10-K 1 g93824e10vk.htm IVAX CORPORATION

Table of Contents

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 10-K

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

**For the fiscal year ended December 31, 2004** **Commission File Number 1-09623**

# IVAX CORPORATION

| **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**

**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**<br>**London Stock Exchange**<br>**Warsaw Stock Exchange** |

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 28, 2005, there were 261,045,330 shares of Common Stock outstanding.

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2004, was approximately $3.8 billion, based on the price at which the equity stock was last sold on the American Stock Exchange on such date of $19.19 per share. Solely for the purpose of this calculation, shares held by directors, executive officers and 10% shareholders of the registrant as of such date have been excluded.




Hopewell EX1056
Hopewell v. Merck
IPR2023-00481

**DOCUMENTS INCORPORATED BY REFERENCE:**

Information required by Part III is incorporated by reference to portions of the Registrant's Proxy Statement for the 2005 Annual Meeting of Shareholders which will be filed with the Securities and Exchange Commission by April 29, 2005.

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**IVAX CORPORATION**

**Annual Report on Form 10-K**
**for the year ended December 31, 2004**

**TABLE OF CONTENTS**

Table of Contents

## PART I

## Item 1. Business

### Business

### Overview

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. We maintain manufacturing operations in Argentina, Chile, the Czech Republic, Germany, Ireland, Italy, Mexico, Peru, Poland, Puerto Rico, the United Kingdom, the United States, the U.S. Virgin Islands and Venezuela. We conduct our research and development programs in Chile, the Czech Republic, Hungary, India, Ireland, Peru, Poland, Puerto Rico, the United Kingdom and the United States. We also have marketing and sales operations in Azerbaijan, Belgium, Bulgaria, China, Costa Rica, Croatia, the Czech Republic, Denmark, the Dominican Republic, El Salvador, Estonia, Finland, France, Germany, Guatemala, Honduras, Hong Kong, Ireland, Kazakhstan, Latvia, Lithuania, The Netherlands, Nicaragua, Norway, Panama, Peru, Poland, Portugal, 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, developing and/or acquiring new proprietary products;
- developing, licensing and/or 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, Development and/or Acquisition of New Proprietary Products*

We expect that new proprietary products that we discover, develop and/or acquire will provide a cornerstone for our future growth.

Table of Contents

Among the proprietary compounds we have 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; and
- one or more of the soft steroids that we are developing for bronchial asthma, allergic rhinitis, dermatology and gastrointestinal indications in both humans and companion animals.

We also have other new compounds in earlier stages of development that are being designed to treat neurological disorders.

***Developing Licensing and/or Marketing Selected Brand Equivalent Pharmaceuticals***

In addition to seeking to develop new proprietary products, we also seek to develop, license and/or market selected brand equivalent pharmaceuticals that no longer enjoy patent protection or that have patents, which we believe our products do not infringe. We seek to develop brand equivalent pharmaceutical products that possess characteristics that we believe could make it difficult for our competitors to develop competing products. Developing selected brand equivalent pharmaceutical products generally involves more time and resources than developing common brand equivalent pharmaceutical products. The characteristics of the selected brand equivalent pharmaceutical 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 with significant sales potential;
- 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 brand equivalent competition and may produce higher profits for a longer period of time than products without these characteristics.

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

We believe we possess significant proprietary technology and development strengths in the areas of respiratory diseases and oncology, including:

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

In the respiratory area, we were the first company to obtain approvals of formulations of certain drugs that did not contain chlorofluorocarbon (CFC). We are also developing several of our products using dry-powder formulations, including CFC-free beclomethasone and albuterol. We intend to continue to leverage our proprietary technology and development strengths in these fields to develop a portfolio of pharmaceutical products.

Table of Contents

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

Acquisitions have in the past helped build our company, and we expect to use carefully selected acquisitions to continue to drive our growth. We primarily intend to pursue acquisitions that we believe will complement our existing businesses or 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 our 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; and
- allow us to penetrate further our existing markets.

In the past five years, we have completed acquisitions of pharmaceutical companies and facilities in Argentina, Chile, Mexico, Peru, Poland and Venezuela, which complement our existing operations and continue the expansion of our European and Latin American operations. Our future plans include the acquisition of additional manufacturing and distribution capabilities in Asia, Europe and Latin America.

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 strategically expand 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 Central and 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. In December 2004, we acquired a leading Polish pharmaceutical company with over 200 sales representatives, which we intend to use as a springboard for significant expansion of our activities in the region.

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 implement cross-marketing and distribution opportunities that may 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***

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

Table of Contents

We believe that we have substantial expertise in the development, manufacture and marketing of respiratory drugs, primarily for bronchial asthma, delivered by metered-dose and dry powder inhalers. Our subsidiary in the United Kingdom, Norton Healthcare Limited, trading as IVAX Pharmaceuticals UK, is the third largest respiratory company in that market based on IMS sales data for 2004. At the core of our respiratory franchise are our advanced delivery systems, which include a patented breath-operated inhaler called BREATHMATIC™ in the United States and Easi-Breathe™ in other countries and a patented dry powder inhaler, as well as conventional metered-dose inhalers.

*BREATHMATIC™/Easi-Breathe™*. We hold patents on our breath-operated inhaler, which is designed to overcome the difficulty many users experience with conventional metered-dose inhalers in coordinating inhalation with the emission of the medication. Our breath-operated inhaler emits the medication automatically in one step upon inhalation, minimizing coordination problems. We market Easi-Breathe™ through our subsidiaries in the Czech Republic, France, Ireland, Mexico, Poland, Russia, the Slovak Republic and the United Kingdom and through distributors in Africa, Asia, Cyprus and Germany.

In October 2001, we acquired from Elan Corporation the United States rights to the intranasal steroid brand product, Nasarel®, for the treatment of allergic rhinitis. In March 2002, we also acquired from the Roche Group the rights to 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 bronchial 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 in Europe, which included QVAR® and Airomir® in Autohaler® and standard metered dose inhalers and over 200 marketing and sales representatives in nine European countries.

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

We are committed to the cost-effective development of proprietary pharmaceuticals directed primarily towards indications we believe have relatively large patient populations or for which we believe 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 neurologic, oncology and respiratory fields and have a variety of proprietary pharmaceuticals in varying stages of development.

Table of Contents

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

We received approval to market CFC-free beclomethasone in Ireland and France in 1997 in our standard metered-dose inhaler and our breath-operated inhaler, the first such approvals for any company anywhere in the world. We have received approval to market CFC-free beclomethasone in our standard metered-dose inhaler in numerous countries, including Argentina, Belgium, Chile, the Czech Republic, Finland, Hong Kong, Italy, Japan, Germany, Mexico, Peru, Portugal, Spain and Venezuela. We have received approval to market CFC-free beclomethasone in our breath-operated inhaler in numerous countries, including Argentina, Belgium, Chile, the Czech Republic, Luxembourg, Mexico, Peru, Poland, Portugal and Spain. We received approval in September 2004 to market QVAR® in our breath-operated inhaler in the United Kingdom.

In April 2000, we received approval to market CFC-free albuterol in the United Kingdom in our standard metered-dose inhaler and our Easi-Breathe™ inhaler. In October 2001, these approvals were used as the basis for obtaining approvals of these two products in other countries, including Argentina, Belgium, the Czech Republic, Denmark, Germany, Ireland, Luxembourg, Mexico, Norway, Peru and Spain. We have also received approval for CFC-free albuterol in our Easi-Breathe™ inhaler in numerous countries, including Holland, Hong Kong and Poland. In October 2004, we received approval to market CFC-free albuterol in our standard metered-dose inhaler in the United States. The NDA in the United States for CFC-free albuterol in our breath-operated inhaler received an approvable letter in 2004 and continues under review.

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 approval to market formoterol in our multi-dose dry powder inhaler in Denmark and in 2003, we received approval to market albuterol in our multi-dose dry powder inhaler in the United Kingdom. We have also received approval to market budesonide in our multi-dose dry powder inhaler in the Czech Republic, Denmark, Estonia, Hungary and the Ukraine. We have completed Phase I clinical trials in the United States with etiprednol dicloacetate, an inhaled soft corticosteroid, in our multi-dose dry powder inhaler. A Phase II clinical trial with etiprednol dicloacetate was commenced in September 2004 for the treatment of bronchial asthma.

We are continuing to develop our breath-operated inhaler for use with various compounds. During 2003, we completed Phase III clinical trials for CFC-free albuterol in our breath-operated inhaler and an NDA was submitted for this product in August 2003. The NDA is presently under review. Phase III clinical trials for QVAR® in our breath-operated inhaler were initiated in 2004 in patients with bronchial asthma.

*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.

Table of Contents

*TP-38.* In pre-clinical trials of our epidermal growth factor (EGF) receptor-targeted gliobastoma therapy, our lead compound, TP-38, was found to be highly specific and toxic to brain cancer cells. In November 2004, positive results were reported for TP-38 in a Phase II multi-center clinical trial in patients with recurrent glioblastoma. We have initiated an expanded Phase II clinical trial involving centers in the United States and Europe. We are initiating a Phase I/II pediatric clinical trial in patients with brain tumors.

*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 are continuing Phase II clinical trials in epilepsy patients. In July 2003, we commenced Phase II clinical trials with patients with recurrent malignant brain tumors in a trial sponsored by the National Cancer Institute and in 2005, we are planning to commence Phase II clinical trials with patients with newly diagnosed glioblastoma. We are planning additional studies using this compound to treat multiple sclerosis and other neurological diseases.

*Asthma and Inflammatory Diseases*. We have developed 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 of etiprednol dicloacetate include possible treatments for bronchial asthma, allergic rhinitis and inflammatory diseases of the large intestine. Etiprednol dicloacetate has successfully completed Phase I clinical trials for safety for oral administration.

Phase I clinical trials with etiprednol dicloacetate in our patented multi-dose inhaler for the indication of bronchial asthma were completed in 2004 and in September 2004, we initiated a Phase II clinical trial.

In addition, in August 2003, we acquired the worldwide rights, exclusive of Japan and certain Asian countries, for loteprednol etabonate for allergic rhinitis. We are now conducting a Phase II study with loteprednol etabonate in children with allergic rhinitis.

***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 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 seeking to obtain marketing authorizations which should 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. (IPI) manufactures and markets approximately 73 brand equivalent prescription drugs in capsule or tablet forms in an aggregate of approximately 169 dosage strengths. We also distribute in the United States approximately 168 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 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.

Table of Contents

In the United Kingdom, we are a leading provider of brand equivalent pharmaceutical products. We market approximately 402 brand equivalent prescription drugs, about half of which we manufacture, in various dosage forms and dosage strengths, constituting an aggregate of approximately 143 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 66% of our revenues in 2004, 62% in 2003 and 56% in 2002.

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

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.

During 2004, we received final United States Food and Drug Administration (FDA) approval of 11 Abbreviated New Drug Applications (ANDAs) for 10 molecules, tentative FDA approval of 3 ANDAs for 3 molecules, approval of 13 Abridged Marketing Authorization Applications or AMAAs (the European equivalent of an ANDA) for 4 molecules in the United Kingdom, and approval of 78 AMAAs for 34 molecules in the other European Union (EU) countries.

As of January 1, 2005, we had ANDAs or its foreign equivalent pending as follows:

| Number Pending | Country |
|---|---|
| 60 (49 molecules) | United States |
| 29 (15 molecules) | United Kingdom |
| 205 (46 molecules) | Other EU Countries |

***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.

*Pending Acquisition of PSI Holdings, Inc.* On February 15, 2005, we entered into a stock purchase agreement pursuant to which we agreed to purchase all of the capital stock of PSI Holdings, Inc., the holding company for Phoenix Scientific, Inc., a manufacturer of generic veterinary pharmaceutical formulations headquartered in St. Joseph, Missouri. The sale is subject to the expiration of applicable Hart Scott Rodino waiting periods and other customary closing conditions. The parties expect to close the transaction in the second quarter of 2005.

*Polfa Kutno*. In December 2004, through a private purchase and two tender offers (the second of which ended in January 2005), we acquired 99.25% of the outstanding shares of Kutnowskie Zaklady Farmaceutyczne "POLFA" S.A., or Polfa Kutno, a leading Polish pharmaceutical company. Polfa Kutno manufactures and sells a number of prescription drugs, such as Ceclor® and Metformax®. In addition to the antibiotics and diabetes sectors, Polfa Kutno's prescription drugs cover central nervous system disorders, osteoporosis and the urology segment. Polfa Kutno is also very active in the over-the-counter (OTC) drug area, including such products as the children's multivitamin Vibovit® and the pain relievers Bestpirin® and Aescin.

Table of Contents

*Laboratorio Chile S.A*. Through two tender offers, the second of which ended in August 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.

*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 to promote its products.

*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.

***Collaborative Agreements***

We also seek to enter into collaborative alliances which we believe will 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.

*Grupo Ferrer*. In October 2004, we entered into a licensing agreement with Grupo Ferrer, an international pharmaceutical company headquartered in Barcelona, Spain, for the final development of citicoline, an oral neuroprotective therapy for the treatment of strokes.

*Nippon Shinyaku.* In October 2004, we entered into a licensing agreement with Nippon Shinyaku to develop and market HMN-214, a polo-like kinase inhibitor that targets pancreatic, prostate and a number of other cancers.

*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®, in the European nations of Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Sweden and the United Kingdom.

Table of Contents

*EIS Eczacibasi IIac Sanayi ve Ticaret A.S.* In May 2003, we entered into an exclusive marketing authorization and supply agreement with EIS Eczacibasi IIac 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 and Phase III 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 gliobastoma. In addition, we license pharmaceutical products from third parties from time to time. We will continue to seek new licenses from third parties, including pharmaceutical companies.

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 that trades on the American Stock Exchange under the symbol "IVD" and is listed on the Boston Stock Exchange. We own approximately 74% of the equity of IVAX Diagnostics.

IVAX Diagnostics, Inc. is the parent corporation of three wholly owned operating subsidiaries: Diamedix Corporation in Miami, Florida, ImmunoVision, Inc. in Springdale, Arkansas, and Delta Biologicals, S.r.l. near Rome, Italy. Through these subsidiaries, IVAX Diagnostics develops, manufactures, and markets diagnostic test kits, or assays, and automated systems that are used to aid in the detection of disease markers primarily in the areas 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 its 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' existing instruments include the Mago® Plus and Aptus®. IVAX Diagnostics has also developed a new proprietary instrument system, the PARSEC™ System, which it expects will receive regulatory approval. The PARSEC System is designed in a modular and scalable format that should enable customers to utilize not only ELISA-based kits, but also other methods such as chemiluminescent-based assays in the future. The design of this new system is expected to give customers the ability to "customize" the configuration of the PARSEC System to the testing and work flow requirements of their particular laboratories. IVAX Diagnostics markets its existing products to clinical reference laboratories, hospital

Table of Contents

laboratories, research institutions and other commercial entities in the United States and in Italy through its direct sales force and through independent distributors in other major markets throughout the world.

**Patents and Proprietary 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. We believe that patents and other proprietary rights are important to our business. Our policy is to file patent applications whenever possible 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 1,490 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.

**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.

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

Table of Contents

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. As a result of recent developments concerning products, such as cox-2 inhibitors and anti-depressants, certain members of the United States Congress and interest groups in the private sector have renewed calls for a far-reaching investigation of the FDA's product approval processes. We cannot predict what impact, if any, these developments may have on us or our business. 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 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.

Table of Contents

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 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.

Table of Contents

**Competition**

The pharmaceutical market is highly competitive and includes many established companies, some of whom possess significantly greater resources than us. Some of our major competitors are:

- Astra Zeneca
- Aventis Pharmaceuticals
- Boehringer Ingelheim
- Bristol-Myers Squibb
- Forest Laboratories
- GlaxoSmithKline
- Eli Lilly
- Mylan Pharmaceuticals
- Novartis Pharmaceuticals
- Pfizer Inc.
- Sandoz
- 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 we believe 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.

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

Table of Contents

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;
- 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.

Table of Contents

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**

The dollar amount of backlog orders for IVAX Pharmaceuticals was $12.7 million as of January 30, 2005, compared to $9.5 million as of January 30, 2004, and for IVAX Pharmaceuticals UK it was $3.2 million as of January 30, 2005, compared to $1.1 million as of January 30, 2004. We expect to fill all of our backlog orders during our current fiscal year.

**Raw Materials**

We believe that 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 approved source. A problem with the availability of raw materials 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. Additionally, in some cases we have listed only one supplier in applications with the FDA. Because raw material sources for pharmaceutical products must generally be approved by regulatory authorities, changes in raw material suppliers or the designation of a new supplier 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.

Table of Contents

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, 2004, we had approximately 10,100 employees worldwide.

**Available Information**

Our Internet website is: 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. Reports we file with the SEC may be read and copied at the SEC’s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

**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. The risks described below are not the only risks that we face. Additional risks not presently known to us or other factors that we do not presently perceive to present significant risks to us at this time may also impair our operations. You should also refer to the other information contained or incorporated by reference in this report.

***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

Table of Contents

products that do not infringe any valid 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 some 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.

**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

Table of Contents

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. Further, some distributors of our products have been reported to have experienced financial difficulties. Any economic difficulties faced by significant 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 or result in claims for substantial damages.**

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 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.

Table of Contents

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.

The outcome of patent litigation is difficult to predict because of the uncertainties inherent in litigation. Our results of operations, financial condition and cash flows could be adversely affected by a delay in obtaining FDA approval to market our products as a result of patent litigation, a delay in obtaining judicial decisions in such litigation, the expense of litigation whether or not we are ultimately successful, the diversion of the attention of management and our technical personnel as a result of the litigation, or an adverse outcome in such litigation. Litigation could prevent us from selling affected products, result in substantial damages or result in the payment of a substantial settlement amount.

Moreover, we often encounter substantial delays in obtaining judicial decisions in connection with patent litigation. During such delays, additional competition may arise, the brand product may be offered as a licensed generic or an OTC product, other brand products may be introduced and promoted to prescribers instead of or in addition to the brand product, additional exclusivities may be awarded to the brand product, additional patents that cover the brand product may issue or be listed in the Orange Book, the labeling of the brand product may change or other matters occur that could delay brand equivalent competition or lessen our economic opportunity for our product.

Because we could invest a significant amount of time and expense in the development of our brand equivalent pharmaceutical products only to be subject to significant additional delays and changes in the economic prospects for our product, we may consider seeking to commercialize our product prior to final resolution of the pending litigation. The risk involved in marketing products prior to final resolution of the litigation can be substantial because the remedies available to the owner of a patent for infringement could include, among other things, damages measured by the profits lost by the patent owner and not by the profits earned by the infringer. Because of the discount pricing typically involved with brand equivalent pharmaceutical products, patented brand products generally realize a significantly higher profit margin than brand equivalent pharmaceutical products. In the case of a willful infringer, the definition of which is unclear, these damages may even be trebled. This profit differential can act as a disincentive to the patent owner to settle patent litigation on terms that could allow our products to be marketed upon the settlement of such litigation. However, in order to realize the economic benefits of some of our products, we may decide to risk an amount, which exceeds the profit we anticipate making on our product, or even the selling price for such product.

**We may not be able to use raw materials purchased or inventories of products made in advance of final approvals or satisfactory resolution of patent litigation.**

From time to time, we purchase raw materials and make commercial quantities of our product candidates prior to the date that we receive FDA final marketing approval or satisfactory resolution of the patent infringement litigation, if any. Purchase of raw materials and production of pre-launch inventories involves the risks that such product(s) may not be approved for marketing by the FDA on a timely basis or ever, that the results of related litigation may not be satisfactory or that we may not be able to find alternative uses for such materials or inventory. If any of these events were to occur or the launch of such products is significantly postponed, we may be required to reassess the net realizable value of the related raw materials or inventory and could, in such case, incur a charge, which may be significant, to write down the value of such materials or inventory. As of December 31, 2004, we had approximately $33.2 million of

Table of Contents

inventories, primarily raw materials, related to certain products pending final approval and/or satisfactory resolution of litigation.

