagnostics tax-free. Also recorded was \$1,041 of nondeductible compensation expense from outstanding options under the IVAX Diagnostics 1999 Stock Option Plan converting to a fair value plan as a result of the merger. IVAX Diagnostics is engaged in the development, manufacture and marketing of diagnostic test kits, reagents and instruments.

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### **(5) Income from Discontinued Operations:**

During June 2003, we recorded income from discontinued operations in the amount of \$22,204, net of tax of \$12,763, or \$0.11 per diluted share, resulting from a number of agreements, for certain patent and product rights and the settlement of litigation related to a contingent sale price dispute from our 1997 sale of McGaw, Inc. to B. Braun Melsungen AG. Under these agreements, we received \$13,896 of cash, net of related expenses incurred in 2003 and recorded a current tax payable of \$5,072. In addition, the agreements provide for additional payments totaling \$25,500 due in five approximately equal annual installments, which were recorded as a receivable discounted at 4%. We also accrued \$1,622 of additional fees related to the settlement and a deferred tax liability of \$7,691.

### **(6) Sale of Product Rights:**

During 1997, we entered into an agreement to sell to Ortho-McNeil Pharmaceutical, Inc. (“OMP”), a subsidiary of Johnson & Johnson, which acquired ALZA Corporation in 2002, certain rights in Elmiron®. The agreement required an up-front payment, as well as milestones and royalties on sales of Elmiron®. A portion of the up-front and milestone payments that we have received and included in other income in prior years, \$33,975 as of January 1, 2004, is refundable through December 31, 2004, and then ratably decreases through 2009, if our patent rights are found to be invalid and a brand equivalent of Elmiron® is introduced by another company.

We believe that the probability of occurrence of our patent rights being found invalid and a brand equivalent of Elmiron® being introduced by another company is remote, because substantially all agreements for the sale and licensing of a product contain representations and warranties by the seller that the underlying patent is valid. Elmiron® possesses strong patent protection and exclusive use legal protections and Elmiron®’s current and expected future market size makes it uneconomical for another company to incur the substantial cost to develop a generic equivalent, perform the long FDA clinical trials and litigate with OMP and us to obtain generic status. If the patent were to be challenged, then we, as the owner of the patent rights, would be entitled to a 30-month statutory delay, during which we would maintain exclusive right to sell Elmiron®. The active ingredient for Elmiron® is manufactured by only one source in the world and is subject to a “know-how” license held by us and because of the unique aspects of Elmiron®, we believe that there is no reliable means for a competitor to demonstrate the bio-equivalence that would be required for approval of a potential generic. The potential refund represents a warranty provision, which is not inconsistent with representations and warranties (typically without quantification of damages) that are present in most sales and licensing agreements. When conducting our analysis of the amount to record of the warranty obligation, we first assessed the chance of an adverse outcome under the warranty arrangement. Since we determined the chance of an adverse outcome to be remote, no provision for the warranty was recorded.

During the fourth quarter of 2002, we received \$20,000 in connection with certain amendments to the contract. Upon acquisition of ALZA by OMP, representatives of OMP made it clear to us that they believed that the existing royalty structure, which provided for escalating royalties at certain sales levels, created a disincentive towards the continued growth of and their investment in the product. In order to address these issues, in exchange for minimum guaranteed royalties through 2006, we agreed to forego our rights to receive increased royalty payments upon sales of Elmiron® by OMP beyond certain sales levels and reduced the royalty rates we would receive at other sales levels. We also provided for the orderly transition of the manufacture of Elmiron® to OMP. As the \$20,000 payment was nonrefundable and since we have no other obligations under the agreement other than those related to the manufacture of Elmiron® on fair market terms, we determined that the \$20,000 up-front payment is the culmination of a separate earnings process and recorded the payment as additional proceeds from the 1997 sale of Elmiron® to OMP. We will continue to receive payments from OMP over the next several years based upon sales of Elmiron® by OMP.

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Royalty and milestone payments from the 1997 sale of rights in Elmiron® and certain other urology products in the United States and Canada to OMP totaled \$12,835 in 2003, \$35,150 in 2002 and \$13,792 in 2001, and are included in other income as additional gain on the sale of product rights. Royalties and milestone payments receivable from OMP included in “Other current assets” in the accompanying consolidated balance sheets totaled \$8,307 at December 31, 2003, \$12,276 at December 31, 2002, and \$11,070 at December 31, 2001.

### (7) Investments in and Advances to Unconsolidated Affiliates:

We have ownership interests of 50% or less in various unconsolidated affiliates. Non-marketable investments in these affiliates totaled \$9,625 at December 31, 2003, and \$6,638 at December 31, 2002, and are included in “Other assets” in the accompanying consolidated balance sheets. Undistributed earnings of these affiliates, as well as our equity in their earnings, were not significant in any of the periods presented in the accompanying consolidated financial statements.

### (8) Debt:

Long-term debt consists of the following:

	December 31,	
	2003	2002
4.5% Convertible Senior Subordinated Notes due 2008. Interest payable semi-annually. 4.8% effective interest rate.	\$ 533,900	\$ 561,200
5.5% Convertible Senior Subordinated Notes due 2007. Interest payable semi-annually. 5.9% effective interest rate.	249,000	250,000
QVAR® related payables	55,368	75,086
European respiratory business related payables	49,003	—
Mortgage note, due August 21, 2008, 4.3% interest rate through August 21, 2005, thereafter prime plus 0.25%	14,857	—
Other international subsidiaries' debt, due from 2004 to 2010, at interest rates ranging from 3.5% to 5.5%	11,814	14,670
Total long-term debt	913,942	900,956
Less: Current portion of long-term debt	58,607	28,617
Long-term debt, net of current portion	<u>\$ 855,335</u>	<u>\$ 872,339</u>

The 4.5% Notes are convertible at any time prior to maturity, unless previously redeemed, into 24.96875 shares of our common stock per \$1,000 of principal amount of the 4.5% Notes. This results in a conversion price of approximately \$40.05 per share. As of December 31, 2003, the 4.5% Notes could convert into 13,331 shares of our common stock. We may redeem the 4.5% Notes on or after May 29, 2004. Unamortized debt issuance costs related to the 4.5% Notes was \$8,816 at December 31, 2003, and \$11,390 at December 31, 2002, which is being amortized using the effective interest method to interest expense over the life of the 4.5% Notes. During 2003, we repurchased \$27,300 of 4.5% Notes for \$24,496, plus accrued interest of \$346, and wrote off debt issuance costs of \$530. This resulted in a gain on the extinguishment of debt of \$2,274. During 2002, we repurchased \$98,800 of 4.5% Notes for \$79,252, plus accrued interest of \$1,257, and wrote off debt issuance costs of \$2,202, resulting in a gain on extinguishment of debt of \$17,346. During 2001, we repurchased \$65,000 of 4.5% Notes for \$52,070, plus accrued interest of \$1,155, and wrote off debt issuance costs of \$1,628. This resulted in a gain on the extinguishment of debt of \$11,302.

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The 5.5% Notes are convertible at any time prior to maturity, unless previously redeemed, into 33.6 shares of our common stock per \$1,000 of principal amount of the 5.5% Notes. This results in a conversion price of approximately \$29.72 per share. As of December 31, 2003, the 5.5% Notes could convert into 8,378 shares of our common stock. We may redeem the 5.5% Notes on or after May 29, 2003. Unamortized debt issuance costs related to the 5.5% Notes was \$2,925 at December 31, 2003, and \$3,905 at December 31, 2002, which is being amortized using the effective interest method to interest expense over the life of the 5.5% Notes. During 2003, we repurchased \$1,000 of 5.5% Notes for \$935, plus accrued interest of \$12, and wrote off debt issuance costs of \$16. This resulted in a gain on the extinguishment of debt of \$49.

As described in Note 2, payments for the acquisition of QVAR® are due through the third anniversary of the effective date. The payments carried no stated interest rate and were discounted at a 3.7% rate resulting in amounts that were recorded as long-term debt in the accompanying consolidated balance sheets of \$55,368 at December 31, 2003, and \$75,086 at December 31, 2002. The current portion of this debt was \$31,000 at December 31, 2003. In addition, payments for the technical files, trademark and related rights to the MDPI are due through June 30, 2005. The payments carried no stated interest rate and were discounted at a 3.5% rate resulting in long-term debt of \$5,868 at December 31, 2003, and \$7,359 at December 31, 2002. The current portion of this debt was \$0 at December 31, 2003.

As described in Note 3, the present value of future minimum royalty payments for the acquisition of a branded respiratory business including license rights and the related marketing and sales forces in nine European countries are due through the third anniversary of the effective date. The payments carried no stated interest rate and were discounted at a 3.0% rate resulting in \$49,003 at December 31, 2003, that was recorded as additional long-term debt in the accompanying consolidated balance sheet. The current portion of this debt was \$24,000 at December 31, 2003.

On August 22, 2003, we executed a mortgage note and borrowed \$15,000 from a financial institution. The note matures on August 21, 2008, and bears interest at an annual rate of 4.3% through August 21, 2005. Thereafter, through the maturity date, the interest rate is adjusted annually based on a variable rate of twenty-five basis points over the prime rate. The note requires monthly principal payments of \$36 plus interest, with a balloon payment of \$12,888 due August 21, 2008. The mortgage covers the land and building at our corporate headquarters in Miami which had a net book value of \$7,921 at December 31, 2003.

During January 2002, we repaid \$48,000 of United States denominated loans held by an Argentine subsidiary resulting in a pretax foreign exchange loss of \$2,824.

Certain of our international subsidiaries maintain relationships with foreign banks providing short-term lines of credit in the aggregate amount of approximately \$23,000 at December 31, 2003, and \$22,000 at December 31, 2002. Short-term borrowings totaled \$17,804 at December 31, 2003, and \$14,935 at December 31, 2002, and are included as "Loans payable" in the accompanying consolidated balance sheets.

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The estimated fair values of long-term debt and notes payable are as follows:

	December 31,	
	2003	2002
4.5% Convertible Senior Subordinated Notes due 2008	\$538,924	\$461,893
5.5% Convertible Senior Subordinated Notes due 2007	255,701	224,173
QVAR <sup>®</sup> related payables	55,368	75,086
European respiratory business related payables	49,003	—
Mortgage note	14,857	—
Other international subsidiaries' debt	11,814	14,671
<b>Total</b>	<b>\$925,667</b>	<b>\$775,823</b>

Fair value of the 4.5% and 5.5% Convertible Senior Subordinated Notes is based on available quoted market prices. We believe that the carrying amounts of other debt approximate the fair value due to it being recently incurred or the short-term nature of the debt.

The stated future maturities of all long-term debt for the next five years and thereafter are approximately \$58,608 for 2004, \$51,968 for 2005, \$2,771 for 2006, \$251,139 for 2007, \$548,056 for 2008 and \$1,400 thereafter.

### **(9) Restructuring Costs:**

During 2003, we incurred \$3,706 of restructuring costs, primarily employee termination benefits, related to restructuring in Europe and Chile.

During 2002, we incurred \$4,242 of restructuring costs, which were substantially paid out during the second quarter, at two subsidiaries, consisting primarily of employee termination benefits.

During 2001, we incurred \$2,367 of restructuring costs, primarily severance, related to the integration of our Argentine operations with the Argentine operations of Lab Chile, which were expensed when paid. In addition, we recorded \$887 of accruals for restructuring the operations of Lab Chile, which are included in non-cash activity in 2001 in the table below.

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The components of the restructuring costs, spending and other activity, as well as the remaining restructuring reserve balances at December 31, 2003, 2002 and 2001 are shown in the table below. These restructuring costs are shown as “Restructuring costs” in the accompanying consolidated statements of operations. The restructuring reserve balances are included in “Accrued expenses and other current liabilities” in the accompanying consolidated balance sheets.

	<u>Employee Termination Benefits</u>	<u>Plant Closures</u>	<u>Total</u>
Balance at January 1, 2001	\$ 110	\$ 619	\$ 729
Accrual of restructuring costs	2,395	(28)	2,367
Cash payments during 2001	(2,756)	(344)	(3,100)
Non-cash activity	718	143	861
	<u>467</u>	<u>390</u>	<u>857</u>
Balance at December 31, 2001	467	390	857
Accrual of restructuring costs	4,398	(156)	4,242
Cash payments during 2002	(4,291)	(241)	(4,532)
Non-cash activity	84	7	91
	<u>658</u>	<u>—</u>	<u>658</u>
Balance at December 31, 2002	658	—	658
Accrual of restructuring costs	3,485	221	3,706
Cash payments during 2003	(2,522)	—	(2,522)
Non-cash activity	106	21	127
	<u>\$ 1,727</u>	<u>\$ 242</u>	<u>\$ 1,969</u>

### (10) Income Taxes:

The provision for income taxes on continuing operations before minority interest consists of the following:

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Current:			
United States Federal	\$ 7,148	\$34,635	\$ 75,547
State	2,764	2,267	4,520
Puerto Rico and the U.S. Virgin Islands	(1,010)	854	860
Foreign	19,558	22,096	16,783
Deferred			
United States	19,894	(7,491)	(48,777)
Foreign	(2,795)	(619)	5,132
Total	<u>\$45,559</u>	<u>\$51,742</u>	<u>\$ 54,065</u>

The components of income from continuing operations before income taxes and minority interest are as follows:

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
United States	\$ 87,938	\$ 83,539	\$209,443
Puerto Rico and the U.S. Virgin Islands	19,417	11,693	17,928
Foreign	37,063	74,267	69,613
Total	<u>\$144,418</u>	<u>\$169,499</u>	<u>\$296,984</u>





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A reconciliation of the difference between the expected provision for income taxes using the statutory United States Federal tax rate and our actual provision is as follows:

	Year Ended December 31,		
	2003	2002	2001
Tax using statutory United States Federal tax rate at 35%	\$50,547	\$ 59,324	\$104,171
Effect of state income taxes	1,797	1,474	2,938
Write-down of non-deductible cost in excess of net assets of acquired companies	—	—	18
Utilization of previously reserved net operating loss and tax credit carryforwards	—	—	(29,590)
Tax effect of intercompany income eliminated on books	—	—	7,600
Reduction of valuation allowance on deferred tax assets	(2,611)	(3,565)	(11,216)
Foreign tax rate differential	(3,555)	(10,131)	(20,253)
Effect of Puerto Rico taxes and tollgate	(1,010)	854	860
Puerto Rico and U.S. possessions tax incentives	(6,057)	(3,881)	(6,275)
Foreign operating losses not benefited	9,692	5,615	13,984
Tax claims and other matters	(2,700)	—	(6,333)
Other	(544)	2,052	(1,839)
Total	\$45,559	\$ 51,742	\$ 54,065

In 2003 and 2002, the effective tax rate was less than the statutory rate primarily due to low tax rates applicable to our Puerto Rico and Waterford, Ireland manufacturing operations and our Swiss and Chilean operations. In 2001, the effective tax rate was lower than the United States statutory income tax rate, principally due to net operating loss and tax credit carryforwards and tax incentives in certain jurisdictions where our manufacturing facilities are located. The domestic current provision was favorably impacted by \$29,590 during 2001 from utilization of previously reserved net operating loss (“NOL”) and tax credit carryforwards. The 2001 domestic current provision was also favorably impacted by the non-taxable gain on the partial sale of IVAX Diagnostics. Payment of the current tax provision will be reduced by \$1,930 for our domestic operations and \$2,303 for our foreign operations for the year ended December 31, 2003, were reduced by \$1,411 for our domestic operations and \$421 for our foreign operations for the year ended December 31, 2002, and were reduced by \$8,040 for our domestic operations and \$2,571 for our foreign operations for the year ended December 31, 2001, representing the incremental impact of compensation expense deductions associated with non-qualified stock option exercises during those years. In addition, during 2001 we recorded \$7,390 of tax effect of prior years’ stock option exercises. These amounts were credited to “Capital in excess of par value.” During 2001, we recognized \$20,000 United States taxable income on the intercompany assignment of a contract. For financial reporting purposes this transaction was eliminated in consolidation.