**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 $141.6 million during 2004 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 spend on 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 commercially successful products.

**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.

Table of Contents

**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.

Although we generally seek acquisitions that we believe will be accretive to our per share earnings, 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 future 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;
- publicity regarding actual or potential medical results for products that we or our competitors have under development;
- period-to-period changes in financial results;
- the integration of people, operations and products from acquisitions;
- market acceptance of existing or new products and prices;
- currency rate fluctuations;
- changes in our research and development budget which is influenced, in part, by the timing of our clinical trials and regulatory proceedings related to our products in development; and

- the timing of orders from distributors and mix of sales among our customers.

Table of Contents

**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. Our net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of major distributors, retail chains and other trade buyers. These fluctuations may result from seasonality, pricing, wholesaler buying decisions or other factors. In addition, many of the major pharmaceutical distributors have experienced downturns and financial constraints which could impact both our sales and the collectibility of our receivables and cause greater consolidation among our customers. 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 particular, Venezuela, where we have operations, was considered a hyperinflationary economic environment through June 30, 2001. Although Venezuela is no longer considered hyperinflationary, its economy continues to experience high inflation rates and devaluation of its currency and could again become hyperinflationary in the near term. The continuing political instability in Venezuela may adversely impact our Venezuelan operations and our consolidated earnings. Approximately 17% of our net revenues for 2004 were attributable to our Latin American operations.

Table of Contents

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

On December 31, 2004, we had approximately $1.1 billion of consolidated indebtedness. We are likely to incur additional indebtedness in the future, in connection with acquisitions or otherwise. 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 $108.0 million of cash flow from operations will be required during 2005 to discharge our annual obligations on our indebtedness outstanding as of December 31, 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.

**We may be unable to fund amounts due upon conversion or repurchase of our “net share settlement” indebtedness.**

As of December 31, 2004, we had approximately $333.0 million of outstanding indebtedness containing a “net share settlement” mechanism and, in February 2005, we completed an exchange offer that resulted in the issuance of an additional $399.0 million of such indebtedness. Upon conversion of that indebtedness, we are required to pay the holder an amount in cash equal to the lesser of the principal amount of the debt and the then applicable conversion value. In addition, on specified dates holders of such indebtedness may require us to repurchase it for an amount equal to 100% of its principal amount plus accrued but unpaid interest. We may not have sufficient funds at any such time to make the required principal payment upon conversion of our “net share settlement” indebtedness or to repurchase that indebtedness when and if required, and we may not be able to raise sufficient funds to satisfy that obligation. Our failure to pay the required amounts on conversion of any of our “net share settlement” notes when converted or to repurchase any of the notes when we are required to do so would result in an event of default with respect to the notes, which could result in the entire outstanding principal balance and accrued but unpaid interest on all of the notes being accelerated and could also result in an event of default under our other outstanding indebtedness.

Table of Contents

**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.

**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 (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 currently 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. On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* which addresses the accounting for transactions in which an entity exchanges it equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires compensation costs related to share-based payment transactions to be recognized in the financial statements. We expect that under the modified prospective method of adoption, during the second half of 2005 we will be required to record additional compensation expense of approximately $2.6 million, net of tax, for unvested awards that were outstanding as of December 31, 2004. We also expect that compensation expense will be required to be recorded for future awards of share-based payments.

Table of Contents

On September 30, 2004, the Emerging Issues Task Force (EITF) of the FASB reached a consensus on Issue No. 04-8, *The Effect of Contingently Convertible Debt on Diluted Earnings per Share*, concluding that contingently convertible debt instruments should be included in diluted earnings per share computations (if dilutive) regardless of whether the market price trigger (or other contingent feature) has been met. This consensus is effective for reporting periods ending after December 15, 2004, and requires prior period earnings per share amounts presented for comparative purposes to be restated utilizing a transition method. The transition method agreed upon by the EITF is a modified restatement approach that results in a company applying the consensus to the terms of the security at the adoption date. As such, if the terms of the security are changed prior to the adoption date, it is the changed terms to which the consensus is applied. We adopted the consensus in the fourth quarter of 2004. The impact of adoption has reduced our reported diluted earnings per share for each of the three month periods ended March 31, 2004, June 30, 2004, and December 31, 2004, by $0.01 per share and for the year ended December 31, 2004 by $0.03 per share and there was no impact on the prior year's reported diluted earnings per share. On February 23, 2005, we completed our offer to exchange our 1.5% convertible senior notes due 2024 (Old 1.5% Notes), which are affected by EITF Issue No. 04-8. The purpose of the offer was to change the conversion settlement provisions of the Old 1.5% Notes. By committing to pay up to the principal amount of the 1.5% convertible senior notes due 2024 (New 1.5% Notes) in cash upon conversion, we believe we will be able to account for the New 1.5% Notes under the "treasury stock" method, which is generally expected to be less dilutive to earnings per share than the "if- converted" method prescribed by EITF Issue No. 04-8. The "treasury stock" method only requires inclusion of the shares to be delivered upon conversion if our common stock is trading at a price in excess of the conversion price based on the average trading price during the preceding quarter and then only to the extent the conversion value is greater than the principal amount of the New 1.5% Notes. We generally expect that since fewer shares will be included in the number of fully diluted shares outstanding under the New 1.5% Notes based on this calculation than would be included for the Old 1.5% Notes under the "if-converted" method, when dilutive, our diluted earnings per share will be greater.

These and other new accounting principles adopted in the future may have a material adverse effect on our financial position or results of operations.

**We may be exposed to product liability claims and there can be no assurance of adequate insurance.**

Like all pharmaceutical companies, the testing, manufacturing and marketing of our products may expose us to potential product liability and other claims resulting from their use. We have been named as a defendant in numerous cases in which a plaintiff alleges personal injury resulting from the use of our products. If any such claims against us are successful, we may be required to make significant compensation payments and suffer the associated adverse publicity. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources. We maintain product liability insurance, but there can be no assurance that our insurance will cover all future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. Our 2005 product liability insurance policy is more expensive with significantly less coverage and higher deductibles than in previous years. If a claim is not covered or if our coverage is insufficient, we may incur significant liability payments that would negatively affect our business, financial position or results of operations.

**Investigations of the calculation of average wholesale prices and allegations of anticompetitive generic drug pricing 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, local 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, counties and municipalities have sued us and certain of our subsidiaries, as well as numerous other pharmaceutical companies, alleging, among other things, that we and the other defendants inflated the price of products paid for by the governmental agency through alleged fraudulent promotion, marketing and sales practices. 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.

The Secretary of State for Health in the United Kingdom has filed suit against certain of our United Kingdom subsidiaries and several other pharmaceutical companies alleging that certain of their actions adversely affected competition in the sale and supply of warfarin, penicillin and ranitidine. The Serious Fraud Office in the United Kingdom is also conducting a criminal investigation into the actions of these companies and their executives, including certain of our United Kingdom subsidiaries and prior

Table of Contents

executives regarding these allegations. There may be further allegations covering additional products. The civil claims seek damages against all defendants in excess of $245 million, plus interests and costs.

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 and adversely affect future results of operations or our financial position. Additionally, whether or not we are ultimately successful in these claims, defending against the growing number of these suits, the expense of litigation, and the diversion of the attention of management will also have an adverse affect on our 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 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, 2005, our executive officers and directors had or shared voting control over approximately 30% of our 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, rose significantly in the past several years and could continue to increase in 2005. Additionally, insurers are continually excluding certain products from product liability coverage. 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.

Table of Contents

**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 1.1719 of a share of our common stock at a price of $9.60 per 1.1719 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.

**We will be exposed to risks relating to evaluations of internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act of 2002.**

We are spending a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and the American Stock Exchange rules. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal control systems, and attestations as to the effectiveness of these systems by our independent public accounting firm. We have expended and expect to continue to expend significant resources and management time documenting and testing our internal control systems and procedures. This process has been complicated by the decentralized nature of our operations and information systems. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to maintain an effective internal control environment could have a material adverse effect on the market price of our stock.

***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.

Table of Contents

**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 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.

Table of Contents

**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 equivalents 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.

Table of Contents

**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. For this purpose any statements contained in this report that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "would," "estimate," "continue" or "pursue," or the negative other variations thereof or comparable terminology are intended to identify forward-looking statements. 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;
- 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 Asia, 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 bronchial 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 our breath-operated inhaler for use with various compounds;
- our ability to market CFC-free albuterol;
- our ability to develop and market TP-38 for recurrent glioblastoma;
- our ability to further develop CFC-free inhalation aerosol products;
- our ability to develop and market etiprednol dicloacetate;
- our ability to develop a corticosteroid with minimal side effects to treat bronchial 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 cystic fibrosis and recurrent glioblastoma;
- 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 our soft steroid compound for inflammatory bowel diseases, bronchial asthma and allergic rhinitis;

- our ability to develop and market loteprednol etabonate for the treatment of allergic rhinitis and

Table of Contents

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;
- our ability to repay cash amounts due upon the conversion or mandatory repurchase of certain of our indebtedness;
- 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 2005 capital expenditures and research and development from existing cash and internally generated funds;
- uncertainties regarding the outcome of pending investigations, litigation, product recalls and other developments affecting the pharmaceutical industry; and
- other matters.

Table of Contents

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:

- that a significant portion of net sales are made to major pharmaceutical and health care products distributors and major retail chains in the United States. Consequently, net sales and quarterly growth comparisons may be affected by fluctuations in the buying patterns of major distributors, retail chains and other trade buyers. These fluctuations may result from seasonality, pricing, wholesaler buying decisions or other factors;

- that we may experience increased pricing pressures both in the United States and abroad from managed care organizations, institutions and government agencies and programs. In the United States, among other developments, consolidation among customers may increase pricing pressures and may result in various customers having greater influence over prescription decisions through formulary decisions and other policies;

- 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;

- that we may increase sales and marketing costs and research spending above current levels;

- our ability to obtain and maintain FDA approval of our manufacturing facilities, the failure of which could result in production stoppage or delays;

- the outcome and timing of any pending or future litigation or investigation (including patent litigation, AWP investigations, and the United Kingdom National Health Service claims), and the cost, expenses and possible diversion of management's time and attention arising from such litigation or investigation;

- 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 paclitaxel product, and other third party sourced products;

- our dependence on sole or limited source suppliers and the risk associated with a production interruption or shipment delay at such suppliers;

- our ability to replace or renew license fees, royalties and development service fees as the related agreements expire or are terminated;

- our ability to renew contracts with customers;

- that many of the major pharmaceutical distributors have experienced downturns and financial constraints which could impact both our sales and the collectibility of our receivables and cause greater consolidation among our customers;

- 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 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 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;

- our ability to use inventory and raw materials in the manner initially intended or to find alternative uses, to the extent such inventory and raw materials relate to products pending final

Table of Contents

approval or satisfactory resolution of litigation, if such approval or resolution is not obtained;

- 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;
- our successful compliance with extensive, costly, complex and evolving governmental regulations and restrictions;
- the use of estimates in the preparation of our financial statement and the possibility that these assumptions may prove incorrect, incomplete or may change;
- our reliance on third-party data for many of our significant estimates;
- our ability to continue to document, maintain and test the effectiveness of our internal control systems and procedures and implement any improvements that may be necessary in order for us to comply with the requirements of the Sarbanes-Oxley Act of 2002 Section 404;
- our ability to identify potential acquisitions and to successfully acquire and integrate such operations or products;
- our ability to incur additional indebtedness in the future, in connection with acquisitions or otherwise;
- our ability to successfully compete in both the branded and brand equivalent pharmaceutical sectors;
- uncertainties concerning our ability to finance or otherwise repay amounts due upon the conversion or mandatory repurchase of certain of our indebtedness;
- 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;
- 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.

Other factors besides those listed here could also adversely affect us. 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.

Except as otherwise expressly indicated, the information in this Form 10-K is as of December 31, 2004. You should know that we also make additional disclosures in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we file from time to time with the Securities and Exchange Commission and that information in those subsequent reports may update or supercede any information contained in this Form 10-K. However, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

**Financial Information about Foreign and Domestic Operations**

Specific financial information with respect to our segments and our foreign and domestic operations is provided in Note 12, Business Segment Information, in the Notes to Consolidated Financial Statements.

Table of Contents

**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, Croatia, the Czech Republic, Estonia, Finland, France, Germany, Hong Kong, Hungary, India, Ireland, Italy, Kazakhstan, Mexico, Latvia, Lithuania, The Netherlands, Nicaragua, Norway, 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, some 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; Opava, Czech Republic; Preston Brook, England; Runcorn, England; Miami, Florida; Falkenhagen, Germany; Waterford, Ireland; Mexico City, Mexico; Ramos Arizpe, Mexico; Northvale, New Jersey; Congers, New York; Lima, Peru; Kutno, Poland; Cidra, Puerto Rico; Guayama, Puerto Rico; St. Croix, the U.S. Virgin Islands; and Guacara, Venezuela. We own the manufacturing facilities in Argentina, Chile, the Czech Republic, England (Preston Brook), Florida, Germany, Mexico, New York, Poland, Puerto Rico and Venezuela and lease our remaining manufacturing facilities. In connection with the sale of the specialty chemicals business, we retained ownership of our manufacturing facility in Rock Hill, South Carolina, which we are seeking to sell.

We believe our facilities as a whole are in satisfactory condition and are suitable for their intended use. We plan to spend between $75 million and $100 million in 2005 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.

Table of Contents

**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 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 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. 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. On September 15, 2003, the United States Court of Appeals for the Eleventh Circuit reversed the order. On September 20, 2001, the District Court entered an order certifying the direct purchaser class and in early 2002, IPI entered into a settlement with the direct purchaser class. In November 2003, the appellate court also issued a ruling de-certifying the class. On remand and following class discovery, the District Court entered an order on June 23, 2004, denying the Direct Purchaser Plaintiffs' renewed motion for class certification. In light of these orders, on August 31, 2004, we elected to terminate the Settlement Agreement with the direct purchasers and requested the return of the settlement payment less notice and Settlement Fund administrative fees. On February 16, 2005, IPI announced to the Court its willingness to re-enter into the settlement with the direct purchasers on substantially the same terms as the previous settlement, provided that the court certifies a settlement class of direct purchasers that is not materially different from the previously de-certified direct purchaser class. On February 25, 2005, the Court indicated its preliminary approval of a settlement containing these terms and provisions, and has scheduled a hearing for April 15, 2005 to determine whether to grant final approval of this settlement. To date, sixteen 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 5,546 cases and has been dismissed from approximately 5,184 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. As of September 1, 2004, claims made against us for the first time may not be afforded insurance coverage. Although it is impossible to

Table of Contents

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 (AWP) Litigation

A number of counties in the State of New York and the City of New York City have filed complaints against IVAX and IPI and other pharmaceutical companies alleging a scheme to overcharge for prescription drugs paid for by Medicaid, a portion of which is paid for by these New York municipalities. IVAX and IPI have been named as defendants in actions filed by the County of Suffolk, the County of Westchester, the County of Nassau, the County of Onondaga, and the City of New York and in each of these cases, the plaintiff seeks the recovery of unspecified damages, including restitution, treble and punitive damages, civil penalties, interest and attorneys fees. Each of these actions was filed in the United States District Court for the applicable district in New York and, thereafter, was either transferred to the United States District Court for the District of Massachusetts as part of the Pharmaceutical Industry Average Wholesale Price Multi-District Litigation, MDL 1456 (MDL), or is in the process of being transferred to the MDL. The County of Suffolk vs. Abbott Laboratories, Inc. et al. action (Suffolk Action) has been treated as the lead case. In the Suffolk Action the court dismissed IVAX and IPI from the complaint by order dated October 26, 2004. Notwithstanding this dismissal, the County of Suffolk has indicated an intent to file an amended complaint naming IVAX and IPI as defendants. By stipulation of the parties, the remaining New York City and New York county actions are being held in abeyance pending a final ruling on the motions to dismiss the Suffolk Action. We intend to vigorously defend ourselves in these actions.

IVAX and IPI were named as defendants, along with other generic drug manufacturers, in The Commonwealth of Massachusetts vs. Mylan Laboratories, et al., filed in the United States District Court for the District of Massachusetts (Massachusetts Action). The Massachusetts Action alleges that through fraudulent and deceptive schemes thirteen manufacturers of generic pharmaceuticals caused Massachusetts to overpay pharmacies by inflating the wholesale acquisition cost of drugs. The state seeks unspecified damages, including injunctive relief, restitution, treble damages, civil penalties, interest, attorney fees and investigation and litigation costs. The case is pending before the same judge that is handling the MDL. The defendants in the Massachusetts Action moved to dismiss the complaint and by order dated February 4, 2005, the Court denied the motion in part, granted the motion in part, and deferred ruling in part. An additional ruling on the motion is expected. We intend to vigorously defend ourselves in this action.

A number of states have filed actions against IVAX and IPI and other pharmaceutical companies alleging schemes to overcharge for prescription drugs paid for by Medicaid. IVAX and IPI have been named as defendants in the following actions filed by the State of Wisconsin, the Commonwealth of Kentucky, the State of Alabama, and the State of Illinois. IVAX and IPI were added as defendants in State of Wisconsin vs. Abbott Laboratories, Inc., et al., Circuit Court of Dane County, Case No. 04 CV 1709 on November 1, 2004. IVAX and IPI were named as defendants in Commonwealth of Kentucky vs. Alpharma, Inc., Franklin Circuit Court, Case No. 04-CI-1487 on November 4, 2004. IVAX and IPI were named as defendants in State of Alabama vs. Abbott Laboratories, Inc., et al., Circuit Court of Montgomery County, Case No. CV-2005-219 on January 26, 2005. IVAX and IPI were named as defendants in The People of the State of Illinois vs. Abbott Laboratories, Inc., Circuit Court of Cook County, Case No. 05CH02474 on February 7, 2005. In each of these actions, the States seek unspecified damages, including treble and punitive damages, interest, civil penalties and attorneys fees. We intend to vigorously defend ourselves in these actions.

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

Table of Contents

industry and IPI practices regarding AWP. IPI has also received correspondence from the States of Nevada, Kentucky, Florida, and Illinois, on behalf of itself and eight 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. 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. On July 20, 2004, the OAG for the State of Florida issued subpoenas to IPI and five other pharmaceutical companies requesting materials to assist in its 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, the Serious Fraud Office expects to conclude its investigation and anticipates bringing charges by October 2005. There is no indication at this time regarding which companies may be charged.

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 27.5 million Pounds Sterling (approximately $52.8 million at the December 31, 2004, 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 31.4 million Pounds Sterling (approximately $60.3 million at the December 31, 2004, currency exchange rate), plus interest and costs.

In July 2004, 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 ranitidine in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate amount of 69.3 million Pounds Sterling (approximately $132.8 million at the December 31, 2004, currency exchange rate), plus interest and costs.

Commercial Matters

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 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

Table of Contents

damages from the 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 filed a motion to dismiss the action in its entirety. On January 4, 2005, the District Court entered an order dismissing the Second Amended Complaint with prejudice and entered judgment in favor of all the named defendants. It is unclear whether the plaintiff intends to appeal this decision.

Patent Litigation

IPI filed ANDA's under paragraph IV of Hatch-Waxman Act to market and sell various strengths of generic gabapentin capsules and tablets, a product marketed by Warner-Lambert under the trademark Neurontin®. As a result of the filing of these ANDAs, Warner Lambert Company, Pfizer and Godecke Aktiengesellschaft filed three separate suits against us and our affiliates for patent infringement. These three consolidated actions are now pending in the United States District Court for the District of New Jersey. Civil Action No. 00-6073 was filed December 14, 2000, Civil Action No. 01-0193 was filed January 12, 2001 and Civil Action No. 01-1537 was filed February 3, 2001. The three suits have been consolidated in a multidistrict litigation in the District of New Jersey with several other cases brought by plaintiffs against other companies seeking to market generic gabapentin. We, along with the other defendants in the consolidated actions, moved for summary judgment of non-infringement and invalidity of Warner-Lambert's patents on various grounds. Oral argument on these motions were held in November 2004. In August 2004, based on our decision to begin commercial sales of non-AB-rated gabapentin tablets, Warner-Lambert sought a temporary restraining order and a preliminary injunction in an effort to prevent us from doing so. Warner-Lambert's request was denied, and we commenced commercial sale of our non-AB-rated gabapentin tablets on August 18, 2004. We also intend to commence commercial sales of the AB-rated gabapentin capsules and tablets shortly prior to the expiration of applicable Hatch-Waxman exclusivity periods as a result of a settlement reached with the generic manufacturer awarded the exclusivity by the FDA. While we expect to be successful in our defense, in the event the court determines that we infringed a valid patent of Warner-Lambert's in our sales of gabapentin, it will result in an injunction against us preventing further sales and substantial damages which could exceed our profit or selling price for these products.