Valuation allowances previously recorded against the foreign and domestic net deferred tax assets of \$2,611 in 2003, \$3,565 in 2002 and \$11,216 in 2001 were reversed due to management’s expectation of increased taxable income in the coming year. The domestic net deferred tax asset was \$79,187 at December 31, 2003, and \$108,654 at December 31, 2002, and the aggregate net deferred tax asset in foreign countries was \$14,930 at December 31, 2003, and \$7,508 at December 31, 2002. As of December 31, 2003 and 2002, the domestic deferred tax asset was not reserved. As of December 31, 2003, the aggregate foreign net deferred tax asset was approximately 66% reserved. Realization of the net deferred tax assets is dependent upon generating sufficient future domestic and foreign taxable income. Although realization is not assured, management believes it is more likely than not that the unreserved portion of the net deferred tax assets will be realized.

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Deferred taxes arise due to temporary differences in reporting of certain income and expense items for book purposes and income tax purposes. A detail of the significant components of deferred tax assets (liabilities) in the accompanying consolidated balance sheets is as follows:

	December 31,	
	2003	2002
Accounts receivable allowances	\$ 66,542	\$ 77,755
Reserves and accruals	13,039	16,969
Differences in capitalization of inventory costs	243	406
Other	6,918	4,809
Amount included in "Other current assets"	86,742	99,939
Basis differences on fixed assets	—	513
Recognition of revenue	219	146
Carrying value of long-term assets	1,340	1,978
Other	4,035	10,564
Tax credits	1,600	1,600
Net operating losses – United States	4,790	5,850
Net operating losses – foreign	34,009	27,783
Amount included in "Other assets"	45,993	48,434
Other, amount included in "Accrued expenses and other current liabilities"	(5,012)	(6,732)
Fixed assets basis difference	(1,631)	(3,055)
Other	(17,124)	(17,374)
Other, amount included in "Other long-term liabilities"	(18,755)	(20,429)
Deferred tax asset	108,968	121,212
Valuation allowance	(34,009)	(27,783)
Net deferred tax asset	\$ 74,959	\$ 93,429

United States income taxes have not been provided on undistributed earnings of Puerto Rican operations or foreign subsidiaries, as such earnings are being retained indefinitely by such subsidiaries for reinvestment. The cumulative amount of such undistributed earnings is approximately \$304,449 as of December 31, 2003. Any United States tax amounts due would be reduced by allowable foreign tax credits.

Income from IVAX Pharmaceuticals' Puerto Rico manufacturing operations is subject to certain tax exemptions under the terms of a grant from the Puerto Rican government, which will expire on January 1, 2021. The grant reduced tax expense by approximately \$6,217 in 2003, \$3,515 in 2002 and \$4,499 in 2001. Under the terms of the grant, IVAX Pharmaceuticals is required to maintain certain employment levels.

We have historically received a United States tax credit under Section 936 of the Internal Revenue Code for certain income generated by our Puerto Rico and Virgin Islands operations. This credit was approximately \$6,057 for 2003, \$3,881 for 2002 and \$6,275 for 2001, and offset the United States tax liability of such operations. In 1996, Congress repealed the Section 936 tax credit and it will be phased out over four years beginning in 2002. Under the current tax law, no tax credit will be available after December 31, 2005.

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At December 31, 2003, we had a limited United States NOL carryforward, which can be used only at an annual rate of \$3,028, and foreign NOL carryforwards, which are comprised of:

<u>Expire</u>	<u>United States</u>	<u>Foreign</u>
2004	\$ —	\$ 5,940
2005	—	14,686
2006	6,056	10,468
2007	2,733	52,772
2008	4,896	14,061
2009	—	6,348
2010	—	10,940
2011	—	497
2012	—	7,200
2013	—	1,408
Indefinite	—	57,417
Total	\$13,685	\$181,737

Minority interest included in the accompanying consolidated statements of operations is net of a provision for income taxes of \$29 in 2003, \$37 in 2002 and \$(67) in 2001.

### **(11) Retirement Plans:**

401(k) Plans - Our employees within the United States and the Virgin Islands are eligible to participate in a 401(k) retirement plan and Puerto Rico employees are eligible to participate in a 165(e) plan, which permit pre-tax employee payroll contributions (subject to certain limitations) and discretionary employer matching contributions. Total matching contributions were \$2,010 in 2003, \$1,454 in 2002 and \$1,275 in 2001.

Pension Plans - Our employees within Ireland are eligible to participate in a defined benefit pension plan. The plan requires employees to share in the costs. As of December 31, 2003, 544 employees were covered by this plan and 145 former members have retained entitlements to deferred benefits. As of December 31, 2002, 560 employees were covered by this plan.

Actuarial assumptions for the plan include: (a) 7.0% for the expected long-term rate of return on plan assets, (b) 5.25% for 2003, 5.5% for 2002 and 6.0% for 2001 for the discount rate calculating the projected benefit obligation and (c) 4.0% for the rate of average future increases in compensation levels.

Net periodic pension costs, representing our contributions to the plan, for the twelve months ended December 31, 2003 and 2002, were as follows:

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
<b>Net Periodic Pension Cost:</b>		
Service cost	\$2,028	\$ 994
Interest cost	846	533
Expected return on plan assets	(675)	(578)
Amortization of transition obligation	233	45
Net periodic pension cost	\$2,432	\$ 994

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A reconciliation of the projected benefit obligation for the pension plan to the recorded accrued pension liability is as follows:

	December 31,	
	2003	2002
Projected benefit obligation for service rendered to date	\$(21,296)	\$(14,315)
Plan assets at fair value, primarily mutual funds	13,176	8,262
Projected benefit obligation in excess of plan assets	(8,120)	(6,053)
Unrecognized net gain	(404)	—
Unrecognized net obligation	7,007	6,053
Accrued pension liability	\$ (1,518)	\$ —

A reconciliation of the pension benefit obligation is as follows:

	December 31,	
	2003	2002
<b>Pension Benefit Obligations:</b>		
Start of year	\$14,315	\$ 8,416
Service cost	2,028	1,606
Employee contribution	659	586
Interest cost	846	533
Benefits paid	(242)	(251)
Unrecognized actuarial gain	404	1,482
Translation adjustment	3,286	1,943
At end of year	\$21,296	\$14,315

A reconciliation of the fair value of the pension assets is as follows:

	December 31,	
	2003	2002
<b>Fair Value of Pension Assets:</b>		
Start of year	\$ 8,262	\$ 7,206
Employer contribution	1,069	994
Employee contribution	659	585
Actual return	1,442	(1,542)
Benefits paid	(242)	(252)
Translation adjustment	1,986	1,271
At end of year	\$13,176	\$ 8,262

The accumulated benefit obligation was \$15,310, of which \$10,514 was vested, at December 31, 2003, and \$6,494, of which \$5,569 was vested, at December 31, 2002.

We sponsored a defined benefit pension plan for employees within the United Kingdom, which was closed in 1998 and contributions to the plan were ceased. As a result of closing the plan, the accumulated benefit obligation, all of which was vested, equals the projected benefit obligation. In addition, we have initiated the process of terminating the pension plan and agreed with the trustees that any excess assets over the Minimum Funding Requirement will not revert to us, which is treated as a plan amendment. A valuation of the funded

status of the plan in relation to the Minimum Funding Requirement under United Kingdom regulations for termination purposes is in process.

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Net pension expenses for the United Kingdom plan were \$482 for 2003 and \$0 for 2002.

A reconciliation of the projected benefit obligation for the United Kingdom pension plan to the recorded accrued pension liability is as follows:

	December 31,	
	2003	2002
Projected benefit obligation for service rendered to date	\$(15,985)	\$(16,008)
Plan assets at fair value, primarily mutual funds	15,985	13,651
Projected benefit obligation in excess of plan assets	—	(2,357)
Unrecognized net obligation	3,939	2,357
Prior service cost	(4,684)	—
Accrued pension liability	\$ (745)	\$ —

As discussed in Note 3, on October 1, 2003, we assumed a defined benefit pension plan in Germany related to the purchase of a branded respiratory business in Europe. As of December 31, 2003, 12 employees were covered by this plan. A receivable from the sellers of \$2,645 as of December 31, 2003, was recorded for the amount of the estimated projected benefit obligation pending resolution of the amount that will be funded by the sellers into the pension plan or to us. In addition, the projected benefit obligation of \$2,746 as of December 31, 2003, is recorded in other long-term liabilities. During the fourth quarter of 2003, \$95 of pension expense was recorded related to the plan.

### (12) Shareholders' Equity:

Equity Compensation Plan Information - The following table summarizes information about equity compensation plans (number of shares in thousands):

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plan approved by security holders:			
1994 Plan	8,450	\$ 15.56	1,405
Equity compensation plans not approved by security holders:			
1997 Plan	11,299	17.40	4,681
1985 Plan	28	9.00	—
Total	19,777	\$ 16.60	6,086

We administer and have stock options outstanding under our 1997 Employee Stock Option Plan ("1997 Plan"), our 1994 Stock Option Plan ("1994 Plan") and our 1985 Stock Option Plan ("1985 Plan"). The options outstanding under the plans assumed in business acquisitions were converted into options to acquire our common stock using the applicable exchange ratios. No additional stock options may be issued under the 1985 Plan. On July 28, 2003, our Board of Directors approved an increase to 23,000 shares of our common stock that may be issued under the 1997 Plan. The 1994 Plan permits the issuance of options to employees, non-employee directors and consultants to purchase up to 13,125 shares of our common stock. Both plans provide that the exercise price of the issued options shall be no less than the fair market value of the common stock on the date of grant and that the option terms shall not exceed ten years.

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The following table presents additional information concerning the activity in the stock option plans (number of shares in thousands):

	2003		2002		2001	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Balance at beginning of year	19,040	\$ 17.40	16,756	\$ 16.98	13,685	\$ 11.88
Granted	4,196	11.85	3,874	17.78	5,097	27.97
Exercised	(1,710)	10.04	(681)	7.72	(1,531)	9.18
Terminated/exchanged	(1,749)	20.30	(909)	20.65	(495)	13.20
Balance at end of year	19,777	16.60	19,040	17.40	16,756	16.98
Exercisable at December 31,	10,133	\$ 15.93	8,771	\$ 13.07	5,804	\$ 9.60

The following table summarizes information about fixed stock options outstanding at December 31, 2003 (number of shares in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable at 12/31/03	Weighted Average Exercise Price
\$ 0.00 - \$3.94	22	0.8	\$ 3.73	22	\$ 3.73
\$ 3.95 - \$7.88	3,246	1.8	5.16	3,246	5.16
\$ 7.89 - \$11.82	3,800	6.8	10.92	239	9.73
\$ 11.83 - \$15.76	3,397	4.9	14.19	2,063	14.47
\$ 15.77 - \$19.70	4,281	5.4	18.91	1,773	18.81
\$ 19.71 - \$23.64	278	4.2	21.58	149	21.75
\$ 23.65 - \$27.58	2,112	4.0	26.06	1,001	26.01
\$ 27.59 - \$31.52	2,109	5.9	28.77	1,277	28.77
\$ 31.53 - \$35.46	313	3.6	34.35	229	34.39
\$ 35.47 - \$39.40	219	4.6	38.19	134	38.24
	19,777	4.8	\$ 16.60	10,133	\$ 15.93

Employee Stock Purchase Program – On June 17, 1999, the IVAX Corporation 1999 Employee Stock Purchase Plan (“ESPP”) was approved at the Annual Meeting of Shareholders. Our Board of Directors also approved the purchase of common stock in the open market, as needed, for the ESPP. The maximum number of shares available for sale under the ESPP is 5,250, subject to future increases as stated in the plan. The ESPP became effective January 1, 2000, for employees based in the United States and Puerto Rico, and allows them to purchase our common stock at 85% of the fair market value on the enrollment date or exercise date, whichever is lower. The maximum amount of stock an employee may purchase in a year is \$25 and subsequent resale is restricted as stated in the plan. The ESPP is accounted for as a non-compensatory plan.

Share Repurchase Program – On March 15, 2002, our Board of Directors expanded the authorization of our share repurchase program by an additional 10,000 shares of common stock or a like-valued amount of our convertible debentures, bringing the total authorized for repurchase to 67,500 shares. From December 31, 1997, through December 31, 2003, we repurchased 54,324 shares of common stock at a total cost, including commissions, of \$562,410. Under Florida law, unless otherwise designated by our Board of Directors, repurchased shares constitute authorized but unissued shares.

We repurchased (including shares repurchased via the physical settlement method disclosed below) 700 shares of our common stock in 2003 at a total cost, including commissions, of \$8,997, 3,882 shares in 2002 for \$59,391 and 6,779 shares in 2001 for \$155,097.



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Put Options – Prior to adopting EITF Issue No. 00-19 in 2001, we reclassified the maximum repurchase obligation for outstanding put options under the physical settlement method of \$84,503 from “Capital in excess of par value” into a separate temporary equity account “Put options.”

During 2001, we issued eight free-standing put options for 1,850 shares, bearing strike prices ranging from \$19.00 to \$31.50, expiring from November 2001 through April 2002, and collected premiums totaling \$4,670 that were credited to “Capital in excess of par value” in the accompanying consolidated balance sheet at December 31, 2001. In addition, we rolled forward (renewed) three put options for 875 shares into two put options for 875 shares prior to expiration, bearing strike prices ranging from \$29.80 to \$31.80, expiring from May 2001 through January 2002 and collected premiums totaling \$153 that were credited to “Capital in excess of par value” in the accompanying consolidated balance sheet at December 31, 2001. In the event the put options were exercised, we had the right to elect to settle by one of three methods: physical settlement by payment in exchange for our shares, net cash settlement or net share settlement. These European style options were exercisable only on the respective expiration dates and would be exercised “in the money” once the strike price per option exceeded the market value of our common stock on the expiration date of the option.

During 2001, seven freestanding put options for 2,063 shares of our common stock expired unexercised, one of which was issued in 2001 for 200 shares. Five put options were exercised for 1,638 shares by the holders at strike prices ranging from \$27.68 to \$31.50 during 2001. We elected the physical settlement method upon the exercise of one put option for 281 shares and paid \$7,785 in exchange for the underlying shares. We elected the net share settlement method for the exercises of the remaining four put options for 1,356 shares and issued 314 shares of our common stock in settlement of the obligation.

During 2002, five put options were exercised for 1,200 shares by the holders at strike prices ranging from \$19.00 to \$32.28. We elected the physical settlement method upon the exercise of two put options for 500 shares and paid \$12,725 in exchange for the underlying shares. We elected the net share settlement method for the exercises of the remaining three put options for 700 shares and issued 971 shares of our common stock in settlement of the obligation.

Diagnostics Warrants – As of December 31, 2003, IVAX Diagnostics has warrants outstanding that expire in February 2005 to purchase up to 400 shares of IVAX Diagnostics’ common stock at a price of \$13.20 per share.

Diagnostics Stock Option and Performance Plans – Effective June 29, 1999, the Board of Directors of IVAX Diagnostics, a wholly-owned subsidiary of ours at the time, approved the IVAX Diagnostics 1999 Stock Option Plan. The plan permits the issuance of options to employees, non-employee directors and consultants of IVAX Diagnostics to purchase up to 2,000 shares of the 50,000 authorized shares of IVAX Diagnostics. In June and August 1999, non-qualified options of 1,145 shares of common stock were granted to employees of IVAX Diagnostics with an exercise price of \$0.73 per share, a vesting schedule of 50% at the end of year two, 25% at the end of years three and four and an expiration date of June to August 2006. On September 30, 1999, prior to the merger of IVAX Diagnostics with b2bstores.com, the Board of Directors of b2bstores.com approved the 1999 Performance Equity Plan (the “Performance Plan”). The Performance Plan authorizes the grant of up to 2,000 shares of common stock to key employees, officers, directors and consultants. Both incentive and non-qualified options may be issued under the Performance Plan. Prior to the creation of the Performance Plan, options to purchase an additional 1,000 shares of common stock were granted by the Board of Directors of b2bstores.com to certain of its former officers. As of December 31, 2003, options for 1,918 shares of common stock were outstanding under these plans and as of December 31, 2002, options for 2,034 shares were outstanding.