Environmental Matters

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 API purchase agreement, 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. On April 27, 2004, the EPA requested API to further address certain groundwater contaminant issues, including monitoring and sampling, relating to the presence of IPE in its facility. On June 14, 2004, API responded to the EPA's April 27, 2004, letter and submitted a revised SWMU Plan. On November 8, 2004, API received the EPA's approval of the SWMU Plan Revision 3.0 dated November 2, 2004. API will now engage in the necessary efforts to conduct the actions delineated in the referenced approved plan.

On November 3, 2004, API received a Notice of Deficiency whereby the EPA states that it is the agency's position that one of the incinerators at the company's plant must be decontaminated and closed pursuant to 40 CFR § 264.351. EPA bases its position on the company's failure to present a Notice of Intent to Comply (NIC) with MACT for such incinerator (due in 1999). API agreed to submit a revised Closure Plan for EPA's review and approval and a revised RCRA Part B application reflecting this closure was filed on February 15, 2005. At this time we are waiting for the agency's response.

Table of Contents

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.

Table of Contents

**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, 2004.

**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, 2005. 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 59, 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.

***Frank Condella, Jr.***

Frank Condella, Jr., age 50, has served as our President, IVAX Pharmaceuticals Europe since July 2003 and Managing Director of Norton Healthcare Limited since July 2002. From January 2000 to October 2001, he was President and Chief Executive Officer of Faulding Pharmaceuticals, F.H. Faulding, Ltd. Adelaide, S.A. Australia and from January 1996 to January 2000, he was a Vice President of Roche Laboratories, Inc.

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

Rafick Henein, age 64, 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 61, 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).

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

Phillip Frost, age 68, 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

Table of Contents

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 a member 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 57, 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.

Table of Contents

## PART II

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

Our common stock is traded on the American Stock Exchange and the Warsaw Stock Exchange under the symbol "IVX," and on the London Stock Exchange under the symbol "IVX.L." As of the close of business on February 28, 2005, there were approximately 3,660 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 2004 and 2003 as reported by the American Stock Exchange:

| 2004 | High | Low |
|---|---|---|
| First Quarter | $ 21.46 | $ 17.81 |
| Second Quarter | 19.83 | 16.93 |
| Third Quarter | 20.76 | 16.03 |
| Fourth Quarter | 19.69 | 13.42 |

| 2003 | High | Low |
|---|---|---|
| First Quarter | $ 10.12 | $ 8.49 |
| Second Quarter | 15.96 | 9.96 |
| Third Quarter | 16.36 | 13.22 |
| Fourth Quarter | 19.40 | 14.16 |

We did not pay cash dividends on our common stock during 2003 or 2004 and we do not intend to pay any cash dividends in the foreseeable future.

Information regarding our equity compensation plans is set forth under page F-37 of this report.

Between August 2000 and March 2002, our Board of Directors increased its authorization of share repurchases under our previously announced share repurchase program by 28.1 million shares. In 2004 we made no repurchases of shares of our common stock.

Table of Contents

## Item 6. Selected Financial Data

The following table sets forth selected historical financial data as of and for the years ended December 31, 2004, 2003, 2002, 2001 and 2000, 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, | | | | |
|---|---|---|---|---|---|
| | 2004(1) | 2003(2) | 2002 | 2001(5) | 2000 |
| **OPERATING DATA** | | | | | |
| Net revenues | $1,837,418 | $1,420,339 | $1,197,244 | $1,215,377 | $ 793,405 |
| Cost of sales (excluding amortization, which is presented below) | 985,125 | 781,383 | 663,708 | 583,588 | 409,903 |
| Gross profit | 852,293 | 638,956 | 533,536 | 631,789 | 383,502 |
| Selling | 272,569 | 212,192 | 168,952 | 143,629 | 92,032 |
| General and administrative | 162,391 | 122,414 | 118,416 | 110,477 | 84,900 |
| Research and development | 141,604 | 108,347 | 76,041 | 88,015 | 65,331 |
| Amortization | 22,488 | 19,719 | 16,158 | 19,412 | 9,042 |
| Restructuring costs (reversal of accrual) | 1,374 | 3,706 | 4,242 | 2,367 | (4,535) |
| Operating income | 251,867 | 172,578 | 149,727 | 267,889 | 136,732 |
| Interest income | 5,545 | 3,710 | 8,090 | 21,249 | 13,986 |
| Interest expense | (41,424) | (43,608) | (48,639) | (41,791) | (14,624) |
| Other income, net | 5,836 | 11,738 | 60,321 | 49,637 | 15,243 |
| Income taxes | 23,757 | 45,559 | 51,742 | 54,065 | 13,214 |
| Minority interest | (40) | 188 | 838 | 344 | (608) |
| Income from continuing operations | 198,027 | 99,047 | 118,595 | 243,263 | 137,515 |
| Income from discontinued operations (3) | — | 22,204 | — | — | — |
| Cumulative effect of accounting change (4) | — | — | 4,161 | — | (6,471) |
| Net income | $ 198,027 | $ 121,251 | $ 122,756 | $ 243,263 | $ 131,044 |
| Basic earnings per common share: | | | | | |
| Continuing operations | $ 0.79 | $ 0.41 | $ 0.49 | $ 0.98 | $ 0.56 |
| Discontinued operations (3) | — | 0.09 | — | — | — |
| Cumulative effect of accounting change (4) | — | — | 0.02 | — | (0.03) |
| Net earnings | $ 0.79 | $ 0.50 | $ 0.51 | $ 0.98 | $ 0.53 |
| Diluted earnings per common share: | | | | | |
| Continuing operations | $ 0.75 | $ 0.40 | $ 0.48 | $ 0.95 | $ 0.54 |
| Discontinued operations (3) | — | 0.09 | — | — | — |
| Cumulative effect of accounting change (4) | — | — | 0.02 | — | (0.03) |
| Net earnings | $ 0.75 | $ 0.49 | $ 0.50 | $ 0.95 | $ 0.51 |
| Weighted average number of common shares outstanding: | | | | | |
| Basic | 249,250 | 244,532 | 243,796 | 248,874 | 245,345 |
| Diluted | 268,792 | 248,625 | 246,722 | 255,798 | 255,073 |
| Cash dividends per common share | $ — | $ — | $ — | $ — | $ — |
| **BALANCE SHEET DATA** | | | | | |
| Working capital | $ 943,222 | $ 509,167 | $ 447,154 | $ 597,578 | $ 438,490 |
| Total assets | 3,212,019 | 2,372,934 | 2,047,759 | 2,105,449 | 1,068,186 |
| Total long-term debt, net of current portion | 1,057,843 | 855,335 | 872,339 | 913,486 | 253,755 |
| Shareholders' equity | $1,490,329 | 962,311 | 684,863 | 718,354 | 484,120 |

(1) Includes the post-acquisition results of companies acquired, either directly or indirectly, primarily Corporacion Medco S.A.C. and Botica Torres de Limatambo S.A.C. on June 2, 2004 and Kutnowskie Zaklady Farmaceutyczne "POLFA" SA on December 15, 2004. Also includes the effects of positive resolution of previously accrued potential service level claims, which increased net revenues and gross profit by $8.1 million and our tax provision by $3.0 million, and reversal of $8.6 million of tax reserves,

relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2.8 million of additional valuation allowance recorded against a deferred tax asset at another European subsidiary. The total impact of these changes increased net income by $10.9 million, or $0.04 per diluted share.

Table of Contents

(2) 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. Also includes the effects of improvements in our return and customer inventory experience, doubtful accounts and analysis of tax reserves that 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 $0.06.

(3) 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.

(4) 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.

(5) 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.

Table of Contents

## 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 captions Risk Factors and Safe Harbor Statement under the Private Securities Litigation Return Act of 1995 in Item 1 of this Form 10-K. In addition, the following discussion and analysis should be read in conjunction with the 2004 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

### Overview

We generated strong revenue growth in 2004 principally due to increased demand, new product launches and the acquisition of businesses. Our revenue growth was also driven by a $25.5 million milestone payment earned under a product collaboration and development agreement with Mayne Group Limited for the marketing and distribution of our injectable paclitaxel product in Europe. Stronger currencies in Europe relative to the dollar also contributed to revenue growth in 2004. During 2004, we continued to invest in our future. We invested $60.4 million more in sales and marketing than in 2003, an increase of 29%, and $33.3 million more in research and development than in 2003, an increase of 31%. Despite these investments, our operating income increased by 46%, from $172.6 million in 2003 to $251.9 million in 2004. During 2004, we acquired, indirectly or directly, Corporacion Medco S.A.C. (Medco), a Peruvian pharmaceutical company, Botica Torres de Limatambo S.A.C. (BTL), a company with a chain of pharmacies in Peru, and approximately 98% of Kutnowskie Zaklady Farmaceutyczne "POLFA" SA (Polfa Kutno), a Polish pharmaceutical company.

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. We launched metformin HCl Extended Release and commenced our 180-day exclusivity period in December 2003. On February 19, 2004, we received final approval and confirmation of our first to file status on glyburide/metformin HCl tablets. We launched this product and commenced our 180-day exclusivity period in May 2004. In the case of both metformin HCl Extended Release and glyburide/metformin HCl, the brand company authorized a competitor to commence sales of a generic version of the branded product concurrently with our launch of the products.

On March 10, 2004, we received approval from the European Commission for the extension of indication of the existing marketing authorization for Paxene® to include treatment of metastatic breast cancer and metastatic ovarian cancer in the 15 member states of the European Union. We had previously entered into a collaboration agreement with the Mayne Group Limited for the manufacture, marketing and distribution of Paxene® in Europe and, in May 2004, the Mayne Group launched the product in many countries in the European Union.

Table of Contents

On April 28, 2004, we received final approval and confirmation of our first to file status from the FDA on gabapentin tablets in 100 mg, 300 mg and 400 mg dosage strengths. The tablet formulation at these strengths is not currently marketed. We were not first to file on the five currently marketed dosage forms of this product. On August 18, 2004, we launched gabapentin tablets in 100 mg, 300 mg and 400 mg strengths to selected customers. In October 2004, three competitors began selling generic gabapentin capsules, which are AB rated with the branded product and therefore, can be automatically substituted. A trial date for the litigation regarding whether our products infringe a patent held by Pfizer has not yet been scheduled, though oral argument on summary judgment motions pending in the case were heard in November 2004. We also intend to commence commercial sales of the AB-rated gabapentin capsules and tablets shortly prior to the expiration of applicable Hatch-Waxman exclusivity periods as a result of a settlement reached with the generic manufacturer awarded the exclusivity by the FDA.

On September 30, 2004, we received UK approval of QVAR® in our patented Easi-breathe™ device and began selling the product in the fourth quarter of 2004. On October 29, 2004, we received FDA approval for our NDA for CFC-free albuterol in a standard metered-dose inhaler and launched the product in December 2004.

As part of our ongoing business strategy, we enter into collaborative alliances, which we believe 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. Our future net revenues and profits will depend and will fluctuate from period to period, in part, based upon our ability to replace or 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 clinical trials and other research and development expenses;
- the timing of regulatory approval of such products;
- the availability and cost of raw materials required to manufacture such products;
- market acceptance and demand for new pharmaceutical products or alternative formulations of existing pharmaceutical products we may develop or sell;
- our ability to manufacture such products efficiently;
- the number and timing of regulatory approvals of competing products;
- the impact of competition from brand name companies that sell or authorize the sale of their own generic products or successfully extend the exclusivity period of their branded products;
- the impact of competitive pricing pressures within the generic pharmaceutical industry;
- the impact of health care reform initiatives in the United States and abroad, particularly as governments seek to contain increases in the costs of health care;

Table of Contents

- the impact of pharmaceutical industry regulations or pending legislation that could affect the pharmaceutical industry;
- the outcome and timing of legal proceedings, particularly those related to Hatch-Waxman Act exclusivity and patent infringement cases;
- court and FDA decisions on exclusivity periods;
- our ability to forecast inventory levels and trends at our customers and their end-customers; and
- our and our competitors' pricing and chargeback policies.

We are spending a substantial amount of management time and resources to comply with changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new Securities and Exchange Commission regulations and the American Stock Exchange rules. In particular, Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal control systems, and attestations as to the effectiveness of these systems by our independent public accounting firm. Included in this report on Form 10-K is a report of our management on the effectiveness of internal controls and an attestation report of our independent auditors with respect thereto. However, we expect to continue to expend significant management time and resources documenting and testing our internal control systems and procedures. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to maintain an effective internal control environment could have a material adverse effect on the market price of our stock.

**Net Revenues and Gross Profit**

The composition of the change in net revenues for the year ended December 31, 2004, compared to the year ended December 31, 2003 (Current Year) and for the year ended December 31, 2003, compared to the year ended December 31, 2002 (Prior Year), by region was as follows (in millions):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | %Change* | 2003 | 2002 | %Change * |
| North America | $ 859.7 | $ 650.6 | 32% | $ 650.6 | $ 508.6 | 28% |
| Europe | 704.0 | 532.4 | 32% | 532.4 | 454.4 | 17% |
| Latin America | 315.8 | 251.9 | 25% | 251.9 | 229.1 | 10% |
| Corporate and other | (42.1) | (14.6) | ** | (14.6) | 5.1 | ** |
| Total net revenues | $ 1,837.4 | $ 1,420.3 | 29% | $ 1,420.3 | $ 1,197.2 | 19% |

* % change based on unrounded numbers

** Not meaningful

The composition of the change in the provisions for sales returns and allowances for the Current Year and for the Prior Year by region was as follows (in millions):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | % Change* | 2003 | 2002 | % Change* |
| North America | $ 752.4 | $ 566.4 | 33% | $ 566.4 | $ 576.3 | (2)% |
| *% of gross product sales* | *47%* | *47%* | | *47%* | *55%* | |
| Europe | 65.1 | 41.1 | 58% | 41.1 | 51.2 | (20)% |
| *% of gross product sales* | *9%* | *8%* | | *8%* | *11%* | |
| Latin America | 56.5 | 36.3 | 56% | 36.3 | 33.8 | 7% |
| *% of gross product sales* | *15%* | *13%* | | *13%* | *13%* | |

* % change based on unrounded numbers

Table of Contents

The composition of the components of the variance in net revenues for the Current Year and for the Prior Year by region was as follows (in millions):

| | Current Year | | | | Prior Year | | | |
|---|---|---|---|---|---|---|---|---|
| | Product Sales | | Other | Currency | Product Sales | | Other | Currency |
| | Price | Volume | Revenue | Exchange | Price | Volume | Revenue | Exchange |
| North America | $(49.6) | $277.3 | $ (18.6) | $ — | $ 55.9 | $ 94.3 | $ (8.2) | $ — |
| Europe | (8.2) | 73.8 | 32.2 | 73.8 | (11.0) | 56.2 | (22.3) | 55.1 |
| Latin America | 24.6 | 38.1 | 2.0 | (0.8) | 18.3 | 26.2 | (0.3) | (21.4) |

The increase in North American net revenues during 2004, as compared to the prior year, was primarily due to volume increases, including the launch of new generic products, partially offset by price decreases from product and customer mix and a decrease in other revenues, primarily product collaboration and development fees received in 2003. Our 2004 net revenues benefited from our limited competition with respect to sales of metformin HCl Extended Release and glyburide/metformin HCl, although sales and gross profit for both products were adversely impacted by sales of an authorized generic version of the branded product concurrently with our launch of the products. The period of limited competition for metformin HCl Extended Release expired in May 2004, and for glyburide/metformin HCl expired in November 2004. Sales and gross profit for metformin HCl Extended Release and glyburide/metformin HCl declined significantly following expiration of our limited competition period. Additionally, while we launched our gabapentin product prior to resolution of patent litigation during the third quarter of 2004, the amount of our sales and gross profit for this product were significantly impacted by three competitors entering the market shortly after our launch. We anticipate that pricing and competitive pressures will continue to adversely impact our revenues and gross profit from sales of generic pharmaceutical products in North America. Our net revenues and gross profit also benefited by $8.1 million for the year ended December 31, 2004, due to positive resolution of previously accrued service level claims (See Application of Critical Accounting Policies).

The increase in North American net revenues during 2003, as compared to the prior year, was due to the impacts of price and volume increases, including the launch of new generic products, partially offset by a decrease in other revenues, primarily product collaboration and development fees. Our net revenues and gross profit also benefited by $13.7 million for the year ended December 31, 2003, due to changes in sales returns and allowances as a result of an improvement in our return and customer inventory experience (See Application of Critical Accounting Policies).

The increase in European net revenues during 2004, as compared to the prior year, was primarily due to volume increases, including the launch of new and acquired products, and favorable effects of currency exchange rates, partially offset by price decreases. Pricing pressures are expected to continue to impact our revenues and gross profit from sales of generic pharmaceutical products in Western Europe. Other revenues included a $25.5 million milestone payment in the first quarter of 2004 and a $5.0 million milestone payment in the second quarter of 2004 earned under two separate product collaboration and development agreements and amortization of previously deferred up-front payments compared to a $6.0 million milestone payment received in the second quarter of 2003.

The increase in European net revenues during 2003, as compared to the prior year, was primarily due to the favorable effects of currency exchange rates and the impact of volume increases, partially offset by the impact of price decreases and a decrease in other revenue, 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 of 2003 under a license and development agreement.

Table of Contents

The increase in Latin American net revenues during 2004, as compared to the prior year, was primarily due to the operations of BTL and Medco, which were indirectly acquired in the second quarter of 2004, as well as price increases primarily in two countries.

The increase in Latin American net revenues during 2003, as compared to the prior year, was primarily due to the impacts of price and volume increases, partially offset by unfavorable effects of currency devaluations and a decrease in other revenues.

The composition of the change in our consolidated net revenues and gross profit for the Current Year and for the Prior Year was as follows (in millions):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | % Change* | 2003 | 2002 | % Change* |
| Net revenues | $1,837.4 | $1,420.3 | 29% | $1,420.3 | $1,197.2 | 19% |
| Cost of sales (excludes amortization) | 985.1 | 781.4 | 26% | 781.4 | 663.7 | 18% |
| Gross profit | $ 852.3 | $ 638.9 | 33% | $ 638.9 | $ 533.5 | 20% |
| *% of net revenues* | *46.4%* | *45.0%* | | *45.0%* | *44.6%* | |

* % change based on unrounded numbers

The improvement in our gross profit percentage (excluding amortization) for the year ended December 31, 2004, was primarily due to the increase in other revenues earned under product collaboration and development agreements. During the year ended December 31, 2004, our consolidated net revenues and gross profit benefited by $8.1 million from the positive resolution of previously accrued potential service level claims. As discussed above, we expect continued pressure on our gross profit related to sales of generic pharmaceutical products in North America and Western Europe as competition continues to intensify in these markets. Amortization of intangibles related to acquired developed drugs is not included in cost of sales.

During the year ended December 31, 2003, our gross profit benefited as a result of an improvement in our return and customer inventory experience increasing net revenues by $13.7 million, due to changes in sales returns and allowances, and reducing cost of sales by $0.8 million due to a change in estimate of inventory obsolescence.

**Operating Expenses**

The composition of the change in consolidated operating expenses for the Current Year and for the Prior Year was as follows (in millions):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | % Change * | 2003 | 2002 | % Change * |
| Selling | $ 272.6 | $ 212.2 | 28% | $ 212.2 | $ 169.0 | 26% |
| *% of net revenues* | *14.8%* | *14.9%* | | *14.9%* | *14.1%* | |
| General and administrative | 162.4 | 122.4 | 33% | 122.4 | 118.4 | 3% |
| *% of net revenues* | *8.8%* | *8.6%* | | *8.6%* | *9.9%* | |
| Research and development | 141.6 | 108.3 | 31% | 108.3 | 76.0 | 43% |
| *% of net revenues* | *7.7%* | *7.6%* | | *7.6%* | *6.4%* | |
| Amortization | 22.5 | 19.8 | 14% | 19.8 | 16.2 | 22% |
| Restructuring | 1.3 | 3.7 | (63)% | 3.7 | 4.2 | (13)% |
| Total operating expenses | $ 600.4 | $ 466.4 | 29% | $ 466.4 | $ 383.8 | 22% |

* % change based on unrounded numbers

Table of Contents

Selling expenses increased in 2004, as compared to 2003, primarily due to increases in the sales forces and selling efforts related to the branded respiratory products we acquired in Europe in the fourth quarter of 2003 and acquisitions of businesses in Latin America in the second quarter of 2004. The increase in selling expenses in 2003, as compared to 2002, 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.

General and administrative expenses increased in 2004, as compared to 2003, primarily due to professional fees for services related to Sarbanes-Oxley Act compliance and due diligence associated with acquisition activities, $9.0 million of start-up costs for two production facilities, one of which had not begun production as of December 31, 2004, acquisitions of products and businesses during 2004 and the fourth quarter of 2003, and incentive compensation. In the fourth quarter of 2004, we reached a settlement of claims we made against the seller of a company acquired in 2001. Since the claims involved breach of representations and warranties under the purchase agreement, the settlement of $10.7 million, primarily cash plus the fair market value of land to be received, was recorded as a reduction of general and administrative expenses in the fourth quarter of 2004. The increase in general and administrative expenses in 2003, as compared to 2002, was 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 in 2004, as compared to 2003, and in 2003, as compared to 2002, was primarily attributable to an increase in various research and development projects and bio-study costs in North America and Europe. Our future level of research and development expenditures are expected to depend on, among other things, the timing and 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.

During 2004, the restructuring costs incurred consisted primarily of employee termination benefits, relating primarily to our United Kingdom and Peruvian operations. During 2003, the restructuring costs incurred, consisted primarily of employee termination benefits, relating primarily to Europe and Chile. During 2002, the restructuring costs incurred consisted primarily of employee termination benefits.

**Other Income (Expense)**

The composition of the change in consolidated other income (expense) for the Current Year and for the Prior Year was as follows (in millions):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | % Change * | 2003 | 2002 | % Change * |
| Interest income | $ 5.5 | $ 3.7 | 49% | $ 3.7 | $ 8.1 | (54)% |
| Interest expense | (41.4) | (43.6) | (5)% | (43.6) | (48.6) | (10)% |
| Other income, net | 5.8 | 11.7 | (50)% | 11.7 | 60.3 | (81)% |
| Total other expense | $ (30.1) | $ (28.2) | 7% | $ (28.2) | $ 19.8 | ** |

* % change based on unrounded numbers

** Not meaningful

Table of Contents

The changes in interest expense in 2004, as compared to 2003, were primarily due to our issuance on March 3, 2004, of $400.0 million of 1.5% Convertible Senior Notes (Old 1.5% Notes), the redemption on May 18, 2004, of our outstanding $249.0 million of 5.5% Convertible Senior Subordinated Notes (5.5% Notes), our issuance on December 22, 2004, of $333.0 million of 1.875% Convertible Senior Notes (1.875% Notes) and the repurchase on December 22, 2004, of $250.0 million of 4.5% Convertible Senior Subordinated Notes (4.5% Notes). See Liquidity and Capital Resources for additional information related to these financing transactions.

The decrease in interest income and interest expense in 2003, as compared to 2002, is primarily due to the early extinguishment of debt.

Other income, net decreased $5.9 million for the year ended December 31, 2004, compared to the prior year. In the second quarter of 2004, we wrote off $8.5 million in redemption premium and debt issuance costs in connection with the redemption of the 5.5% Notes. In the fourth quarter of 2004, we wrote off $3.2 million in debt issuance costs and recognized a pretax gain on repurchase of the 4.5% Notes of $3.8 million. We realized $2.3 million of gains on the repurchase of indebtedness in the prior year. In addition, during 2004 we recorded $8.0 million of foreign currency losses compared to $10.0 million of foreign currency losses in the prior year. During 2004, we earned $15.9 million of royalty and other payments recorded as additional consideration for the 1997 sale of certain rights in Elmiron® to Ortho-McNeil Pharmaceutical, Inc. (OMP), a subsidiary of Johnson & Johnson, compared to $12.8 million in the prior year.

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 indebtedness 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 also earned $12.8 million in 2003 of royalty and other payments recorded as additional consideration for the 1997 sale of certain rights in Elmiron® to OMP 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 OMP which acquired ALZA Corporation (ALZA) in 2002. We originally entered into an agreement to sell to ALZA 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 on the amendment is the culmination of a separate earnings process and recorded the payment as additional proceeds from the 1997 sale of Elmiron® to OMP. (See Application of Critical Accounting Policies). We will continue to receive payments from OMP over the next several years based upon sales of Elmiron® by OMP.

Table of Contents

**Net Income**

The composition of the change in our consolidated income for the Current Year and for the Prior Year was as follows (in millions, except per share data):

| | Current Year | | | Prior Year | | |
|---|---|---|---|---|---|---|
| | 2004 | 2003 | % Change* | 2003 | 2002 | % Change* |
| Income from: | | | | | | |
| Continuing operations | $ 198.0 | $ 99.1 | 100% | $ 99.1 | $ 118.6 | (17)% |
| Discontinued operations | — | 22.2 | ** | 22.2 | — | ** |
| Cumulative effect of accounting change | — | — | ** | — | 4.2 | ** |
| Net income | $ 198.0 | $ 121.3 | 63% | $ 121.3 | $ 122.8 | (1)% |

* % change based on unrounded numbers

** Not meaningful

| | Current Year | | | |
|---|---|---|---|---|
| | Basic Earnings | | Diluted Earnings | |
| | 2004 | 2003 | 2004 | 2003 |
| Earnings per common share: | | | | |
| Continuing operations | $ 0.79 | $ 0.41 | $ 0.75 | $ 0.40 |
| Discontinued operations | — | 0.09 | — | 0.09 |
| Net earnings | $ 0.79 | $ 0.50 | $ 0.75 | $ 0.49 |

Our tax provision and net income benefited by $27.0 million in 2004 due to the merger of two of our subsidiaries (See Income Taxes). During 2004, our net revenues and gross profit also benefited by $8.1 million, $5.1 million net of tax, due to the positive resolution of previously accrued potential service level claims. In addition, our tax provision and net income benefited by net changes of $5.7 million from the reversal of $8.6 million of tax reserves, relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2.8 million of additional valuation allowance recorded against a deferred tax asset at another European subsidiary (See Income Taxes). The total impact of these changes increased net income by $10.9 million, or $0.04 per diluted share. During 2003, as a result of improvements in our return and customer inventory experience, doubtful accounts and analysis of 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 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 $0.06. See Recently Issued Accounting Standards for a discussion of the impact of EITF Issue No. 04-8 on our calculation of diluted earnings per share in 2004.

| | Prior Year | | | |
|---|---|---|---|---|
| | Basic Earnings | | Diluted Earnings | |
| | 2003 | 2002 | 2003 | 2002 |
| Earnings per common share: | | | | |
| Continuing operations | $ 0.41 | $ 0.49 | $ 0.40 | $ 0.48 |
| Discontinued operations | 0.09 | — | 0.09 | |
| Cumulative effect of accounting change | — | 0.02 | — | 0.02 |
| Net earnings | $ 0.50 | $ 0.51 | $ 0.49 | $ 0.50 |

Table of Contents

During the second quarter of 2003, we recorded income from discontinued operations of $22.2 million, net of tax of $12.8 million, or $0.09 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*.

**Foreign Currency**

Our sales by subsidiaries located outside the United States accounted for approximately 51% of our worldwide sales in 2004 and 2003. The majority of these sales were denominated in currencies of the local country. As such, our reported profits and cash flows are exposed to changes in currency 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. As a result of exchange rate differences, net revenues increased by $73.6 million for the year ended December 31, 2004, as compared to the year ended December 31, 2003, and increased by $34.8 million for the year ended December 31, 2003, as compared to the year ended December 31, 2002.

**Recently Issued Accounting Standards**

On September 30, 2004, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board (FASB) reached a conclusion on Issue No. 04-8, *The Effect of Contingently Convertible Debt on Diluted Earnings per Share,* concluding that contingently convertible debt instruments should be included in diluted earnings per share computations (if dilutive) regardless of whether the market price trigger (or other contingent feature) has been met. This consensus is effective for reporting periods ending after December 15, 2004, and requires prior period earnings per share amounts presented for comparative purposes to be restated utilizing a transition method. The transition method agreed upon by the EITF is a modified restatement approach that results in a company applying the consensus to the terms of the security at the adoption date. As such, if the terms of the security are changed prior to the adoption date, it is the changed terms to which the consensus is applied. We adopted the consensus in the fourth quarter of 2004. The impact of adoption has reduced our reported diluted earnings per share for each of the three month periods ended March 31, 2004, June 30, 2004, and December 31, 2004, by $0.01 per share and for the year ended December 31, 2004 by $0.03 per share. There was no impact on the prior years' reported diluted earnings per share. In response to the adoption of the consensus, on February 23, 2005, we completed an exchange offer pursuant to which we offered to exchange each $1,000 principal amount of our outstanding 1.5% convertible senior notes due 2024 (Old 1.5% Notes) that was validly tendered and accepted for exchange for (i) $1,000 principal amount of our new 1.5% convertible senior notes due 2024 (New 1.5% Notes); and (ii) a one-time cash payment equal to $2.50 per $1,000 principal amount of such Old 1.5% Notes validly tendered and accepted for exchange. The New 1.5% Notes are substantially identical to the Old 1.5% Notes except that the New 1.5% Notes contain a "net share settlement" feature under which we committed to pay up to the principal amount of the New 1.5% Notes in cash upon conversion. As a result, we believe we will be able to account for the New 1.5% Notes under the "treasury stock" method, which is generally expected to be less dilutive to earnings per share than the "if- converted" method prescribed by EITF Issue No. 04-8.

On November 24, 2004, the FASB issued SFAS No. 151, *Inventory Costs,* an amendment of ARB No. 43, Chapter 4, which clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material to be recognized as current period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. It is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The impact of adoption of this statement is not expected to be significant.

Table of Contents

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* which addresses the accounting for transactions in which an entity exchanges it equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires compensation costs related to share-based payment transactions to be recognized in the financial statements. It applies to all awards granted after the effective date and is not applied to awards granted in periods before the effective date, except to the extent that the prior periods' awards are modified, repurchased or cancelled after the date. This Statement can be adopted under two methods, the modified prospective or the modified retrospective applications. Under the modified prospective application, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date should be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards should be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosure under SFAS No. 123. Changes to the grant-date fair value of awards granted before the effective date of this Statement are precluded. The compensation cost for those earlier awards should be attributed to periods beginning on or after the effective date of this Statement using the attribution method that was used under SFAS No. 123, except that the method of recognizing forfeitures only as they occur should be continued. Any unearned or deferred compensation related to those earlier awards should be eliminated against the appropriate equity accounts. The modified retrospective application may be applied to all prior years that SFAS No. 123 was effective or only to prior interim periods in the year of initial adoption if the effective date of SFAS No. 123 (as revised) does not coincide with the beginning of the fiscal year. It is effective as of the first interim or annual reporting period that begins after June 15, 2005. The cumulative effect of the initial application of this Statement, if any, is to be recognized as of the effective date. Upon adoption, we will be required to reclassify excess tax benefits, as defined in the Statement, from stock option exercises from Cash flows from operating activities to Cash flows from financing activities in the Consolidated Statement of Cash Flows. We expect that under the modified prospective method of adoption, during the second half of 2005 we will be required to record additional compensation expense of approximately $2.6 million, net of tax, for unvested awards that were outstanding as of December 31, 2004. We also expect that compensation expense will be required to be recorded for future awards of share-based payments, including employee stock purchases under our Employee Stock Purchase Plan, if not amended prior to adoption.

On December 20, 2004, our Compensation Committee accelerated the vesting of all of our unvested stock options previously awarded to officers and employees which had an exercise price greater than $15.39, the closing price of our common stock on the American Stock Exchange on December 20, 2004. As a result of the acceleration, options to acquire approximately 8.2 million shares of our common stock (representing approximately 29% of the total outstanding options), which otherwise would have vested from time to time over the next 46 months, became immediately exercisable. Approximately 65% of the accelerated options would have vested in any event over the next 15 months. If we had already adopted the fair value method, the acceleration of the options would have increased compensation expense $38.8 million in 2004 and would have decreased compensation expense $18.3 million in 2005, $10.0 million in 2006, $9.0 million in 2007 and $2.0 million in 2008.

Our Compensation Committee's decision to accelerate the vesting of these options and to grant immediately exercisable options in February 2005, was in response to the issuance by the FASB of SFAS No. 123 (revised 2004), *Share-Based Payment*. By virtue of these measures, we believe it will potentially result in our not being required to recognize any compensation expense in the current year or in future periods associated with these options.

Additionally, the stock options to acquire approximately 1.4 million shares of our common stock recently granted to our officers and employees on February 23, 2005 were immediately exercisable. The options have a term of only five years (as opposed to the customary 7-10 year term) and, except with respect to options granted to our top three executive officers, the awards were only approximately 25% of the level of awards granted historically. In determining the grants to our top three executive officers, the Compensation Committee considered, among other things, that increases to base salary were modest and that none of these executive officers received a cash bonus for 2004 performance, notwithstanding the superior financial results achieved by us in 2004.

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 2004 and 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 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.

Table of Contents

**Liquidity and Capital Resources**

At December 31, 2004, working capital was $943.2 million compared to $509.2 million at December 31, 2003, and $447.1 million at December 31, 2002. Cash and cash equivalents were $392.0 million at December 31, 2004, compared to $134.3 million at December 31, 2003, and $155.4 million at December 31, 2002. Short-term marketable securities were $6.1 million at December 31, 2004, compared to $23.1 million at December 31, 2003, and $28.9 million at December 31, 2002. In the Consolidated Balance Sheets and Statements of Cash Flows, we reclassified from cash and cash equivalents to marketable securities $12.6 million as of December 31, 2003 and $21.0 million as of December 31, 2001.

Net cash of $113.0 million was provided by operating activities during 2004 compared to $82.6 million in 2003 and $151.1 million in 2002. The increase in cash provided by operating activities during 2004 was primarily due to an increase in net income and an increase in accounts payable, accrued expenses and other liabilities compared to only a minor change in accounts payable, accrued expenses and other liabilities in the prior year primarily due to higher payments of income tax in 2003. Our accounts receivable increased during 2004 as a result of new product launches primarily in North America. Our accounts receivable increased at a rate greater than the increase in our annual sales due to our sales increasing more from the third to the fourth quarter of 2004 than they increased from the third to the fourth quarter of 2003. This larger increase in our sales in 2004 impacted the growth rate of our accounts receivable more than the growth rate of our annual sales due to the smaller balance of accounts receivable compared to our annual sales. Our accounts receivable also grew at a faster rate than our sales due to the acquisition of Polfa Kutno on December 15, 2004, which added the full accounts receivable balance, but only 2 weeks of sales. Our inventories and accounts payable increased at a rate similar to the increase in cost of sales. During 2004, we recorded a deferred tax benefit compared to a deferred tax provision in the prior year primarily due to the $27.0 million tax benefit from the merger of two of our Chilean subsidiaries discussed below under Income Taxes. Our pre-launch inventories use operating cash and will not generate cash inflows unless such products receive regulatory approval and are launched prior to expiration or we find an alternative use for these inventories. The decrease in cash provided by operating activities during 2003 compared to 2002 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.

Net cash of $72.3 million was used for investing activities during 2004 compared to $88.3 million used by investing activities in 2003 and $49.3 million provided by investing activities in 2002. Our level of capital expenditures has remained stable as we continue to improve and expand our manufacturing capacity. During 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. The first installment

Table of Contents

payment of $5.5 million was received in June 2004. During 2002, we received $20.0 million in connection with certain amendments to the contract for the 1997 sale of Elmiron® with OMP. Our agreement with OMP, provides for specified minimum royalty payments to us due for the period 2003 through 2006, based upon sales of Elmiron® by OMP.

On February 15, 2005, we entered into an agreement to acquire Phoenix Scientific, Inc., a generic veterinary pharmaceutical manufacturing company. The closing of the acquisition transaction is subject to certain customary conditions including clearance under the Hart-Scott-Rodino Antitrust Improvement Act and is expected to occur during the second quarter of 2005. Under the terms of the agreement, we will pay a combination of $75.0 million in common stock and $196.9 million in cash. Phoenix currently has outstanding $150.0 million of senior secured notes, bearing interest at 11.5%, which mature on October 1, 2009. The effective interest rate on these notes is 13.4%. Following the closing of the transaction, Phoenix will be required to offer to repurchase these notes at 101% of the principal amount plus accrued and unpaid interest through the payment date. We may cause Phoenix to redeem or refinance the notes immediately prior to closing of the transaction. Under the terms of the indenture governing the notes, Phoenix will be required to pay a premium for redemption of these notes based upon the date of redemption. If the notes are redeemed prior to October 2, 2005, the redemption price will be 109.2% of the principal amount plus accrued and unpaid interest through the payment date. We plan to acquire Phoenix to expand our growth in our existing veterinary operations.

On June 1, 2004, we indirectly acquired from Recordati Industria Chimica e Farmaceutica S.p.A. (Recordati) approximately 0.5 million shares of Polfa Kutno, by purchasing the outstanding securities of KZFPK Holdings, Inc., a Delaware corporation, for approximately 2.2 million shares of our common stock, valued at $41.6 million. The shares purchased represented 24.99% of the total share capital in Polfa Kutno, a pharmaceutical company listed on the Warsaw Stock Exchange. On December 15, 2004, we acquired 97.23% of the remaining outstanding shares of Polfa Kutno in exchange for 9.6 million shares of our common stock, valued at $152.5 million. The total purchase price, including acquisition costs in connection with this transaction and the transaction with Recordati of $12.3 million was $206.3 million. On February 2, 2005, we completed the cash tender offer for an additional 0.02 million shares for approximately $2.7 million, increasing our ownership in Polfa Kutno to 99.25%. Polfa Kutno markets and manufactures a wide variety of prescription and over-the-counter pharmaceutical products.

On June 2, 2004, we acquired Medco, a Peruvian pharmaceutical company, by purchasing the outstanding securities of Medco's parent, Inversiones Catamarn S.A. – Inveran for 0.8 million shares of our common stock, valued at $15.9 million, and $0.1 million in cash, less a working capital purchase price adjustment refund of $0.7 million. Medco develops, manufactures and sells branded over-the-counter and prescription products, as well as generic prescription pharmaceutical products in Peru.

On June 2, 2004, we indirectly acquired BTL, a Peruvian retail pharmacy company, by purchasing the outstanding securities of one of BTL's parents, ASSA Investments S.A., and exercising an option to acquire the outstanding securities of the other parent, ASSA Inc., for $3.5 million in cash, net of cash acquired of $0.2 million, forgiveness of a note receivable previously held by us with a recorded value of $1.7 million and related costs of $2.2 million, of which $0.2 million is held in escrow. BTL operates a chain of retail pharmacies in Peru.

On January 24, 2003, we acquired API in Puerto Rico from Chemo Iberica S.A. and Quimica Sintetica S.A. for 1.3 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.