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Diagnostics Share Repurchase Program – During 2002, IVAX Diagnostics' Board of Directors authorized the repurchase of up to 2,000 shares of its publicly held common stock. During 2002, IVAX Diagnostics repurchased publicly held common stock. As of December 31, 2003, we held approximately 20,000 shares of the total 27,659 IVAX Diagnostics common shares outstanding, or 72% ownership.

Convertible Debt – See Note 8, Debt, for comments regarding convertible senior subordinated notes.

Dividends – We did not pay dividends during the years ended December 31, 2003, 2002 and 2001.

### **(13) Business Segment Information:**

IVAX is a multinational company with subsidiaries that operate in the pharmaceutical business and are engaged in the research, development, manufacture, marketing and sale of pharmaceutical products. Pharmaceutical products include prescription drugs and over-the-counter products. We review financial information, allocate resources and manage our business by major operating subsidiary. However, our pharmaceutical subsidiaries utilize similar production processes, and sell similar types of products to similar types of customers under similar regulatory environments using similar methods of distribution. We also expect these subsidiaries to have similar long-term financial performance. Since these pharmaceutical subsidiaries meet the aggregation criteria under paragraph 17 of SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, the pharmaceutical operating subsidiaries are aggregated into one reportable segment, pharmaceutical, and all other subsidiaries are reported in Corporate and other.

To provide additional information, we have disaggregated our pharmaceutical segment results into the geographic regions in which the subsidiaries are located. The North America region contains our subsidiaries in the United States and Canada. The Europe region contains subsidiaries located in Europe. Latin America consists of subsidiaries in South America and Mexico. Corporate and other includes the diagnostic subsidiaries, animal health subsidiary and subsidiaries located in other geographic regions as well as corporate activities and elimination of intercompany transactions.

The information provided is based on internal reports and was developed and utilized by management for the sole purpose of tracking trends and changes in the results of the regions. The information, including the allocations of expense and overhead, was calculated based on a management approach and may not reflect the actual economic costs, contributions or results of operations of the regions as stand-alone businesses. If a different basis of presentation or allocation were utilized, the relative contributions of the regions might differ but the relative trends would, in management's view, likely not be materially impacted.

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The table below sets forth net revenues and profits in the regional presentation.

	North America	Europe	Latin America	Corporate and Other	Total IVAX
<b>2003</b>					
External net sales	\$626,590	\$437,574	\$251,067	\$ 53,671	\$1,368,902
Intercompany sales	1,222	69,330	—	(70,552)	—
Other revenues	22,767	25,568	838	2,264	51,437
Net revenues	650,579	532,472	251,905	(14,617)	1,420,339
Asset impairment and restructuring	—	3,404	302	—	3,706
Operating income (loss)	131,087	5,678	50,948	(15,135)	172,578
Interest income	3	619	1,126	1,962	3,710
Interest expense	(1,470)	101	(946)	(41,293)	(43,608)
Other income (expense)	6,633	(5,495)	(2,026)	10,982	10,094
Equity earnings of affiliates	—	—	—	1,644	1,644
Tax provision (benefit)	40,663	3,892	13,195	(12,191)	45,559
Income (loss) from continuing operations before minority interest	95,590	(2,989)	35,907	(29,649)	98,859
<b>2002</b>					
External net sales	\$476,085	\$371,987	\$227,933	\$ 44,713	\$1,120,718
Intercompany sales	1,554	40,872	—	(42,426)	—
Other revenues	30,971	41,573	1,204	2,778	76,526
Net revenues	508,610	454,432	229,137	5,065	1,197,244
Asset impairment and restructuring	(183)	3,382	1,043	—	4,242
Operating income (loss)	100,360	36,911	33,699	(21,243)	149,727
Interest income	4	2,031	2,500	3,555	8,090
Interest expense	(1,265)	(1,029)	(1,728)	(44,617)	(48,639)
Other income (expense)	28,558	(4,883)	1,929	33,839	59,443
Equity earnings of affiliates	—	—	—	878	878
Tax provision (benefit)	43,146	11,654	9,201	(12,259)	51,742
Income from continuing operations before minority interest	84,511	21,376	27,199	(15,329)	117,757
<b>2001</b>					
External net sales	\$582,471	\$302,569	\$222,444	\$ 36,554	\$1,144,038
Intercompany sales	2,838	61,267	—	(64,105)	—
Other revenues	9,652	55,269	1,740	4,678	71,339
Net revenues	594,961	419,105	224,184	(22,873)	1,215,377
Asset impairment and restructuring	—	343	2,024	—	2,367
Operating income (loss)	200,054	36,795	32,652	(1,612)	267,889
Interest income	79	2,981	1,933	16,256	21,249
Interest expense	(36)	(999)	(4,506)	(36,250)	(41,791)
Other income (expense)	33,969	(13,152)	4,277	23,473	48,567
Equity earnings of affiliates	—	—	28	1,042	1,070
Tax provision (benefit)	75,407	9,438	13,495	(44,275)	54,065
Income from continuing operations before minority interest	158,659	16,187	20,889	47,184	242,919

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In 2002, the Argentine peso and Venezuelan bolivar devalued significantly in relation to the United States dollar. As a result, the operating results and net asset position in these currencies decreased significantly when converted into United States dollars.

The following table reconciles long-lived assets by geographic region to the consolidated total:

Year	North America	Europe	Latin America	Corporate and Other	Total IVAX
2003	\$ 339,353	\$ 432,668	\$ 466,329	\$ 126,884	\$ 1,365,234
2002	310,422	306,361	423,576	108,589	1,148,948
2001	207,608	226,071	544,638	107,826	1,086,143

Long-lived assets exclude the long-term net deferred tax asset included in "Other assets" on the accompanying consolidated balance sheets.

The following table shows additions to long-lived assets and depreciation/amortization by region:

Region	Additions to Long-Lived Assets			Depreciation/Amortization		
	2003	2002	2001	2003	2002	2001
North America	\$ 37,914	\$ 116,900	\$ 159,395	\$ 28,416	\$ 21,845	\$ 13,324
Europe	124,442	68,784	49,204	36,948	26,252	20,372
Latin America	8,466	14,996	458,755	7,896	7,711	12,763

We sell products in a large number of countries; however, only two countries, the United States and the United Kingdom, have net revenues that are material to consolidated net revenues. Additionally, we have material amounts of long-lived assets in the United States, the United Kingdom and Chile. The following table summarizes net revenues based on the location of the third party customer and long-lived assets based on the country of physical location:

GEOGRAPHIC AREAS:		United States	United Kingdom	Chile	Other	Total
Net revenues	2003	\$ 700,283	\$ 232,517	\$ 75,560	\$ 411,979	\$ 1,420,339
	2002	570,676	218,097	81,630	326,841	1,197,244
	2001	567,507	262,037	39,856	345,977	1,215,377
Long-lived assets	2003	465,956	226,466	265,069	407,743	1,365,234
	2002	417,696	192,729	220,080	318,443	1,148,948
	2001	317,345	147,891	243,520	377,387	1,086,143

### NET REVENUES BY PRODUCT TYPE:

		Net Revenues		
		2003	2002	2001
Proprietary and branded		\$ 539,507	\$ 530,607	\$ 528,652
Generic pharmaceutical		880,832	666,637	686,725
Total		\$ 1,420,339	\$ 1,197,244	\$ 1,215,377

No single customer accounted for 10% or more of our consolidated net revenues for any of the three years ended December 31, 2003. Other revenues included in net revenues in the accompanying consolidated statements of operations consist of license fees, royalties, and development service fees.

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In October 2002, we entered into a new agreement with Bristol-Myers Squibb that superseded, effective November 2002, the prior product collaboration agreement. The new agreement, which in part relates to some of the subject matter of the earlier agreement, also encompasses additional arrangements between the parties and had a term of ten months.

### (14) Commitments and Contingencies:

Sales of Businesses and Gain on Sale – Significant assumptions in the preparation of the financial statements include our belief that the outcome of contingencies indemnified by us in the sale of certain businesses will not have a material effect on future operations and that the probability of a refund of previously recognized gain on sale of product rights is remote.