Table of Contents

On September 23, 2003, we acquired Advanced Tobacco Products, Inc. (ATP) for 0.3 million shares of our common stock, valued at $4.1 million. 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, The Netherlands, Finland, Norway, Denmark and Sweden. The agreement covers the products QVAR® (CFC-free beclomethasone dipropionate), Airomir® (CFC-free salbutamol, known in the United States as albuterol) in Autohaler® 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 and $24.0 million on the first anniversary. In addition, $24.0 million is due on the second anniversary 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.

On April 22, 2002, we acquired an exclusive United States license to the patent rights to market QVAR® (beclomethasone dipropionate HFA), an aerosol inhaler prescribed to treat asthma. In addition, we have an option to obtain ownership of the United States QVAR® 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, $20.0 million was paid on the first anniversary and $30.0 million was paid on the second anniversary. We are entitled to reduce the purchase price by $4.0 million for required pediatric trials. The remaining payments due from us are: $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.

Net cash of $209.2 million was provided by financing activities during 2004 compared to $29.5 million used in 2003 and $179.3 million used by financing activities in 2002.

On March 3, 2004, we issued $400.0 million of the Old 1.5% Notes to certain qualified institutional buyers. After expenses we received net proceeds of approximately $390.5 million. Under certain circumstances, the Old 1.5% Notes are convertible, unless previously redeemed, into 41.85925 shares of our common stock per $1,000 of principal amount of the Old 1.5% Notes. This ratio results in a conversion price of approximately $23.89 per share. As of December 31, 2004, 16.7 million shares of our common stock are reserved for issuance in connection with the conversion of the Old 1.5% Notes. We may redeem the Old 1.5% Notes on or after March 1, 2011. Beginning with the six-month period commencing on March 1, 2011, in addition to the stated interest of 1.5%, we will pay contingent interest of 0.36% of the market value of the Old 1.5% Notes if, during specified testing periods, the average trading price of the Old 1.5% Notes is 120% or more of the principal value. In addition, holders of the Old 1.5% Notes may require us to repurchase the notes at 100% of the principal amount plus accrued and unpaid interest on each of March 1, 2011, 2014, and 2019, and upon certain events.

Table of Contents

The Old 1.5% Notes can be converted into shares of our common stock prior to stated maturity under the following circumstances:

- during any fiscal quarter if the closing sale price of our common stock for at least 20 consecutive trading days in the 30 consecutive trading-day period ending on the last trading day of the immediately preceding fiscal quarter exceeds 120% of the conversion price on that 30th trading day;
- during any five consecutive trading-day period immediately following any five consecutive trading-day period (Note Measurement Period) in which the average market price for the notes during that Note Measurement Period was less than 95% of the average conversion value for the notes during such period; provided, however, that, beginning on March 1, 2019, holders may not convert their notes if the closing sale price of our common stock on the trading day immediately preceding the day on which the notes are surrendered for conversion is greater than 100% of the conversion price but equal to or less than 120% of the conversion price;
- upon the occurrence of specified corporate transactions; or
- if we have called the notes for redemption.

A portion of the net proceeds from this offering were used to redeem our outstanding 5.5% Notes and the remaining net proceeds have been and will be used for general corporate purposes, including acquisitions of, and investments in, products, technologies and companies, capital expenditures and working capital.

In response to the adoption of the EITF consensus discussed above under Recently Issued Accounting Standards, on February 23, 2005, we completed an exchange offer pursuant to which we offered to exchange each $1,000 principal amount of our Old 1.5% Notes that was validly tendered and accepted for exchange for $1,000 principal amount of New 1.5% Notes; and (ii) a one-time cash payment equal to $2.50 per $1,000 principal amount of such Old 1.5% Notes validly tendered and accepted for exchange. The New 1.5% Notes are substantially identical to the Old 1.5% Notes, including as to convertibility, except that the New 1.5% Notes contain a “net share settlement” feature under which we committed to pay up to the principal amount of the New 1.5% Notes in cash upon conversion. This “net share settlement” feature is described below under the description of our 1.875% Notes. As a result, we believe we will be able to account for the New 1.5% Notes under the “treasury stock” method, which is generally expected to be less dilutive to earnings per share than the “if- converted” method prescribed by EITF Issue No. 04-8. We accepted for exchange $399.0 million of our Old 1.5% Notes in the exchange offer and, as a result only $1.0 million principal amount of the Old 1.5% Notes currently remain outstanding. As of December 31, 2004, 16.7 million shares of our common stock are reserved for issuance in connection with the conversion of our Old 1.5% Notes and our New 1.5% Notes.

On May 18, 2004, we redeemed our outstanding 5.5% Notes in accordance with their terms at 102.357% of the aggregate principal amount outstanding of $249.0 million plus accrued interest. We paid $254.9 million in cash to redeem the notes and wrote off the redemption premium and debt issuance costs of $8.5 million in connection with the redemption. The 1.5% interest rate on the notes issued in March 2004 is 4% lower than the notes that were redeemed and will result in reduced interest expense in future periods.

On December 22, 2004, we issued $333.0 million of our 1.875% Notes at 98.5% of the principal amount to certain qualified institutional buyers. After expenses, we received net proceeds of approximately $324.7 million. Under certain circumstances, the 1.875% Notes are convertible into cash and, if applicable, shares of our common stock based on an initial conversion rate, subject to adjustment, of 48.1301 shares of our common stock per $1,000 of principal amount of the 1.875% Notes. This ratio results in an initial conversion price of approximately $20.78 per share. As of December 31, 2004, 16.0 million shares of our common stock were reserved for issuance in connection with the conversion of the 1.875% Notes. We may redeem the 1.875% Notes on or after December 15, 2010. Beginning with the six-month period commencing on December 15, 2010, in addition to the stated interest of 1.875%, we will pay contingent interest of 0.29% of the market value of the 1.875% Notes if, during specified testing periods, the average trading price of the 1.875% Notes is 120% or more of the principal value. In

Table of Contents

addition, holders of the 1.875% Notes may require us to repurchase the notes at 100% of the principal amount plus accrued and unpaid interest on each of December 15, 2010, 2014, and 2019, and upon certain events.

The 1.875% Notes can be convertible prior to the stated maturity under the following circumstances:

- during any fiscal quarter if the closing sale price of our common stock for at least 20 consecutive trading days in the 30 consecutive trading day period ending on the last trading day of the immediately preceding fiscal quarter exceeds 120% of the conversion price on that 30th trading day;
- during any five consecutive trading day period immediately following any five consecutive trading day period (Note Measurement Period) in which the average market price for the notes during that Note Measurement Period was less than 95% of the average conversion value for the notes during such period;
- upon the occurrence of specified corporate transactions; or
- if we have called the notes for redemption.

The aggregate value (Conversion Value) of the cash and, if applicable, shares of common stock per $1,000 principal amount of notes that will be received upon conversion by a holder of the notes will be equal to the product of:

- the conversion rate then in effect; and
- the average of the daily volume-weighted average price per share of our common stock for each of the 10 consecutive trading days beginning on the second trading day immediately following the day the notes are tendered for conversion (10-day Weighted Average Price).

We will deliver the Conversion Value of the notes surrendered for conversion to converting holders as follows:

- a cash amount (Principal Return) equal to the lesser of (1) the aggregate Conversion Value of the notes to be converted or (2) the aggregate principal amount of the notes to be converted; and
- if the aggregate Conversion Value of the notes to be converted is greater than the Principal Return, an amount in whole shares equal to the quotient of (1) the aggregate Conversion Value less the Principal Return and (2) the 10-day Weighted Average Price; and
- a cash amount in lieu of any fractional shares of our common stock.

A portion of the net proceeds from this offering was used to repurchase a portion of our outstanding 4.5% Notes and the remaining net proceeds have been and will be used for general corporate purposes. On December 22, 2004, we repurchased $250.0 million of our outstanding 4.5% Notes in accordance with their terms at 98.5% of the aggregate principal amount plus accrued interest of $1.2 million. We paid $246.3 million in cash to repurchase the notes and wrote off debt issuance costs in the amount of $3.2 million in connection with the repurchase and recognized a net gain on the repurchase of $0.5 million.

The aggregate outstanding principal amount of our 1.875% Notes and our New 1.5% Notes is currently approximately $732.0 million. Both our 1.875% Notes and our New 1.5% Notes contain a “net share settlement” mechanism as describe above, under which, upon conversion of these notes, we are required to pay the holder of the converted notes an amount in cash equal to the lesser of the principal amount of the debt and the then applicable conversion value. In addition, on specified dates holders of our Old 1.5% Notes (of which $1.0 million are presently outstanding), our 1.875% Notes and our New 1.5% Notes may require us to repurchase that indebtedness at an amount equal to 100% of its principal

Table of Contents

amount plus accrued but unpaid interest. We may not have sufficient funds at such time to make the required principal payment upon conversion of our "net share settlement" indebtedness or to repurchase that indebtedness or our Old 1.5% Notes when and if required, and we may not be able to timely raise sufficient funds to satisfy that obligation. Our failure to pay the required amounts on conversion of any of our "net share settlement" notes when converted or to repurchase any of the Old 1.5% Notes, 1.875% Notes or our New 1.5% Notes when we are required to do so would result in an event of default with respect to all of those notes, which could result in the entire outstanding principal balance and accrued but unpaid interest on all of those notes being accelerated and could also result in an event of default under our other outstanding indebtedness.

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 prime plus 0.25%. 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, Florida.

Between August 2000 and March 2002, our Board of Directors increased its authorization of share repurchases under our previously announced share repurchase program by 28.1 million shares. In 2004, we made no repurchases of shares of our common stock. In 2003, we repurchased (including shares repurchased via the physical settlement method disclosed below) 0.9 million shares of our common stock at a total cost, including commissions, of $9.0 million, 4.9 million shares in 2002 for $59.4 million and 8.5 million shares in 2001 for $155.1 million. At December 31, 2004, we had the authority to purchase a remaining 16.5 million shares of our common stock or a like-valued amount of our convertible debentures under the March 2002 authorization. During 2002, in connection with our share repurchase program, five put options that we issued in 2001 were exercised for 1.5 million shares by the holders at strike prices ranging from $15.20 to $25.82. We elected the physical settlement method upon the exercise of two put options for 0.6 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 0.9 million shares and issued 1.2 million shares of our common stock in settlement of the obligation. Upon exercise of the put options, 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.

We plan to spend between $130 million and $140 million in 2005 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, among other things, 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 $75 million and $100 million in 2005 to improve and expand our pharmaceutical and other related facilities. We plan to fund these expenditures from internally generated funds.

Table of Contents

Contractual Obligations

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

| Obligation | Total | Due in Less Than 1 Year | Due in 1-3 Years | Due in 4-5 Years | Due After 5 Years |
|---|---|---|---|---|---|
| Long-term debt | $1,117,988 | $ 60,145 | $21,772 | $302,697 | $733,374 |
| Loans payable* | 18,825 | 18,825 | — | — | — |
| Capital lease obligations | 4,335 | 2,522 | 1,796 | 17 | — |
| Operating leases | 43,186 | 10,122 | 15,363 | 11,245 | 6,456 |
| Unconditional purchase obligations | 38,065 | 38,065 | — | — | — |
| Other long-term obligations | 32,320 | — | 16,098 | 4,071 | 12,151 |
| Total cash obligations | $1,254,719 | $ 129,679 | $55,029 | $318,030 | $751,981 |

* Obligations do not included future interest payments.

As of December 31, 2004, we had approximately $37.6 million of non-cancelable raw material purchase obligations. A substantial portion of this material is for use in production of our gabapentin products. As noted above under Part I. Item 3. “Legal Proceedings,” in the event the court determines that we infringed a valid patent of Warner-Lambert’s in our sales of gabapentin, we would be prevented from further sales of gabapentin and, we would be required either to default on our purchase obligations (which could subject us to damages) or attempt to identify an alternate use for such materials; otherwise, we will not be able to recover the value of those materials.

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 23.4 million shares of our common stock that can be issued in connection with the acquisition of businesses, assets or securities. During 2004, we issued an aggregate of 3.0 million shares under the shelf registration statement in connection with the acquisitions of Medco and 24.99% of Polfa Kutno. During 2003, we issued an aggregate of 1.3 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 46.2 million shares of our common stock under our shelf registration statements in connection with the acquisition of businesses, assets or securities. In addition to the shares covered by our shelf registration statement on Form S-4, as part of our proposed acquisition of Phoenix described above, we have agreed to issue $75.0 million of our common stock to the shareholders of Phoenix’ parent company, PSI Holdings, at the closing.

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 0.4 million shares under the universal shelf registration statement in connection with the net settlement of the put options discussed above. Under this

Table of Contents

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 $23.8 million tax provision for 2004 compared to $45.6 million in 2003 and $51.7 million in 2002. Our effective tax rate was 11% for 2004, 32% for 2003 and 31% for 2002. In 2004, our effective tax rate was less than the statutory rate primarily due to lower tax rates applicable to certain of our foreign operations and to the tax benefits resulting from the October 1, 2004, merger of two of our Chilean subsidiaries. The tax benefit from the merger resulted from a step-up in the tax basis of the assets existing at the time of the merger, as permitted under local tax regulations. The tax benefit associated with the merger is estimated to be $27.0 million, net of a valuation allowance of $6.5 million. The $2.9 million net decrease in our estimate of the tax benefit from the prior quarter was due to a $0.2 million decrease in the gross deferred tax asset and a $2.7 million increase in the valuation allowance for the recovery period beyond five years, primarily from revision of the estimated amounts at which various issues connected with the merger are expected to be settled. The revised net benefit reflects our best estimate of the amount expected to be realized upon settlement of all merger-related issues. It is reasonably possible that an additional loss, in the range of $0 to $3.0 million could occur upon audit of the merger and related returns. In accordance with SFAS No. 5, *Accounting for Contingencies*, this possible loss has not been accrued as it is not probable. The benefit of the merger was partially offset by $3.3 million of additional taxes arising from an intercompany dividend paid prior to the merger. We recorded a valuation allowance against the Chilean merger deferred tax asset for the amount of the tax benefit that would be realizable beyond five years because we cannot reliably forecast beyond five years due to the political and economic uncertainties in Latin America. Also included in 2004 results is a net tax benefit of $5.7 million resulting from the reversal of tax reserves in the amount of $8.6 million, relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2.8 million of additional valuation allowance recorded against the deferred tax asset at another European subsidiary due to insufficient positive evidence that the deferred tax asset will be realized. 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.

Our income tax payable is less than the current tax provision by the amount of tax benefit we receive from compensation expense deductions associated with non-qualified stock option exercises. These payments will be reduced by $5.0 million for domestic operations and $0.7 million for foreign operations for the year ended December 31, 2004, were reduced by $1.9 million for our domestic operations and $2.3 million for our foreign operations for the year ended December 31, 2003, and 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, representing the incremental impact of compensation expense deductions associated with non-qualified stock option exercises during those years. These amounts were credited to "Capital in excess of par value" in the accompanying consolidated balance sheets.

As of December 31, 2004, the deferred tax benefit of $10.8 million related to 2004 losses of foreign subsidiaries has been fully reserved through establishment of valuation allowances. On a cumulative basis, $48.8 million of tax benefit from net operating loss carryovers has been fully reserved through establishment of a valuation allowance. The valuation allowance previously recorded against the foreign net deferred tax assets of $2.6 million was reversed in 2003 due to management's expectation of increased taxable income in 2004. The domestic net deferred tax asset was $80.4 million at December 31, 2004, and $79.2 million at December 31, 2003, and the aggregate net deferred tax asset in foreign countries was $23.9 million at December 31, 2004, and $14.9 million at December 31, 2003. The domestic deferred tax was not reserved at December 31, 2004 or 2003. The aggregate net foreign deferred tax does not reflect the benefit of fully reserved tax loss carryforwards. The 2004 amount, however, is net of a $6.5 million valuation allowance established for the Chilean merger. Realization of the net deferred tax assets is dependent upon generating sufficient future domestic and foreign taxable

Table of Contents

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 as well as by changes in domestic and foreign tax laws.

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 $4.7 million in 2004, $6.2 million in 2003 and $3.5 million in 2002. 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 $5.3 million in 2004, $6.1 million in 2003 and $3.9 million for 2002 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. Under current tax law, no tax credit will be available after December 31, 2005.

On October 22, 2004, the American Jobs Creation Act of 2004 was signed into law. Management has reviewed the provisions affecting the company and has determined that it is not in the company's best interest to repatriate any foreign earnings at this time. Such earnings will continue to be reinvested in our growing foreign operations. The principal reason for deciding against repatriation at a low tax rate is the absence of excess cash in our foreign subsidiaries. Repatriation would require local borrowing to fund the dividend payment, and such borrowing would be at a rate significantly higher than our current average borrowing rate. Management has also reviewed the provisions related to the reduced tax rate on domestic production activities. Since most of our products are manufactured outside the United States, this new tax provision is not expected to have a significant impact on the company's tax position.

**Application of 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. Included within these policies are certain policies which contain critical accounting estimates and, therefore, have been deemed to be "critical accounting policies." Critical accounting estimates are those which require management to make assumptions about matters that were uncertain at the time the estimate was made and for which the use of different estimates, which reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur from period to period, could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations. During 2004, our net revenues and gross profit benefited by $8.1 million, $5.1 million net of tax, due to the positive resolution of potential service level claims. The potential service level claims related to contractual penalties payable in the event we were unable to fulfill specific purchase orders within defined parameters. Service level penalty amounts were accrued based on our interpretation of the contracts and claims history. These amounts were reversed following a determination that the amounts were not owed based upon agreements with the customers. In addition, our tax provision and net income benefited by net changes of $5.8 million from the reversal of $8.6 million, relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2.8 million of additional valuation allowance recorded against a deferred

Table of Contents

tax asset at another European subsidiary. The total impact of these changes increased net income by $10.9 million, or $0.04 per diluted share, for the year ended December 31, 2004. During 2003, as a result of improvements in our return and customer inventory experience, doubtful accounts and analysis of 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 $0.06. We have identified the following to be our critical accounting policies, estimates or assumptions: the determination of revenue provisions; our expectation that pre-launch inventory will be approved and/or be launched in the near future; the determination of impairment of goodwill and intangibles; the amount of tax benefit to be received from the merger of two of our Chilean subsidiaries and the impact of existing legal matters.

**Revenue Provisions**

Revenues and the related cost of sales are recognized when title to our products and the risks and rewards of ownership pass to our customers and when provisions for revenue dilution estimates, including chargebacks, returns, shelf stock adjustments, discounts, promotional allowances, rebates, reimbursements relating to Medicaid and Medicare and other allowances are reasonably determinable. Accruals for these provisions are presented in the Consolidated Financial Statements as reductions to “Accounts receivable” and within “Other current liabilities.” Accounts receivable are presented net of allowances relating to these provisions, which were $147.3 million at December 31, 2004 and $136.5 million at December 31, 2003. In addition, other current liabilities include $127.2 million at December 31, 2004 and $110.1 million at December 31, 2003, for revenue dilution estimates. Our policy regarding sales to customers is that we do not recognize revenue from, or the cost of, such sales where we believe the customer has more than a demonstrably reasonable level of inventory. We make this assessment based on historical demand, purchases and estimated inventory levels.

We estimate allowances for revenue dilution items using a combination of information received from third parties, including market data, inventory reports from our major U.S. wholesale customers, historical information and analysis that we perform. The key assumptions used to arrive at our best estimate of revenue dilution reserves are our estimate of inventories that are on-hand in our distribution channels, our estimate of future price declines and our estimate of potential returns. The same basic set of factors is considered in each analysis that we perform. The factors we use are estimated customer inventory levels, contractual prices and related terms, the number of other competing generic equivalents that are expected in the market, the expected size of the market and any expected trends regarding market growth or contraction. Our estimates of inventory at wholesale customers and in the distribution channels are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts, promotional and other credits are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms. We believe that such provisions are determinable due to the limited number of assumptions involved and the consistency of historical experience. Provisions for chargebacks, returns and shelf stock adjustments involve more subjective judgments and are more complex in nature. These provisions are discussed in further detail below.