Leases – We lease office, plant and warehouse facilities and automobiles under non-cancelable operating leases. Motor vehicles, production equipment and certain manufacturing facilities are also leased under capital leases. Rent expense totaled approximately \$8,039 in 2003, \$7,755 in 2002 and \$8,686 in 2001. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2003 and 2002, were not material. The future minimum lease payments under non-cancelable operating leases with initial or remaining terms of one year or more at December 31, 2003, were as follows:

	<u>Operating Leases</u>
2004	\$ 6,183
2005	3,753
2006	2,094
2007	1,532
2008	1,509
Thereafter	4,785
	<hr/>
Total minimum lease payments	\$ 19,856
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### Legal Proceedings (amounts in thousands) –

#### Terazosin Litigation

On December 21, 1998, an action purporting to be a class action, styled Louisiana Wholesale Drug Co. vs. Abbott Laboratories, Geneva Pharmaceuticals, Inc. and Zenith Goldline Pharmaceuticals, Inc., was filed against IVAX Pharmaceuticals, Inc. (“IPI”) and others in the United States District Court for the Southern District of Florida, alleging a violation of Section 1 of the Sherman Antitrust Act. Plaintiffs purport to represent a class consisting of customers who purchased a certain proprietary drug directly from Abbott Laboratories during the period beginning on October 29, 1998. Plaintiffs allege that, by settling patent-related litigation against Abbott in exchange for quarterly payments, the defendants engaged in an unlawful restraint of trade. The complaint seeks unspecified treble damages and injunctive relief. Eighteen additional class action lawsuits containing allegations similar to those in the Louisiana Wholesale case were filed in various jurisdictions between July 1999 and February 2001, the majority of which have been consolidated with the Louisiana Wholesale case. On December 13, 2000, plaintiffs’ motion for summary judgment on the issue of whether the settlement agreement constituted a per se violation of Section 1 of the Sherman Antitrust Act in the Louisiana Wholesale case was granted, but on September 15, 2003, the United States Court of Appeals for the Eleventh Circuit reversed the order. On March 13, 2000, the Federal Trade Commission (“FTC”) announced that it had issued complaints against, and negotiated consent decrees with, Abbott Laboratories and Geneva Pharmaceuticals arising out of an investigation of the same subject matter that is involved in these lawsuits. The FTC took no action against IPI. To date, seventeen of the actions naming IPI have either been settled or dismissed.

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### Fen-Phen Litigation

IPI has been named in a number of individual and class action lawsuits in both state and federal courts involving the diet drug combination of fenfluramine and phentermine, commonly known as “fen-phen.” Generally, these lawsuits seek damages for personal injury, wrongful death and loss of consortium, as well as punitive damages, under a variety of liability theories including strict products liability, breach of warranty and negligence. IPI did not manufacture either fenfluramine or phentermine, but did distribute the brand equivalent version of phentermine manufactured by Eon Labs Manufacturing, Inc. (“Eon”) and Camall Company. Although IPI had a very small market share, to date, IPI has been named in approximately 5,542 cases and has been dismissed from approximately 4,966 of these cases, with additional dismissals pending. IPI intends to vigorously defend all of the lawsuits, and while management believes that its defense will succeed, as with any litigation, there can be no assurance of this. Currently Eon is paying for approximately 50% of IPI’s costs in defending these suits and is fully indemnifying IPI against any damages IPI may suffer as a result of cases involving product manufactured by Eon. In the event Eon discontinues providing this defense and indemnity, IPI has its own product liability insurance. While IPI’s insurance carriers have issued reservations of rights, IPI believes that it has adequate coverage. Although it is impossible to predict with certainty the outcome of litigation, we do not believe this litigation will have a material adverse impact on our financial condition or results of operation.

### Average Wholesale Price Litigation

On July 12, 2002, an action purporting to be a class action styled John Rice v. Abbott Laboratories, Inc., et al. (the “Rice Action”) was filed against IPI and others in the Superior Court of the State of California, alleging violations of California’s Business & Professional Code §17200 et seq. with respect to the way pharmaceutical companies report their AWP. Plaintiffs allege that each defendant reported an AWP to Medicare and Medicaid which materially misrepresented the actual prices paid to defendants by physicians and pharmacies for prescription drugs. The complaint seeks unspecified damages, including punitive damages, and injunctive relief. Two other class actions, Thompson v. Abbott Laboratories, Inc., et al. (the “Thompson Action”) and Turner v. Abbott Laboratories, Inc., et al. (the “Turner Action”), containing similar allegations against IPI and others were filed in California courts in August and September 2002, respectively, as well. All three cases were removed to federal court and transferred to the Pharmaceutical Industry Average Wholesale Price Multi-District Litigation in the United States District Court for the District of Massachusetts. On November 23, 2003, the plaintiff in the Rice Action dismissed his action against IPI and other defendants without prejudice. On January 9, 2004, the court denied the motions filed by the plaintiffs in the Thompson Action and the Turner Action to remand the cases to state court and further ruled that the claims in these actions were preempted by ERISA. In February 2004, the plaintiffs in the Thompson Action and the Turner Action also dismissed their actions against IPI and other defendants.

On September 29, 2003, we received a copy of a Summons and Complaint filed by the Commonwealth of Massachusetts against IVAX Corporation, and various other manufacturers of generic pharmaceutical products, alleging that all defendant manufacturers inflated the prices of generic pharmaceutical products paid for by the Massachusetts Medicaid Program through alleged fraudulent promotion, marketing and sales practices, resulting in millions of dollars in overpayments. The Complaint also alleges that the defendant manufacturers reported understated drug pricing to the federal government, which had the effect of reducing rebate payments to the Commonwealth under rebate agreements. The complaint alleges violations of the Massachusetts Medicaid False Claims Act, the Massachusetts False Claims Act and common law fraud, along with claims for unjust enrichment, breach of contract and breach of the duty of good faith and fair dealing. The Commonwealth seeks injunctive relief, restitution, treble damages, civil penalties, attorneys’ fees, and investigative and litigation costs. A motion to dismiss this action was filed on January 29, 2004, and is pending. We intend to vigorously defend ourselves in this matter and against these allegations.

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On September 15, 2003, IPI and we were served with an Amended Complaint filed in the United States District Court for the District of Massachusetts in the case styled County of Suffolk vs. Abbott Laboratories, Inc., et al. and on August 25, 2003, we were served with a similar complaint filed in the United States District Court for the Southern District of New York in the case styled County of Westchester vs. Abbott Laboratories, Inc. et al. In each of these cases, the plaintiffs allege that the defendants violated the Racketeering Influenced and Corrupt Organizations Act (“RICO”), the Federal Medicaid Statute, New York Social Services Law, New York Department of Health Regulations, and New York General Business Law. The plaintiffs also seek the recovery of damages for unfair trade practices, fraud, breach of contract and under the theory of unjust enrichment. The plaintiffs also seek unspecified damages, including treble and punitive damages, civil penalties, declaratory and injunctive relief and restitution, allegedly suffered by the plaintiffs as a result of the defendants’ alleged unlawful scheme to overcharge for prescription medications paid for by Medicaid. The plaintiffs allege that through promotional, discounting, and pricing practices, the defendants reported false and inflated average wholesale prices or wholesale acquisition costs and failed to report their best prices as required by federal and state rebate statutes resulting in the plaintiffs overpaying for certain medications. A motion to dismiss these actions was filed and remains pending. We intend to vigorously defend ourselves in these cases and against these allegations.

IPI, along with numerous other pharmaceutical companies, has received inquiries from and responded to requests for records and information from the Committee on Energy and Commerce of the United States House of Representatives in connection with the Committee’s investigation into certain industry and IPI practices regarding average wholesale price. IPI has also received correspondence from the States of Nevada, Kentucky, Florida, and Illinois, on behalf of itself and 8 other states, indicating that the Office of the Attorney General (OAG) for these states are investigating allegations of purportedly improper pricing practices related to the average manufacturer price and best price calculations. We or our subsidiaries have not been named as a defendant in a suit filed by or on behalf of any state, but as a result of the investigation the OAG for the states have advised us that we are required to maintain all records related to the investigation. We are cooperating fully with these requests. The outcome of these investigations could include the imposition of substantial fines, penalties and injunctive or administrative remedies.