*Chargebacks* - The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We market products directly to wholesalers, distributors, retail pharmacy chains, independent pharmacies, mail order pharmacies and group purchasing organizations. We also market products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as “indirect customers.” We enter into

Table of Contents

agreements with indirect customers to establish contract pricing for certain products. The indirect customers then select a wholesaler from which to actually purchase the products at these contracted prices. Alternatively, certain wholesalers may enter into agreements with indirect customers, which establish contract pricing for certain products, which the wholesalers provide. Under either arrangement, we will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. Such credit is called a chargeback. The provision for chargebacks is based on our historical chargeback experience and estimated wholesaler inventory levels, as well as expected sell-through levels by our wholesale customers to indirect customers. Our estimates of inventory at wholesale customers and in the distribution channels are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We continually monitor our provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from established reserves.

*Returns* - Consistent with industry practice, we maintain a return policy in certain markets that allows our customers to return product within a specified period prior to, and subsequent to, the product's expiration date. Our estimate of the provision for returns is based upon our historical experience with actual returns and estimated levels of inventory in the distribution channel. We make adjustments to the provision for returns in the event that it appears that actual product returns may differ from our established reserves.

*Shelf Stock Adjustments* - Shelf stock adjustments are credits issued to reflect decreases in the selling prices of our products and are based upon our estimates of the amount of product that our customers have remaining in their inventories at the time of the anticipated price reduction. Decreases in our selling prices are discretionary decisions we make to reflect market conditions. 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. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with certain customers, estimated launch dates of competing products, estimated declines in market price and estimates of inventory held by the customer. These estimates are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We regularly monitor these and other factors and evaluate our reserves and estimates as additional information becomes available.

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. During the first quarter of 2004, we earned a $25.5 million milestone payment under a product collaboration and development agreement with Mayne Group Limited for the marketing and distribution of our injectable paclitaxel product in Europe. This agreement is a multiple-element revenue arrangement containing a development and regulatory approval component. When the obligations and criteria for earning the milestone were satisfied, the milestone was recognized in other revenue. The arrangement also includes a license component containing a profit-split arrangement and an up-front payment that we received and deferred that is being amortized to other revenue over the license term due to obligations under the license agreement. In addition, the agreement contained a short-term supply arrangement that we determined contained fair market terms. During the second quarter of 2004, we earned a $5.0 million milestone payment under another product collaboration and development agreement that is a multiple-element revenue arrangement for which an up-front payment was deferred in a prior year and is being amortized to other revenues over the obligation period. During 2003, we earned approximately $6.0 million in milestone payments under a license and development agreement. Other revenues included $0.3 million in 2002 of amortization of

Table of Contents

revenue deferred in accordance with SAB No. 101. Upon termination of a license agreement, during 2002, the remaining $6.0 million of deferred revenue was recognized in income.

Gain on Sale of Product Rights – During 1997, we entered into an agreement to sell to OMP 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, $28.3 million as of January 1, 2005, is refundable through December 31, 2005, 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. 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 $20.0 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 had 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 $15.9 million in 2004, $12.8 million in 2003 and $35.2 million in 2002 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 $7.2 million at December 31, 2004, $8.3 million at December 31, 2003 and $12.3 million at December 31, 2002.

Table of Contents

**Pre-launch Inventories**

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 inventories). 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, 2004, we had approximately $33.2 million of inventories, primarily raw materials, 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. Approximately 53% of our pre-launch inventories represents inventories for which the brand product's patent protection has expired and we are awaiting regulatory approval to sell our generic equivalent. 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 Goodwill and Intangibles**

We have recorded on our consolidated balance sheet both goodwill and intangible assets, which consist of patents and technologies, trademarks, product registrations and other licenses. Intangible assets with definite lives are amortized and reviewed for impairment when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Goodwill and indefinite-lived intangible assets are tested for impairment annually.

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. Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the assets being tested. Impairment of definite-lived intangibles is determined to exist when undiscounted cash flows related to the assets are less than the carrying value of the assets. Any impairment amount is charged to operations. Because the process of testing for impairment involves management making estimates with respect to future sales volumes, pricing, new product launches, anticipated cost environment and overall market conditions and because these estimates form the basis for the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates. We test the goodwill related to the acquisition of the respiratory business in Europe on a regional basis since the business and sales are throughout Europe. During the year ended December 31, 2004, we determined through our estimates that no impairment of goodwill or intangible assets existed. We are continuing to monitor the intangibles related to our operations in France as competition in the generic pharmaceutical environment in this region remains strong and we continue to incur operating losses. Additionally, we are monitoring our Nasarel® asset as patents related to competitive brand products expire, new generic products are introduced and products are transitioned to over-the-counter, all of which could have an adverse impact on revenues and gross profit related to this product. We will continue to assess the carrying value of our goodwill and intangible assets in accordance with applicable accounting guidance.

Table of Contents

**Income Taxes**

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income in the jurisdictions associated with these carryforwards. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

We believe that our estimates for the valuation allowances reserved against the deferred tax assets are appropriate based on current facts and circumstances. However, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate of these factors.

We prepare and file tax returns based on our interpretation of tax laws and regulations and record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various taxing authorities. Such examinations may result in future tax and interest assessments by these taxing authorities. Inherent uncertainties exist in estimates of tax contingencies due to changes in tax law resulting from legislation, regulation and/or as concluded through the various jurisdictions' tax court systems. We record a liability for tax contingencies when we believe it is probable that we will be assessed and the amount of the contingency can be reasonably estimated. The tax contingency reserve is adjusted for changes in facts and circumstances, and additional uncertainties. For example, adjustments could result from significant amendments to existing tax law and the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe that our estimates for tax contingency reserves are appropriate and sufficient to pay assessments that may result from examinations of our tax returns; however, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate and the amount ultimately paid upon resolution of issues raised may differ from the amounts accrued.

During 2004, we recorded a tax benefit of $27.0 million, net of a valuation allowance of $6.5 million, related to the merger of two of our Chilean subsidiaries. The tax benefit from the merger resulted from a step-up in the tax basis of the assets existing at the time of the merger, as permitted under local tax regulations. We recorded a valuation allowance for the amount of benefit we expect to receive beyond five years as we cannot reliably forecast beyond five years due to the political and economic uncertainties in Latin America. We consider this a significant accounting estimate due to the complexity of the local tax regulations and rulings regarding these mergers. However, the net benefit recorded reflects our best estimate, in consultation with our tax and legal advisors, of the amount expected to be realized upon settlement of all merger-related issues. It is reasonably possible that an additional loss, in the range of $0 to $3.0 million could occur upon audit of the merger and related returns. In accordance with SFAS No. 5, this possible loss has not been accrued as it is not probable.

**Legal Matters**

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 13, Commitments and Contingencies, in the Notes to Consolidated Financial Statements, but their respective outcomes cannot be predicted. Because of the subjective nature inherent in assessing the outcome of litigation and because of the potential that an adverse outcome in a legal proceeding could have a material impact on our financial position or results of operations, such estimates are considered to be critical accounting estimates. Any of such lawsuits, if determined

Table of Contents

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 ANDA applicants that successfully challenge these patents, we frequently become involved in patent infringement litigation brought by branded pharmaceutical companies. Although these lawsuits generally 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.

Table of Contents

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

In the normal course of doing business we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

Foreign Currency Exchange Rate Risk –Although we do not speculate in the foreign exchange market, we may 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. 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 exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. 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. 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 $21.5 million at December 31, 2004, and $16.2 million at December 31, 2003, in foreign exchange forward contracts outstanding, primarily to hedge Euro-based operating cash flows against Pounds Sterling. If Pounds Sterling were to strengthen by 5% in relation to the Euro, our hedged foreign currency cash-flows expense would increase by $1.1 million, offset by a gain of $1.1 million on the derivative contracts, with a net effect of zero.

Interest Rate Risk – Our only material debt obligations relate to the 4.5% Notes, which bear a fixed rate of interest, the Old 1.5% Notes and the New 1.5% Notes, which generally bear a fixed rate of interest unless, after March 1, 2011, certain conditions are met, the 1.875% Notes, which generally bear a fixed rate of interest unless, after December 15, 2010, certain conditions are met (see discussion of the Old 1.5% Notes, the New 1.5% Notes and 1.875% Notes under Liquidity and Capital Resources), and the amounts we owe for the purchase of QVAR® 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-52.

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

Not applicable.

Table of Contents

## 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.

***Internal Control Over Financial Reporting***

Management's report on our internal control over financial reporting is included on page F-2 hereof. The report of our independent registered public accounting firm related to management's assessment of the effectiveness of internal control over financial reporting is included on page F-3 hereof.

***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.

***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.

## Item 9B. Other Information

Not applicable.

Table of Contents

## 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 2005 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission by April 29, 2005. 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 2005 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission by April 29, 2005.

### 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 2005 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission by April 29, 2005.

### Item 13. Certain Relationships and Related Transactions

The information required by Item 13 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission by April 29, 2005.

### Item 14. Principal Accountant Fees and Services

The information required by Item 14 is incorporated by reference to our Proxy Statement for our 2005 Annual Meeting of Shareholders, which will be filed with the Securities and Exchange Commission by April 29, 2005.

Table of Contents

## PART IV

### Item 15. Exhibits and Financial Statement Schedule

**(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:

| | |
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| Schedule II | Valuation and Qualifying Accounts for the three years ended December 31, 2004 |

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**

| Exhibit Number | Description | Method of Filing |
|---|---|---|
| 3.1 | Restated Articles of Incorporation. | Filed herewith. |
| 3.2 | Amended and Restated Bylaws. | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2002. |
| 4.1 | Indenture, dated as of May 4, 2001, between IVAX Corporation and U.S. Bank National Association, as Trustee, with respect to the 4 1/2% Convertible Senior Subordinated Notes due 2008. | Incorporated by reference to our Registration Statement on Form S-3 dated July 31, 2001. |
| 4.2 | Form of 4 1/2% Convertible Senior Subordinated Notes due 2008. | Incorporated by reference to our Registration Statement on Form S-3 dated July 31, 2001. |
| 4.3 | Indenture, dated as of December 22, 2004, between IVAX Corporation and U.S. Bank Trust National Association, as Trustee, with respect to the 1.875% Convertible Senior Notes due 2024. | Incorporated by reference to our Registration Statement on Form S-3 dated February 11, 2005. |
| 4.4 | Form of 1.875% Convertible Senior Notes due 2024 in Global Form. | Incorporated by reference to our Registration Statement on Form S-3 dated February 11, 2005. |

Table of Contents

| Exhibit Number | Description | Method of Filing |
|---|---|---|
| 4.5 | Indenture, dated as of February 23, 2005, between the registrant and U.S. Bank National Association, as Trustee, with respect to the 1.5% Convertible Senior Notes due 2024. | Incorporated by reference to our Application for Qualification of Indenture on Form T-3 filed with the Commission on February 22, 2005. |
| 4.6 | Form of 1.5% Convertible Senior Notes due 2024 in Global Form. | Incorporated by reference to our Application for Qualification of Indenture on Form T-3 filed with the Commission on February 22, 2005. |
| 4.7 | Rights Agreement, dated December 29, 1997, between IVAX Corporation and ChaseMellon Shareholder Services, L.L.C. | Incorporated by reference to our Current Report on Form 8-K dated December 19, 1997. |
| 4.8 | Amendment No. 1, dated May 12, 2000, to the Rights Agreement dated December 29, 1997, between IVAX Corporation and ChaseMellon Shareholder Services, L.L.C. | Incorporated by reference to our Current Report on Form 8-K dated June 25, 2004. |
| 10.1 | IVAX Corporation 1994 Stock Option Plan. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1997. |
| 10.2 | IVAX Corporation 1997 Stock Option Plan. | Incorporated by reference to our Registration Statement on Form S-8 dated December 22, 1997. |
| 10.3 | IVAX Corporation 1999 Employee Stock Purchase Plan. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1999. |
| 10.4 | IVAX Corporation 2004 Incentive Compensation Plan. | Incorporated by reference to our Definitive Proxy Statement dated May 24, 2004. |
| 10.5 | Form of Non-Qualified Stock Option Agreement (Employee). | Incorporated by reference to our Current Report on Form 8-K dated March 11, 2005. |
| 10.6 | Form of Non-Qualified Stock Option Agreement (Non-Employee Director). | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2004. |
| 10.7 | Form of Indemnification Agreement for Directors. | Incorporated by reference to our Registration Statement on Form 8-B dated July 28, 1993. |

Table of Contents

| Exhibit Number | Description | Method of Filing |
|---|---|---|
| 10.8 | Form of Indemnification Agreement for Officers. | Incorporated by reference to our Registration Statement on Form 8-B dated July 28, 1993. |
| 10.9 | Form of Employment Agreement (Change in Control) between IVAX Corporation and certain of its executive officers. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1998. |
| 10.10 | Employment Agreement, dated November 28, 1997, between IVAX Corporation and Phillip Frost, M.D. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1997. |
| 10.11 | Employment Agreement, dated as of May 26, 1998, between the registrant and Neil Flanzraich. | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 1998. |
| 10.12 | Employment Agreement, dated January 19, 1998, between IVAX Corporation and Jane Hsiao, Ph.D. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1997. |
| 10.13 | Employment Agreement, dated July 28, 1997, between IVAX Corporation and Rafick G. Henein, Ph.D. | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 1997. |
| 10.13a | Amendment dated June 12, 2003, to Employment Agreement between IVAX Corporation and Rafick G. Henein, Ph.D. | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003. |
| 10.13b | Restated Second Amendment to Employment Agreement between IVAX Corporation and Rafick G. Henein, Ph.D., dated October 29, 2004. | Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2004. |
| 10.14 | Warrant to Purchase Shares of Common Stock of IVAX Corporation dated November 29, 2002 between IVAX Corporation and Frost Gamma Limited Partnership. | Filed herewith. |
| 10.15 | Registration Rights Agreement, dated December 22, 2004, between IVAX Corporation and UBS Securities LLC, as Initial Purchaser, with respect to the 1.875% Convertible Senior Notes due 2024. | Incorporated by reference to our Registration Statement on Form S-3 dated February 11, 2005. |
| 10.16 | 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 1.5% Convertible Senior Notes due 2024. | Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2003. |

Table of Contents

| Exhibit Number | Description | Method of Filing |
|---|---|---|
| 10.17 | Stock Purchase Agreement by and among IVAX Corporation, PSI Holdings, Inc., Phoenix Scientific, Inc. and certain other parties thereto, dated February 15, 2005. | Incorporated by reference to our Current Report on Form 8-K dated February 15, 2005. |
| 21 | Subsidiaries of IVAX Corporation. | Filed herewith. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. | 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. |

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 16, 2005

By: /s/ Phillip Frost, M.D.
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.

| Name | Capacity | Date |
|---|---|---|
| /s/ Phillip Frost, M.D.<br>Phillip Frost, M.D. | Chairman of the Board and Chief Executive Officer (Principal Executive Officer) | March 16, 2005 |
| /s/ Thomas E. Beier<br>Thomas E. Beier | Chief Financial Officer (Principal Financial Officer) | March 16, 2005 |
| /s/ Thomas E. McClary<br>Thomas E. McClary | Chief Accounting Officer (Principal Accounting Officer) | March 16, 2005 |
| /s/ Betty G. Amos<br>Betty G. Amos | Director | March16, 2005 |
| /s/ Mark Andrews<br>Mark Andrews | Director | March 16, 2005 |
| /s/ Ernst Biekert, Ph.D.<br>Ernst Biekert, Ph.D. | Director | March 16, 2005 |
| /s/ Paul L. Cejas<br>Paul L. Cejas | Director | March 16, 2005 |

Table of Contents

| Name | Capacity | Date |
|---|---|---|
| /s/ Jack Fishman, Ph.D.<br>Jack Fishman, Ph.D. | Director | March 16, 2005 |
| /s/ Neil Flanzraich<br>Neil Flanzraich | Director, President and Vice Chairman | March 16, 2005 |
| /s/ Bruce W. Greer<br>Bruce W. Greer | Director | March 16, 2005 |
| /s/ Jane Hsiao, Ph.D.<br>Jane Hsiao, Ph.D. | Director and Vice Chairman- Technical and Regulatory Affairs | March 16, 2005 |
| /s/ Richard M. Krasno, Ph.D.<br>Richard M. Krasno, Ph.D. | Director | March 16, 2005 |
| /s/ David A. Lieberman<br>David A. Lieberman | Director | March16, 2005 |
| /s/ Richard C. Pfenniger, Jr.<br>Richard C. Pfenniger, Jr. | Director | March 16, 2005 |
| /s/ Bertram Pitt, M.D.<br>Bertram Pitt, M.D. | Director | March 16, 2005 |

Table of Contents

**IVAX CORPORATION AND SUBSIDIARIES**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Table of Contents

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. As permitted, we have excluded from our evaluation the 2004 acquisitions of Kutnowskie Zaklady Farmaceutyczne "POLFA" SA, Corporacion Medco S.A.C., and Botica Torres de Limatambo S.A.C., which are included in the 2004 Consolidated Financial Statements of IVAX Corporation and which in the aggregate represent 9.3% of consolidated total assets, 16.3% of consolidated shareholders' equity as of December 31, 2004, 2.3% of consolidated net revenues and 1.3% of consolidated net income for the year ended December 31, 2004. Based on our evaluation, under the Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2004. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report which is included herein.

Table of Contents

## Report of Independent Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that IVAX Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). IVAX Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the following acquisitions completed by IVAX Corporation in 2004: Kutnowskie Zaklady Farmaceutyczne "POLFA" SA; Corporacion Medco S.A.C.; and Botica Torres de Limatambo S.A.C., which are included in the 2004 consolidated financial statements of IVAX Corporation and constituted 9.3% and 16.3% of consolidated total assets and shareholders' equity, respectively, as of December 31, 2004 and 2.3% and 1.3% of consolidated net revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of IVAX Corporation also did not include an evaluation of the internal control over financial reporting of the entities referred to above.