### United Kingdom Serious Fraud Office Investigation and Related Litigation

In April 2002, we received notice of an investigation by United Kingdom National Health Service officials concerning prices charged by generic drug companies, including Norton Healthcare Limited, trading as IVAX Pharmaceuticals UK, for penicillin-based antibiotics and warfarin sold in the United Kingdom from 1996 to 2000. This is an investigation by the Serious Fraud Office of the United Kingdom involving all pharmaceutical companies that sold these products in the United Kingdom during this period. According to statements by investigating agencies, this is a complex investigation expected to continue for some time and there is no indication from the agencies when or if charges will be made against any of these companies. We are cooperating fully with this investigation.

In December 2002, the Secretary of State for Health, on behalf of itself and others, filed a civil claim for damages and interest against Norton Healthcare, Norton Pharmaceuticals and other defendants alleging that certain of their actions adversely affected competition in the sale and supply of warfarin in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate aggregate amount of 28,600 Pounds Sterling (approximately \$51,100 at the December 31, 2003, currency exchange rate), plus interest and costs.

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In December, 2003, the Secretary of State for Health, on behalf of itself and others, filed a civil claim for damages and interest against Norton Healthcare, Norton Pharmaceuticals and other defendants alleging that certain of their actions which adversely affected competition in the sale and supply of Penicillin in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate amount of 30,500 Pounds Sterling (approximately \$54,500 at the December 31, 2003, currency exchange rate), plus interest and costs.

On April 22, 2003, we received notice that we were named as a defendant along with approximately 25 other pharmaceutical manufacturers in a complaint filed in the US District Court for the Northern District of Texas by an individual who has filed the action purportedly in the name of the United States government, styled United States of America, ex. rel. Paul King v. Alcon Laboratories, Inc., et al. In this suit, the plaintiff seeks to recover damages from the defendants, including us, for allegedly defrauding and conspiring to defraud the United States government by having made sales of drugs to various federal governmental agencies or causing the United States government to reimburse individuals or entities for drug products that did not comply with Current Good Manufacturing Practices and other regulations and laws. The suit seeks the recovery of treble damages from us and the other defendants, jointly and severally, which plaintiff alleges exceeds thirty billion dollars, plus the recovery of attorneys' fees, interest, civil penalties, costs, and other relief. On February 23, 2004, Plaintiff was granted leave to file a Second Amended Complaint, in response to which we intend to move to dismiss the action in its entirety. We intend to vigorously defend ourselves in this action and against these allegations.

On April 22, 2003, GenPharm, Inc. filed a complaint in the United States District Court for the District of Puerto Rico against API for damages and equitable relief, including declaratory relief and specific performance, arising out of API's alleged breach of agreements and failure to supply GenPharm with an active pharmaceutical ingredient. The complaint also seeks the recovery of damages for API's alleged negligence in failing to maintain production facilities in accordance with FDA standards. The plaintiff seeks to recover millions of dollars in damages, along with interest, costs and expenses, including attorneys' fees and other fees and costs. The plaintiff also filed a motion for preliminary relief seeking the attachment of approximately 165 kilograms of the active pharmaceutical ingredient, which we vigorously opposed. API and Genpharm have agreed in principle to settle the litigation in its entirety, the details of which settlement are being finalized. The complaint has been tendered to the sellers of API for defense and indemnity based on the terms of the agreement by which API was sold to us, but the sellers have denied responsibility for the claim.

### Environmental Related Proceedings

On January 22, 2003, our subsidiary, API, received an Administrative Compliance Order issued by the United States Environmental Protection Agency dated January 2, 2003, alleging that API was not in compliance with certain conditions of the National Pollutant Discharge Elimination System Permit and certain pretreatment standards. The Order required that API submit particular certified documentation associated with achieving compliance with the given standards. The Order further required that API submit certified information concerning stormwater pollution control matters and costs. API filed its response to the Order and the EPA ordered the matter closed on August 30, 2003.

On April 4, 2003, API received an Order on Consent from The Puerto Rico Aqueduct and Sewer Authority ("PRASA"), which required that API follow a PRASA-approved compliance plan in order to achieve compliance with certain pretreatment standards. This Order also establishes interim limits applicable during the implementation of the compliance plan and attaches stipulated penalties for each day of non-compliance with the prescribed activities and reports schedule. On June 11, 2003, API submitted to PRASA certifications of compliance with two pretreatment standards identified in the Order on Consent. API negotiated with PRASA the final terms of the Order on Consent for the two remaining pretreatment standards, which was signed and finalized on June 30, 2003.



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On April 28, 2003, API received an EPA issued Administrative Complaint dated April 15, 2003, which proposes that a civil penalty of approximately \$19 be assessed against API for the alleged violation of certain conditions of its NPDES Multi-Sector General Permit. The complaint alleges that API failed to perform certain quarterly visual examinations and conduct an appropriate analysis of parameters during monitoring periods specified in the NPDES general permit. The complaint has been tendered to the sellers of API for defense and indemnity based on the terms of the agreement by which API was sold to us. API responded to the complaint and the parties agreed to settle the matter. A Final Consent Agreement and Final Order was signed by the EPA on November 23, 2003, and the settlement amount of \$8 was paid by the sellers of API.

On July 16, 2003, API received an EPA letter requesting API to submit a revised Solid Waste Management Unit (SWMU) Plan, including additional sampling and investigation elements, concerning the alleged presence of isopropyl ether (IPE) in its facility. This matter was tendered to the sellers of API for indemnity based on the terms of the agreement by which API was sold to us, but sellers have denied responsibility for this claim. On November 7, 2003, API filed its response to the EPA's July 16, 2003, letter and submitted a revised SWMU Plan to cooperate with the agency.

### Other Litigation

We are involved in various other legal proceedings arising in the ordinary course of business, some of which involve substantial amounts. In order to obtain brand equivalent approvals prior to the expiration of patents on branded products, and to benefit from the exclusivity allowed to ANDA applicants that successfully challenge these patents, we frequently become involved in patent infringement litigation brought by branded pharmaceutical companies. Although these lawsuits involve products that are not yet marketed and therefore pose little or no risk of liability for damages, the legal fees and costs incurred in defending such litigation can be substantial. While it is not feasible to predict or determine the outcome or the total cost of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings will not have a material adverse impact on our financial position or results of operations.

We intend to vigorously defend each of the foregoing lawsuits, but their respective outcomes cannot be predicted. Any of such lawsuits, if determined adversely to us, could have a material adverse effect on our financial position and results of operations. Our ultimate liability with respect to any of the foregoing proceedings is not presently determinable.

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### (15) Quarterly Financial Information (Unaudited):

The following tables summarize selected quarterly data of IVAX for the years ended December 31, 2003 and 2002:

	First Quarter	Second Quarter	Third Quarter (1)	Fourth Quarter (2)	Full Year
<b>2003</b>					
Net revenues	\$ 317,693	\$ 342,985	\$ 360,638	\$ 399,023	\$ 1,420,339
Gross profit	146,143	150,952	160,536	181,325	638,956
Income from continuing operations	28,985	19,086	21,631	29,345	99,047
Income from discontinued operations, net of tax	—	22,204	—	—	22,204
Net income	28,985	41,290	21,631	29,345	121,251
Basic earnings per common share:					
Continuing operations	0.15	0.10	0.11	0.15	0.51
Discontinued operations	—	0.11	—	—	0.11
Net earnings	0.15	0.21	0.11	0.15	0.62
Diluted earnings per common share:					
Continuing operations	0.15	0.10	0.11	0.15	0.50
Discontinued operations	—	0.11	—	—	0.11
Net earnings	0.15	0.21	0.11	0.15	0.61
<b>2002</b>					
Net revenues	\$ 272,222	\$ 280,406	\$ 319,394	\$ 325,222	\$ 1,197,244
Gross profit	121,975	130,563	142,802	138,196	533,536
Income from continuing operations	19,300	31,722	30,803	36,770	118,595
Net income	23,461	31,722	30,803	36,770	122,756
Basic earnings per common share:					
Continuing operations	0.10	0.16	0.16	0.19	0.61
Cumulative effect of accounting change	0.02	—	—	—	0.02
Net earnings	0.12	0.16	0.16	0.19	0.63
Diluted earnings per common share:					
Continuing operations	0.10	0.16	0.16	0.19	0.60
Cumulative effect of accounting change	0.02	—	—	—	0.02
Net earnings	0.12	0.16	0.16	0.19	0.62