In our opinion, management's assessment that IVAX Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, IVAX Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of IVAX Corporation and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 and our report dated March 9, 2005, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 9, 2005

Table of Contents

## Report of Independent Registered Public Accounting Firm

**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, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IVAX Corporation and subsidiaries as of December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of computing diluted earnings per share regarding the Company's contingent convertible debt during the year ended December 31, 2004. Also 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.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of IVAX Corporation and subsidiaries' internal control over financial reporting as of December 31, 2004, based on the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2005, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida
March 9, 2005

Table of Contents

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

| | December 31, 2004 | December 31, 2003 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 391,988 | $ 134,270 |
| Marketable securities | 6,058 | 23,070 |
| Accounts receivable, net of allowances for doubtful accounts of $19,212 in 2004 and $17,675 in 2003 | 392,418 | 264,317 |
| Inventories, net | 524,644 | 413,872 |
| Other current assets | 206,535 | 160,187 |
| Total current assets | 1,521,643 | 995,716 |
| Property, plant and equipment, net | 604,647 | 502,942 |
| Goodwill, net | 682,778 | 489,665 |
| Intangible assets, net | 336,594 | 314,361 |
| Other assets | 66,357 | 70,250 |
| Total assets | $3,212,019 | $2,372,934 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 177,537 | $ 139,990 |
| Current portion of long-term debt | 60,145 | 58,607 |
| Loans payable | 18,825 | 17,804 |
| Accrued income taxes payable | 34,125 | 27,990 |
| Accrued expenses and other current liabilities | 287,789 | 242,158 |
| Total current liabilities | 578,421 | 486,549 |
| Long-term debt, net of current portion | 1,057,843 | 855,335 |
| Other long-term liabilities | 72,855 | 56,208 |
| Minority interest | 12,571 | 12,531 |
| Commitments and contingencies | | |
| Shareholders' equity: | | |
| Common stock, $0.10 par value, authorized 546,875 shares, issued and outstanding 260,531 shares in 2004 and 245,885 in 2003 | 26,053 | 24,589 |
| Capital in excess of par value | 571,143 | 336,313 |
| Retained earnings | 888,503 | 690,476 |
| Accumulated other comprehensive income (loss) | 4,630 | (89,067) |
| Total shareholders' equity | 1,490,329 | 962,311 |
| Total liabilities and shareholders' equity | $3,212,019 | $2,372,934 |

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

Table of Contents

**IVAX CORPORATION AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
(In thousands, except per share data)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Net revenues | $1,837,418 | $1,420,339 | $1,197,244 |
| Cost of sales (excluding amortization, which is presented below) | 985,125 | 781,383 | 663,708 |
| Gross profit | 852,293 | 638,956 | 533,536 |
| Operating expenses: | | | |
| Selling | 272,569 | 212,192 | 168,952 |
| General and administrative | 162,391 | 122,414 | 118,416 |
| Research and development | 141,604 | 108,347 | 76,041 |
| Amortization of intangible assets | 22,488 | 19,719 | 16,158 |
| Restructuring costs | 1,374 | 3,706 | 4,242 |
| Total operating expenses | 600,426 | 466,378 | 383,809 |
| Operating income | 251,867 | 172,578 | 149,727 |
| Other income (expense): | | | |
| Interest income | 5,545 | 3,710 | 8,090 |
| Interest expense | (41,424) | (43,608) | (48,639) |
| Other income, net | 5,836 | 11,738 | 60,321 |
| Total other income (expense) | (30,043) | (28,160) | 19,772 |
| Income before income taxes and minority interest | 221,824 | 144,418 | 169,499 |
| Provision for income taxes | 23,757 | 45,559 | 51,742 |
| Income before minority interest | 198,067 | 98,859 | 117,757 |
| Minority interest | (40) | 188 | 838 |
| Income from continuing operations | 198,027 | 99,047 | 118,595 |
| Income from discontinued operations, net of tax of $12,763 | — | 22,204 | — |
| Cumulative effect of accounting change | — | — | 4,161 |
| Net income | $ 198,027 | $ 121,251 | $ 122,756 |
| | | | |
| Basic earnings per common share: | | | |
| Continuing operations | $ 0.79 | $ 0.41 | $ 0.49 |
| Discontinued operations | — | 0.09 | — |
| Cumulative effect of accounting change | — | — | 0.02 |
| Net income | $ 0.79 | $ 0.50 | $ 0.51 |
| | | | |
| Diluted earnings per common share: | | | |
| Continuing operations | $ 0.75 | $ 0.40 | $ 0.48 |
| Discontinued operations | — | 0.09 | — |
| Cumulative effect of accounting change | — | — | 0.02 |
| Net income | $ 0.75 | $ 0.49 | $ 0.50 |
| | | | |
| Weighted average number of common shares outstanding: | | | |
| Basic | 249,250 | 244,532 | 243,796 |
| Diluted | 268,792 | 248,625 | 246,722 |

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

Table of Contents

**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 Income (Loss) | Total |
|---|---|---|---|---|---|---|---|
| | Number of Shares | Amount | | | | | |
| **BALANCE**, January 1, 2002 | 245,654 | $24,565 | $323,182 | $ 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 | 851 | 85 | 5,171 | — | — | — | 5,256 |
| Tax benefit of option exercises | — | — | 1,467 | — | — | — | 1,467 |
| Employee stock purchases | 99 | 10 | 918 | — | — | — | 928 |
| Repurchase of common stock | (4,853) | (485) | (46,218) | (12,725) | — | — | (59,428) |
| Shares issued to settle put options | 1,214 | 121 | 21,804 | (21,925) | — | — | — |
| Value of stock options issued to non-employees | — | — | 184 | — | — | — | 184 |
| **BALANCE**, December 31, 2002 | 242,965 | 24,296 | 306,508 | — | 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 | 2,138 | 214 | 16,961 | — | — | — | 17,175 |
| Tax benefit of option exercises | — | — | 4,278 | — | — | — | 4,278 |
| Employee stock purchases | 111 | 11 | 1,027 | — | — | — | 1,038 |
| Repurchase of common stock | (875) | (87) | (8,910) | — | — | — | (8,997) |
| Shares issued in acquisitions | 1,546 | 155 | 16,335 | — | — | — | 16,490 |
| Value of stock options issued to non-employees | — | — | 114 | — | — | — | 114 |
| **BALANCE**, December 31, 2003 | 245,885 | 24,589 | 336,313 | — | 690,476 | (89,067) | 962,311 |
| Comprehensive income: | | | | | | | |
| Net income | — | — | — | | 198,027 | — | 198,027 |
| Translation adjustment | — | — | — | | — | 94,828 | 94,828 |
| Unrealized net gain on available-for-sale equity securities and derivatives, net of tax | — | — | — | — | — | (1,131) | (1,131) |
| Comprehensive income | | | | | | | 291,724 |
| Exercise of stock options | 1,938 | 194 | 18,443 | — | — | — | 18,637 |
| Tax benefit of option exercises | — | — | 5,774 | — | — | — | 5,774 |
| Employee stock purchases | 100 | 10 | 1,519 | — | — | — | 1,529 |
| Shares issued in acquisitions | 12,608 | 1,260 | 208,814 | — | — | — | 210,074 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Value of stock options issued to non-employees | — | — | 280 | — | — | — | 280 |
| **BALANCE**, December 31, 2004 | 260,531 | $26,053 | $571,143 | $ — | $888,503 | $ 4,630 | $1,490,329 |

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

Table of Contents

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Cash flows from operating activities: | | | |
| Net income | $ 198,027 | $ 121,251 | $ 122,756 |
| Adjustments to reconcile net income to net cash flows from operating activities: | | | |
| Restructuring costs | 1,374 | 3,706 | 4,242 |
| Depreciation and amortization | 82,903 | 76,808 | 59,877 |
| Deferred tax (benefit) provision | (16,793) | 17,099 | (8,110) |
| Tax benefit of stock option exercises | 5,774 | 4,278 | 1,467 |
| Value of stock options issued to non-employees | 280 | 114 | 184 |
| Provision for (reversal of) doubtful accounts | 2,627 | (1,948) | 4,239 |
| Provision for inventory obsolescence | 44,421 | 31,017 | 15,446 |
| Interest accretion on notes receivable and payable, net | 2,026 | 2,378 | 1,935 |
| Minority interest in loss (earnings) | 40 | (188) | (838) |
| Equity in earnings of unconsolidated affiliates | (1,174) | (1,645) | (877) |
| (Gains) losses on sale of marketable securities | (1,634) | 1,106 | (4) |
| Gains on sale of product rights | (15,926) | (12,835) | (35,150) |
| (Gains) loss on sale of assets, net | (130) | 119 | 2,930 |
| Losses (gains) on extinguishment of debt | 2,063 | (2,323) | (17,346) |
| Income from discontinued operations | — | (22,204) | — |
| Cumulative effect of accounting change | — | — | (4,161) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (104,023) | (18,465) | 12,493 |
| Inventories | (115,453) | (111,953) | (68,591) |
| Other current assets | (23,415) | 671 | (293) |
| Other assets | 3,046 | 753 | 5,800 |
| Accounts payable, accrued expenses and other current liabilities | 46,420 | (3,880) | 48,318 |
| Other long-term liabilities | 2,548 | (1,261) | 6,821 |
| Net cash flows from operating activities | 113,001 | 82,598 | 151,138 |
| Cash flows from investing activities: | | | |
| Proceeds from sale of product rights | 15,926 | 12,835 | 35,150 |
| Capital expenditures | (98,814) | (95,358) | (98,670) |
| Proceeds from sales of assets | 2,069 | 2,025 | 1,602 |
| Acquisitions of intangible assets | (2,017) | (7,798) | (38,274) |
| Acquisitions of businesses, net of cash acquired | (15,111) | (27,110) | 3,629 |
| Investment in affiliates | 903 | 3,658 | (3,677) |
| Purchases of marketable securities | (1,194,379) | (344,770) | (454,864) |
| Proceeds from sales of marketable securities | 1,213,667 | 359,371 | 604,379 |
| Net proceeds from discontinued operations | 5,500 | 8,824 | — |
| Net cash flows from investing activities | (72,256) | (88,323) | 49,275 |
| Cash flows from financing activities: | | | |
| Borrowings on long-term debt and loans payable | 812,225 | 28,598 | 12,745 |
| Payments on long-term debt and loans payable | (623,204) | (67,298) | (138,812) |
| Exercise of stock options and employee stock purchases | 20,166 | 18,213 | 6,184 |
| Repurchase of common stock | — | (8,997) | (59,428) |
| Net cash flows from financing activities | 209,187 | (29,484) | (179,311) |
| Effect of exchange rate changes on cash and cash equivalents | 7,786 | 14,071 | (23,008) |
| Net increase (decrease) in cash and cash equivalents | 257,718 | (21,138) | (1,906) |
| Cash and cash equivalents at the beginning of the year | 134,270 | 155,408 | 157,314 |

| | | | |
|---|---|---|---|
| Cash and cash equivalents at the end of the year | $ 391,988 | $ 134,270 | $ 155,408 |

(Continued)

Table of Contents

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Supplemental disclosures: | | | |
| Interest paid, net of capitalized interest | $ 32,495 | $39,619 | $44,671 |
| Income tax payments | $ 34,431 | $51,907 | $46,585 |
| Income tax refunds | $ 7,892 | $ — | $ — |
| Supplemental schedule of non-cash investing and financing activities: | | | |
| Purchase of intangible assets through the issuance of debt | | | $80,054 |
| Information with respect to acquisitions accounted for under the purchase method of accounting is summarized as follows: | | | |
| Fair value of assets acquired | $113,138 | $55,890 | |
| Liabilities assumed | (52,158) | (4,874) | |
| Net assets acquired | 60,980 | 51,016 | |
| Purchase price: | | | |
| Cash, net of cash acquired | 2,640 | 25,592 | |
| Acquisition costs | 12,471 | 1,518 | |
| Forgiveness of note receivable and related cost | 3,916 | — | |
| Present value of future minimum royalty payments | — | 48,638 | |
| Fair market value of stock and options issued | 210,074 | 16,490 | |
| Total | 229,101 | 92,238 | |
| Goodwill | $168,121 | $41,222 | |

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

Table of Contents

**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. In accordance with the provisions of Financial Accounting Standards Board (FASB) Interpretation No. 46R, *Consolidation of Variable Interest Entities,* we consolidate variable interest entities for which management has concluded that IVAX is the primary beneficiary. Entities that do not meet the definition of a variable interest entity are subject to the provision of Accounting Research Bulletin (ARB) No. 51, *Consolidated Financial Statements,* and are consolidated when management has determined that IVAX has the controlling financial interest. 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. All significant intercompany balances and transactions have been eliminated in consolidation. For purposes of these financial statements, North America includes the United States and Canada. Mexico is included within Latin America.

Reclassifications – Certain amounts presented in the accompanying consolidated financial statements for prior periods have been reclassified to conform to the current year presentation. In the Consolidated Balance Sheets and Statements of Cash Flows, we reclassified from cash and cash equivalents to marketable securities $12,600 as of December 31, 2003 and $20,950 as of December 31, 2001.

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 the allowance for doubtful accounts receivable, deferred tax assets and valuation allowances, inventory writedowns and reserves, environmental reserves, litigation, the useful lives of intangible assets and sales returns and allowances, including, but not limited to, chargebacks, rebates, returns and shelf-stock adjustments.

Table of Contents

During the year ended December 31, 2004, our net revenues and gross profit benefited by $8,100, $5,144 net of tax, due to the positive resolution of previously accrued potential service level claims. In addition, our tax provision and net income benefited by net changes of $5,749 from the reversal of $8,577 of tax reserves, relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2,828 of additional valuation allowance recorded against a deferred tax asset at another European subsidiary (see Note 9, Income Taxes, for additional information). The total impact of these changes increased net income by $10,893, or $0.04 per diluted share.

During the year ended December 31, 2003, as a result of improvements in our return and customer inventory experience, doubtful accounts and analysis of 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 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 $0.06.

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.

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 rates resetting every 28 or 35 days through an auction mechanism. 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 income (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.

We have investments in 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 income (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.

Table of Contents

Investments in marketable securities consist of the following:

| | December 31, 2004 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Market Value |
| Mutual funds | $ 1,408 | $ — | $ — | $ 1,408 |
| Auction rate securities | 4,650 | — | — | 4,650 |
| Equity securities | 156 | 57 | — | 213 |
| Corporate bonds | 14 | — | — | 14 |
| Total marketable securities | 6,228 | 57 | — | 6,285 |
| Less: Short-term marketable securities | 6,058 | — | — | 6,058 |
| Long-term marketable securities | $ 170 | $ 57 | $ — | $ 227 |

| | December 31, 2003 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Market Value |
| Mutual funds | $ 8,776 | $ — | $ — | $ 8,776 |
| Auction rate securities | 14,260 | — | — | 14,260 |
| Equity securities | 1,016 | 434 | — | 1,450 |
| Total marketable securities | 24,052 | 434 | — | 24,486 |
| Less: Short-term marketable securities | 23,070 | — | — | 23,070 |
| Long-term marketable securities | $ 982 | $ 434 | $ — | $ 1,416 |

Concentration of Credit Risk – We sell a significant amount of brand equivalent pharmaceutical products to a relatively small number of retail drug chains and drug wholesalers, primarily in the United States, which represents an essential part of the distribution chain of pharmaceutical products in the United States. The total net accounts receivable balances of our two subsidiaries that sell to this concentration of customers represented approximately 38% of our accounts receivable balances as of December 31, 2004, and 25% as of December 31, 2003.

Accounts receivable are recorded concurrently with sales unless there is significant uncertainty regarding collection, in which case the sale is not recorded in revenues. Credit is extended to customers based on 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. Some of the factors that we consider in determining whether to record an allowance against accounts receivable include the age of the receivable, historical write-off experience and current economic conditions.

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.

Other Concentrations — 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.

Table of Contents

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, | |
|---|---|---|
| | 2004 | 2003 |
| Raw materials | $194,183 | $155,159 |
| Work-in-process | 81,202 | 65,194 |
| Finished goods | 249,259 | 193,519 |
| Total inventories | $524,644 | $413,872 |

Pre-launch Inventories – 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 inventories). 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, 2004, we had approximately $33,198 in inventories, primarily raw materials, 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. Approximately 53% of our pre-launch inventories represents inventories for which the brand product's patent protection has expired and we are awaiting regulatory approval to sell our generic equivalent.

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Land | $ 38,159 | $ 24,758 |
| Buildings and improvements | 341,787 | 255,863 |
| Machinery and equipment | 397,340 | 323,210 |
| Furniture and computer equipment | 109,249 | 92,875 |
| Construction in process | 62,382 | 84,428 |
| Total cost | 948,917 | 781,134 |
| Less: Accumulated depreciation and amortization | 344,270 | 278,192 |
| Property, plant and equipment, net | $604,647 | $502,942 |

Table of Contents

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 - 10 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 $59,029 in 2004, $56,387 in 2003 and $42,848 in 2002.

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 – Total interest costs incurred were $46,208 in 2004, $45,717 in 2003 and $49,069 in 2002, of which the amount capitalized on certain construction projects was $4,784 in 2004, $2,109 in 2003 and $430 in 2002.

Impairment of Goodwill and Intangibles — We have recorded on our balance sheet both goodwill and intangible assets, which consist of patents and technologies, trademarks, product registrations and other licenses. Intangible assets with definite lives are amortized and reviewed for impairment when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Goodwill and indefinite-lived intangible assets are tested for impairment annually.

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. Impairment of goodwill and indefinite-lived intangibles is determined to exist when the fair value is less than the carrying value of the assets being tested. Impairment of definite-lived intangibles is determined to exist when undiscounted cash flows related to the assets are less than the carrying value of the assets. Any impairment amount is charged to operations. Because the process of testing for impairment involves management making estimates with respect to future sales volumes, pricing, new product launches, anticipated cost environment and overall market conditions and because these estimates form the basis for the determination of whether or not an impairment charge should be recorded, these estimates are considered to be critical accounting estimates. We test the goodwill related to the acquisition of the respiratory business in Europe on a regional basis since the business and sales are throughout Europe. During the year ended December 31, 2004, we determined through our estimates that no impairment of goodwill or intangible assets existed. We are continuing to monitor the intangibles related to our operations in France as competition in the generic pharmaceutical environment in this region remains strong and we continue to incur operating losses. Additionally, we are monitoring our Nasarel asset as patents related to competitive brand products expire, new generic products are introduced and products are transitioned to over-the-counter, all of which could have an adverse impact on revenues and gross profit related to this product. We will continue to assess the carrying value of our goodwill and intangible assets in accordance with applicable accounting guidance.

Table of Contents

Intangible assets with definite lives are amortized and carried at cost less accumulated amortization. Intangible assets with indefinite lives are carried at cost. Intangible assets consist of the following:

| | December 31, | | | |
|---|---|---|---|---|
| | 2004 | | 2003 | |
| | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization |
| Amortized intangible assets: | | | | |
| Patents and related licenses | $ 76,867 | $ 55,494 | $ 79,655 | $ 52,481 |
| Trademarks | 146,107 | 30,042 | 136,249 | 18,416 |
| Licenses and other intangibles | 217,799 | 45,589 | 166,079 | 22,086 |
| Total | $440,773 | $ 131,125 | $381,983 | $ 92,983 |
| Unamortized intangible assets: | | | | |
| Trademarks and product registrations | $ 26,946 | | $ 25,361 | |

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 14.4 years at December 31, 2004, and 15.6 years at December 31, 2003. Certain of our amortization expense is included in research and development expense. Amortization expense was $23,015 in 2004, $20,421 in 2003 and $17,029 in 2002.

Estimated intangible assets amortization expense for the next five years is approximately $26,822 in 2005, $25,469 in 2006, $27,292 in 2007, $25,631 in 2008, and $25,540 in 2009.

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 income (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. If the economy of Venezuela again becomes hyperinflationary, the local currency financial statements of our Venezuelan operations will be remeasured into United States dollars 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.

Table of Contents

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 6, Investments In and Advances to Unconsolidated Affiliates, and Note 7, Debt).

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. These gains and losses are recorded in the same income statement captions as the related hedged cash flows. Gains and losses on the ineffective portion of these hedges are recorded in "Other income, net" in the accompanying consolidated statement of operations. Prior to maturity, unrealized gains or losses are recorded, net of tax, in "Accumulated other comprehensive income (loss)" in the accompanying consolidated balance sheets. 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 $21,535 at December 31, 2004, which mature in January 2005 through July 2005, and $16,188 at December 31, 2003, which matured from January 2004 through July 2004, primarily to hedge Euro-based operating cash flows against Pounds Sterling. If Pounds Sterling were to strengthen by 5% in relation to the Euro, our hedged foreign currency cash-flows expense would increase by $1,077, offset by a gain of $1,077 on the derivative contracts, with a net effect of zero. 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.

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 $8,013 in 2004, $10,013 in 2003 and $1,056 in 2002, which are included in "Other income, net" in the accompanying consolidated statements of operations.

Revenue Recognition – Revenues and the related cost of sales are recognized when title to our products and the risks and rewards of ownership pass to our customers and when provisions for revenue dilution items, including chargebacks, returns, shelf stock adjustments, discounts, promotional allowances, rebates, reimbursements relating to Medicaid and Medicare and other allowances are reasonably determinable. These revenue dilution provisions totaled $875,871 in 2004, $647,264 in 2003 and $664,565 in 2002. The reserve balances related to these provisions are included in the following balance sheet accounts:

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Accounts receivable | $147,330 | $136,475 |
| Accrued expenses | 127,240 | 110,079 |
| Total sales returns and allowances reserves | $274,570 | $246,554 |

Table of Contents

Our policy regarding sales to customers is that we do not recognize revenue from, or the cost of, such sales where we believe the customer has more than a demonstrably reasonable level of inventory. We make this assessment based on historical demand, purchases and estimated inventory levels.