- (1) As a result of recent return and customer inventory experience, our estimates of product returns and other sales allowances and inventory obsolescence decreased during the third quarter of 2003 and, accordingly, we recognized increased net revenues and reduced cost of sales during the third quarter of 2003. During the three months ended September 30, 2003, these changes increased net revenues by \$10,170, reduced cost of sales by \$2,457, increased net income by \$7,943 and increased diluted earnings per share by \$0.04.
- (2) As a result of our recent return, customer inventory experience, analysis of allowance for doubtful accounts and tax reserves, our estimates of product returns, inventory obsolescence, allowance for doubtful accounts and income tax exposures changed and, accordingly, we recognized reduced net revenues, increased cost of sales, reduced bad debt expense and reduced income tax provision during the fourth quarter of 2003. During the three months ended December 31, 2003, these changes reduced net revenues by \$102, increased cost of sales by \$335, reduced bad debt expense by \$3,673, reduced the tax provision by \$2,000, increased net income by \$4,025 and increased diluted earnings per share by \$0.02.

### (16) Related Party Transactions:

Whitman Education Group, Inc. ("Whitman") leases office space from us in Miami, Florida. Whitman leased approximately 11,567 square feet during 2003 at an annual rate of \$292, 13,849 square feet during 2002 at an annual rate of \$290 and 12,428 square feet during 2001 at an annual rate of \$233. Whitman was acquired by an unaffiliated entity, Career Education Corporation on July 1, 2003.

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Following the acquisition, the lease was terminated and Whitman is to vacate the facility no later than March 31, 2004. Prior to the acquisition, Dr. Frost, our Chairman of the Board of Directors and Chief Executive Officer, was Chairman of the Board of Directors of Whitman. Mr. Flanzraich, our Vice Chairman, President and a Director, was a Director of Whitman, and Mr. Pfenniger, one of our Directors, was Chief Executive Officer and Vice Chairman of the Board of Directors of Whitman. In addition, Dr. Frost was a principal shareholder of Whitman.

We paid \$2,504 in 2003, \$2,702 in 2002 and \$2,023 in 2001 to PharmAir Corporation for use of an airplane. PharmAir Corporation is indirectly, beneficially owned by our Chairman and CEO.

### **(17) Subsequent Event:**

On March 3, 2004, we issued \$400,000 of our 1.5% Convertible Senior Notes due 2024. Under certain circumstances, the 1.5% Notes are convertible, unless previously redeemed, into 33.4874 shares of our common stock per \$1,000 of principal amount of the 1.5% Notes. This ratio results in a conversion price of approximately \$29.86 per share. We may redeem the 1.5% Notes on or after March 1, 2011. Beginning with the six-month period commencing on March 1, 2011, we will pay contingent interest on the 1.5% Notes during a six-month interest period if the average trading price of the 1.5% Notes is above a specified level. In addition, holders of the 1.5% Notes may require us to repurchase the notes on each of March 1, 2011, 2014, and 2019 and upon certain events.

Net proceeds from this offering of approximately \$390,500 are expected to be used to redeem our outstanding 5.5% Convertible Senior Subordinated Notes and for general corporate purposes, including potential acquisitions of, and investments in, products, technologies and companies, capital expenditures and working capital. At December 31, 2003, we had approximately \$249,000 of our 5.5% Notes outstanding. The 5.5% Notes are, unless previously redeemed, convertible into 33.6 shares of our common stock per \$1,000 principal amount. In the event the 5.5% Notes are redeemed between May 16, 2004 and May 16, 2005, we expect that approximately \$254,869 in cash will be used to redeem the notes, and that a one-time financial charge of approximately \$8,553 will be incurred in connection with the redemption.

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To the Board of Directors and Shareholders  
IVAX Corporation

We have audited the consolidated financial statements of IVAX Corporation as of December 31, 2003 and 2002, and for the years then ended, and have issued our report thereon dated February 18, 2004 (except for Note 17, as to which the date is March 3, 2004) (included elsewhere in this Form 10-K). Our audit also included Schedule II—Valuation and Qualifying Accounts as of December 31, 2003 and 2002, and for the years then ended, included in this Annual Report on Form 10-K. This schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on this schedule based on our audits. The financial statement schedule of IVAX Corporation for the year ended December 31, 2001, was subjected to the auditing procedures applied by other auditors, who have ceased operations, in their audit of the consolidated financial statements for that year and whose report dated February 12, 2002, indicated that such financial statement schedule fairly stated in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

In our opinion, the financial statement schedules as of December 31, 2003 and 2002, and for the years then ended, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Miami, Florida  
February 18, 2004, except for Note 17, as  
to which the date is March 3, 2004

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[Table of Contents](#)**REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS**

To the Board of Directors and Shareholders  
of IVAX Corporation:

We have audited in accordance with auditing standards generally accepted in the United States, the financial statements included in IVAX Corporation's annual report to shareholders incorporated by reference in this Form 10-K, and have issued our report thereon dated February 12, 2002 (except with respect to the matters discussed in Note 16, as to which the date is March 15, 2002). Our audit was made for the purpose of forming an opinion on those statements taken as a whole. The Financial Statement Schedule II listed in Item 14 is the responsibility of the Company's management and is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This financial statement schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

ARTHUR ANDERSEN LLP

Miami, Florida,  
February 12, 2002.

THIS IS A COPY OF THE AUDIT REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH IVAX CORPORATION'S FILING ON FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2001. THIS AUDIT REPORT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP IN CONNECTION WITH THIS FILING ON FORM 10-K. SEE EXHIBIT 23.2 FOR FURTHER DISCUSSION.

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## SCHEDULE II

**IVAX CORPORATION AND SUBSIDIARIES**  
**VALUATION AND QUALIFYING ACCOUNTS**  
**THREE YEARS ENDED DECEMBER 31, 2003**  
(in thousands)

ALLOWANCE FOR DOUBTFUL ACCOUNTS

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Charged to Cost and Expenses</u>	<u>Net Deductions</u>	<u>Other</u>	<u>Balance at End of Year</u>
Year ended December 31, 2001	\$ 19,703	1,143	(2,575)	3,399	\$ 21,670
Year ended December 31, 2002	\$ 21,670	4,239	(2,153)	(2,037)	\$ 21,719
Year ended December 31, 2003	\$ 21,719	(1,948)	(2,893)	797	\$ 17,675

ENVIRONMENTAL ACCRUALS

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Charged to Cost and Expenses</u>	<u>Net Deductions</u>	<u>Other</u>	<u>Balance at End of Year</u>
Year ended December 31, 2001	\$ 1,584	663	(346)	—	\$ 1,901
Year ended December 31, 2002	\$ 1,901	1,272	(1,822)	—	\$ 1,351
Year ended December 31, 2003	\$ 1,351	1,110	(1,783)	500	\$ 1,178

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<b>EXHIBIT NUMBER</b>	<b>DESCRIPTION OF DOCUMENT</b>
4.6	Indenture, dated as of March 3, 2004, between IVAX Corporation and U.S. Bank Trust National Association, as Trustee, with respect to the \$400,000,000 1 1/2 % Convertible Senior Notes due 2024.
4.7	Form of 1 1/2% Convertible Senior Notes due 2024.
10.18	Registration Rights Agreement, dated March 3, 2004, between IVAX Corporation and UBS Securities LLC, as the Initial Purchaser and as agent for the other Initial Purchasers, with respect to the \$400,000,000 1 1/2% Convertible Senior Notes due 2024.
21	Subsidiaries of IVAX Corporation.
23.1	Consent of Ernst & Young LLP.
23.2	Information Regarding Consent of Arthur Andersen LLP.
31.1	Certificate of the Chief Executive Officer of IVAX Corporation pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a).
31.2	Certificate of the Chief Financial Officer of IVAX Corporation pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a).
32.1	Certificate of the Chief Executive Officer of IVAX Corporation pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certificate of the Chief Financial Officer of IVAX Corporation pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.