We estimate allowances for revenue dilution items using a combination of information received from third parties, including market data, inventory reports from our major U.S. wholesale customers, historical information and analysis that we perform. The key assumptions used to arrive at our best estimate of revenue dilution reserves are our estimate of inventories that are on-hand in our distribution channels, our estimate of future price declines and our estimate of potential returns. The same basic set of factors is considered in each analysis that we perform. The factors we use are estimated customer inventory levels, contractual prices and related terms, the number of other competing generic equivalents that are expected in the market, the expected size of the market and any expected trends regarding market growth or contraction. Our estimates of inventory at wholesale customers and in the distribution channels are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts, promotional and other credits are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms. We believe that such provisions are determinable due to the limited number of assumptions involved and the consistency of historical experience. Provisions for chargebacks, returns and shelf stock adjustments involve more subjective judgments and are more complex in nature. These provisions are discussed in further detail below.

*Chargebacks* - The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We market products directly to wholesalers, distributors, retail pharmacy chains, independent pharmacies, mail order pharmacies and group purchasing organizations. We also market products indirectly to independent pharmacies, managed care organizations, hospitals, nursing homes and pharmacy benefit management companies, collectively referred to as “indirect customers.” We enter into agreements with indirect customers to establish contract pricing for certain products. The indirect customers then select a wholesaler from which to actually purchase the products at these contracted prices. Alternatively, certain wholesalers may enter into agreements with indirect customers, which establish contract pricing for certain products, which the wholesalers provide. Under either arrangement, we will provide credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler’s invoice price. Such credit is called a chargeback. The provision for chargebacks is based on our historical chargeback experience and estimated wholesaler inventory levels, as well as expected sell-through levels by our wholesale customers to indirect customers. Our estimates of inventory at wholesale customers and in the distribution channels are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We continually monitor our provision for chargebacks and make adjustments when we believe that actual chargebacks may differ from established reserves.

*Returns* - Consistent with industry practice, we maintain a return policy in certain markets that allows our customers to return product within a specified period prior to, and subsequent to, the product’s expiration date. Our estimate of the provision for returns is based upon our historical experience with actual returns and estimated levels of inventory in the distribution channel. We make adjustments to the provision for returns in the event that it appears that actual product returns may differ from our established reserves.

Table of Contents

*Shelf Stock Adjustments* - Shelf stock adjustments are credits issued to reflect decreases in the selling prices of our products and are based upon our estimates of the amount of product that our customers have remaining in their inventories at the time of the anticipated price reduction. Decreases in our selling prices are discretionary decisions we make to reflect market conditions. 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. Amounts recorded for estimated shelf stock adjustments are based upon specified terms with certain customers, estimated launch dates of competing products, estimated declines in market price and estimates of inventory held by the customer. These estimates are subject to inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates, and reflect other limitations. We regularly monitor these and other factors and evaluate our reserves and estimates as additional information becomes available.

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. During the first quarter of 2004, we earned a $25,500 milestone payment under a product collaboration and development agreement with Mayne Group Limited for the marketing and distribution of our injectable paclitaxel product in Europe. This agreement is a multiple-element revenue arrangement containing a development and regulatory approval component. When the obligations and criteria for earning the milestone were satisfied, the milestone was recognized in other revenue. The arrangement also includes a license component containing a profit-split arrangement and an up-front payment that we received and deferred that is being amortized to other revenue over the license term due to obligations under the license agreement. In addition, the agreement contained a short-term supply arrangement that we determined contained fair market terms. During the second quarter of 2004, we earned a $5,000 milestone payment under another product collaboration and development agreement that is a multiple-element revenue arrangement for which an up-front payment was deferred in a prior year and is being amortized to other revenues over the obligation period. During 2003, we earned approximately $6,000 in milestone payments under a license and development agreement. Other revenues included $318 in 2002 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.

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 $2,318 in 2004, $1,837 in 2003 and $745 in 2002.

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.

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

Table of Contents

Sale of Subsidiary Stock – Our accounting policy for sales of subsidiary stock is income statement recognition. Accordingly, gains and losses on sales are recorded in "Other income, net" in the consolidated statement of operations.

Income Taxes – The provision for current 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 9, Income Taxes).

We have recorded valuation allowances against certain of our deferred tax assets, primarily those that have been generated from net operating losses in certain taxing jurisdictions. In evaluating whether we would more likely than not recover these deferred tax assets, we have not assumed any future taxable income in the jurisdictions associated with these carryforwards. Implementation of tax planning strategies to recover these deferred tax assets or future income generation in these jurisdictions could lead to the reversal of these valuation allowances and a reduction of income tax expense.

We believe that our estimates for the valuation allowances reserved against the deferred tax assets are appropriate based on current facts and circumstances. However, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate of these factors.

We prepare and file tax returns based on our interpretation of tax laws and regulations and record estimates based on these judgments and interpretations. In the normal course of business, our tax returns are subject to examination by various taxing authorities. Such examinations may result in future tax and interest assessments by these taxing authorities. Inherent uncertainties exist in estimates of tax contingencies due to changes in tax law resulting from legislation, regulation and/or as concluded through the various jurisdictions' tax court systems. We record a liability for tax contingencies when we believe it is probable that we will be assessed and the amount of the contingency can be reasonably estimated. The tax contingency reserve is adjusted for changes in facts and circumstances, and additional uncertainties. For example, adjustments could result from significant amendments to existing tax law and the issuance of regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination. We believe that our estimates for tax contingency reserves are appropriate and sufficient to pay assessments that may result from examinations of our tax returns; however, other people applying reasonable judgment to the same facts and circumstances could develop a different estimate and the amount ultimately paid upon resolution of issues raised may differ from the amounts accrued.

Table of Contents

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Numerator: | | | |
| Income from continuing operations | $198,027 | $ 99,047 | $118,595 |
| Interest expense on 1.5% contingently convertible debt, net of tax | 3,952 | — | — |
| Adjusted income from continuing operations | $201,979 | $ 99,047 | $118,595 |
| Denominator: | | | |
| Basic weighted average number of shares outstanding | 249,250 | 244,532 | 243,796 |
| Effect of dilutive securities – stock options and warrants | 5,680 | 4,093 | 2,926 |
| Conversion equivalent of 1.5% contingently convertible debt | 13,862 | — | — |
| Diluted weighted average number of shares outstanding | 268,792 | 248,625 | 246,722 |
| Not included in the calculation of diluted earnings per share because their impact is antidilutive: | | | |
| Stock options outstanding | 6,063 | 11,271 | 17,086 |
| Convertible debt | 16,910 | 27,369 | 29,554 |

See Note 16, Subsequent Events, for discussion of our exchange of 1.5% contingently convertible notes for new notes. Had this exchange occurred prior to December 15, 2004, we expect that the majority of conversion equivalent shares would not have been required to be included in our calculation of dilutive earnings per share.

Accumulated Other Comprehensive Income (Loss) – Other comprehensive income 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 income (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 Statement of Financial Accounting Standard (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 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.

Table of Contents

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, are indicated below (see Note 11, Shareholder's Equity, for comments regarding the acceleration of vesting of stock options in 2004):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Net income as reported | $198,027 | $121,251 | $122,756 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | 54,549 | 16,851 | 16,477 |
| Pro forma net income | 143,478 | $104,400 | $106,279 |
| Basic net income per share as reported | $ 0.79 | $ 0.50 | $ 0.51 |
| Pro forma basic net income per share | $ 0.58 | $ 0.43 | $ 0.44 |
| Diluted net income per share as reported | $ 0.75 | $ 0.49 | $ 0.50 |
| Pro forma diluted net income per share | $ 0.54 | $ 0.42 | $ 0.43 |
| Pro forma weighted average fair value of options granted | $ 7.20 | $ 4.15 | $ 6.40 |
| Expected life (years) | 4.6 | 4.8 | 5.3 |
| Risk-free interest rate | 3.1-4.6% | 2.7-4.0% | 3.4-4.8% |
| Expected volatility | 25% | 26% | 27% |
| Dividend yield | 0% | 0% | 0% |

Valuations are based on highly subjective assumptions about the future, including stock price volatility and exercise patterns. During the fourth quarter of 2004, it was determined that our stock option program did not include the impact of forfeitures in the report of the fair value of compensation expense. Accordingly, the amount reported for 2003 was reduced by $3,851 and for 2002 was reduced by $2,557 to reflect the impact of forfeitures.

Recently Issued Accounting Standards – On September 30, 2004, the EITF reached a consensus on Issue No. 04-8, *The Effect of Contingently Convertible Debt on Diluted Earnings per Share,* concluding that contingently convertible debt instruments should be included in diluted earnings per share computations (if dilutive) regardless of whether the market price trigger (or other contingent feature) has been met. This consensus is effective for reporting periods ending after December 15, 2004, and requires prior period earnings per share amounts presented for comparative purposes to be restated utilizing a transition method. The transition method agreed upon by the EITF is a modified restatement approach that results in a company applying the consensus to the terms of the security at the adoption date. As such, if the terms of the security are changed prior to the adoption date, it is the changed terms to which the consensus is applied. We adopted the consensus in the fourth quarter of 2004. The impact of adoption has reduced our reported diluted earnings per share for each of the three month periods ended March 31, 2004, June 30, 2004, and December 31, 2004, by $0.01 per share and for the year ended December 31, 2004 by $0.03 per share. There was no impact on the prior years' reported diluted earnings per share.

On November 24, 2004, the FASB issued SFAS No. 151, *Inventory Costs,* an amendment of ARB No. 43, Chapter 4, which clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material be recognized as current period charges. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. It is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The impact of adoption of this statement is not expected to be significant.

Table of Contents

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* which addresses the accounting for transactions in which an entity exchanges it equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires compensation costs related to share-based payment transactions to be recognized in the financial statements. It applies to all awards granted after the effective date and is not applied to awards granted in periods before the effective date, except to the extent that the prior periods' awards are modified, repurchased or cancelled after the effective date. This Statement can be adopted under two methods, the modified prospective or the modified retrospective applications. Under the modified prospective application, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date should be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards should be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosure under SFAS No. 123. Changes to the grant-date fair value of awards granted before the effective date of this Statement are precluded. The compensation cost for those earlier awards should be attributed to periods beginning on or after the effective date of this Statement using the attribution method that was used under SFAS No. 123, except that the method of recognizing forfeitures only as they occur should be continued. Any unearned or deferred compensation related to those earlier awards should be eliminated against the appropriate equity accounts. The modified retrospective application may be applied to all prior years that SFAS No. 123 was effective or only to prior interim periods in the year of initial adoption if the effective date of SFAS No. 123 (as revised) does not coincide with the beginning of the fiscal year. It is effective as of the first interim or annual reporting period that begins after June 15, 2005. The cumulative effect of the initial application of this Statement, if any, is to be recognized as of the effective date. Upon adoption, we will be required to reclassify excess tax benefits, as defined in the Statement, from stock option exercises from Cash flows from operating activities to Cash flows from financing activities in the Consolidated Statement of Cash Flows. We expect that under the modified prospective method of adoption, during the second half of 2005 we will be required to record additional compensation expense of approximately $2,586, net of tax, for unvested awards that were outstanding as of December 31, 2004. We also expect that compensation expense will be required to be recorded for future awards of share-based payments, including employee stock purchases under our Employee Stock Purchase Plan, if not amended prior to adoption.

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 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 of 2002 and no impairments were indicated. During 2004 and 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 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.

**(3) Mergers and Acquisitions:**

On June 1, 2004, we indirectly acquired from Recordati Industria Chimica e Farmaceutica S.p.A. (Recordati) 469 shares of Kutnowskie Zaklady Farmaceutyczne "POLFA" SA (Polfa Kutno), by purchasing the outstanding securities of KZFPK Holdings, Inc., a Delaware corporation, for 2,169 shares of our common stock, valued at $41,627. The shares purchased represent 24.99% of the total share capital in Polfa Kutno, a pharmaceutical company listed on the Warsaw Stock Exchange. On December 15, 2004, we acquired 97.23% of the remaining outstanding shares of Polfa Kutno in exchange for 9,606 shares of our common stock, valued at $152,549. The total purchase price, including acquisition costs in connection with this transaction and the transaction with Recordati of $12,252 less cash acquired of $95, was $206,333. Polfa Kutno markets and manufactures a wide variety of prescription and over-the-counter pharmaceutical products, which we believe will complement our existing businesses and will provide new products and marketing opportunities. 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, including final determination of the liability for restructuring. The excess of the purchase price over the net assets acquired has been recorded as goodwill pending receipt of final information on the fair value of assets acquired and liabilities assumed. We recorded $737 of equity in earnings of Polfa Kutno during the period June 1, 2004, through December 15, 2004. The operating results of Polfa Kutno are included in the consolidated financial statements subsequent to the December 15, 2004, the trade settlement date.

Table of Contents

On June 2, 2004, we acquired Corporacion Medco S.A.C. (Medco), a Peruvian pharmaceutical company, by purchasing the outstanding securities of Medco's parent, Inversiones Catamaran S.A. – Inveran, a corporation organized under the laws of Panama, for 833 shares of our common stock, valued at $15,898, and $100 in cash. The total purchase price, including acquisition costs of $188 less cash acquired of $198 and a working capital purchase price adjustment refund of $668, was $15,320. Medco develops, manufactures and sells branded over-the-counter and prescription products, as well as generic prescription pharmaceutical products, in Peru. We acquired Medco to further our growth in the Peruvian market and to provide new product opportunities. 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 Medco are included in the consolidated financial statements subsequent to the June 2, 2004, acquisition date.

On June 2, 2004, we indirectly acquired Botica Torres de Limatambo S.A.C. (BTL), a Peruvian retail pharmacy company, by purchasing the outstanding securities of one of BTL's parents, ASSA Investments S.A., and exercising an option (Option) to acquire the outstanding securities of the other parent, ASSA Inc., for $3,501 in cash, net of cash acquired of $249, forgiveness of a note receivable previously held by us with a recorded value of $1,728 and related costs of $2,188, and other costs incurred of $31, of which $188 is held in escrow. The note receivable was secured by the Option. BTL operates a retail pharmacy chain in Peru. We acquired BTL to further our growth in the Peruvian market and to explore retail pharmacy market opportunities. 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 BTL are included in the consolidated financial statements subsequent to the June 2, 2004, acquisition date.

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 | $ 44,946 |
| Property, plant and equipment | 35,147 |
| Intangible assets | 31,495 |
| Other assets | 1,550 |
| Total assets acquired | 113,138 |
| Current liabilities | 38,416 |
| Long-term debt | 13,742 |
| Total liabilities assumed | 52,158 |
| Net assets acquired | $ 60,980 |
| Purchase price: | |
| Cash, net of cash acquired | $ 2,640 |
| Acquisition costs | 12,471 |
| Forgiveness of note receivable and related cost | 3,916 |
| Fair market value of stock issued | 210,074 |
| Total | $229,101 |
| Goodwill | $168,121 |

The results of operations prior to the acquisitions were not significant in relation to our results of operations.

Table of Contents

On January 24, 2003, we acquired ChemSource Corporation in Puerto Rico from Chemo Iberica S.A. and Quimica Sintetica S.A. for 1,250 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 September 23, 2003, we acquired Advanced Tobacco Products, Inc. (ATP), for 296 shares of our common stock, valued at $4,097. 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. 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 September 23, 2003, acquisition date.

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 and $24,000 on the first anniversary. In addition, $24,000 is due on the second anniversary 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. 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.

**(4) 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 $0.09 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

Table of Contents

additional fees related to the settlement and a deferred tax liability of $7,691. The first installment payment of $5,500 was received in June 2004.

**(5) 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 (ALZA) 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, $28,313 as of January 1, 2005, is refundable through December 31, 2005, 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. 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 the 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 had 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 was 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 $15,926 in 2004, $12,835 in 2003 and $35,150 in 2002, 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 $7,210 at December 31, 2004, $8,307 at December 31, 2003 and $12,276 at December 31, 2002.

Table of Contents

**(6) 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 $7,414 at December 31, 2004, and $9,625 at December 31, 2003, 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.

**(7) Debt:**

Long-term debt consists of the following:

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| 1.5% Convertible Senior Notes due 2024. Interest payable semi-annually. 1.8% effective interest rate. | $ 400,000 | $ — |
| 1.875% Convertible Senior Notes due 2024. Interest payable semi-annually. 2.3% effective interest rate. | 328,022 | — |
| 4.5% Convertible Senior Subordinated Notes due 2008. Interest payable semi-annually. 4.8% effective interest rate. | 283,900 | 533,900 |
| 5.5% Convertible Senior Subordinated Notes due 2007. Interest payable semi-annually. 5.9% effective interest rate. | — | 249,000 |
| QVAR® related payables | 25,681 | 55,368 |
| European respiratory business related payables | 26,314 | 49,003 |
| Mortgage note, due August 21, 2008, 4.3% interest rate through August 21, 2005, thereafter prime plus 0.25% | 14,427 | 14,857 |
| Other subsidiaries' debt, due from 2005 to 2010, at interest rates ranging from 3% to 12% | 39,644 | 11,814 |
| Total long-term debt | 1,117,988 | 913,942 |
| Less: Current portion of long-term debt | 60,145 | 58,607 |
| Long-term debt, net of current portion | $1,057,843 | $855,335 |

On December 22, 2004, we issued $333,000 of our 1.875% Convertible Senior Notes due 2024 (1.875% Notes) at 98.5% of the principal amount to certain qualified institutional buyers. After expenses, we received net proceeds of approximately $324,675. Under certain circumstances, the 1.875% Notes are convertible into cash and, if applicable, shares of our common stock based on an initial conversion rate, subject to adjustment, of 48.1301 shares of our common stock per $1,000 of principal amount of the 1.875% Notes. This ratio results in an initial conversion price of approximately $20.78 per share. As of December 31, 2004, 16,027 shares of our common stock are reserved for issuance in connection with the conversion of the 1.875% Notes. We may redeem the 1.875% Notes on or after December 15, 2010. Beginning with the six-month period commencing on December 15, 2010, in addition to the stated interest of 1.875%, we will pay contingent interest of 0.29% of the market value of the 1.875% Notes if, during specified testing periods, the average trading price of the 1.875% Notes is 120% or more of the principal value. In addition, holders of the 1.875% Notes may require us to repurchase the notes at 100% of the principal amount on each of December 15, 2010, 2014, and 2019, and upon certain events.

Table of Contents

The 1.875% Notes can be converted prior to the stated maturity under the following circumstances:

- during any fiscal quarter (beginning with the quarter ended March 31, 2005) if the closing sale price of our common stock for at least 20 consecutive trading days in the 30 consecutive trading day period ending on the last trading day of the immediately preceding fiscal quarter exceeds 120% of the conversion price on that 30th trading day;
- during any five consecutive trading day period immediately following any five consecutive trading day period (Note Measurement Period) in which the average market price for the notes during that Note Measurement Period was less than 95% of the average conversion value for the notes during such period;
- upon the occurrence of specified corporate transactions; or
- if we have called the notes for redemption.

The aggregate value (Conversion Value) of the cash and, if applicable, shares of our common stock per $1,000 principal amount of notes that will be received upon conversion by a holder of the notes will be equal to the product of:

- the conversion rate then in effect; and
- the average of the daily volume-weighted average price per share of our common stock for each of the 10 consecutive trading days beginning on the second trading day immediately following the day the notes are tendered for conversion (10-day Weighted Average Price).

We will deliver the Conversion Value of the notes surrendered for conversion to converting holders as follows:

- a cash amount (Principal Return) equal to the lesser of (1) the aggregate Conversion Value of the notes to be converted or (2) the aggregate principal amount of the notes to be converted; and
- if the aggregate Conversion Value of the notes to be converted is greater than the Principal Return, an amount in whole shares equal to the quotient of (1) the aggregate Conversion Value less the Principal Return and (2) the 10-day Weighted Average Price; and
- a cash amount in lieu of any fractional shares of our common stock.

Shares underlying the 1.875% Notes were not included in our calculation of diluted earnings per share because our share price as of December 31, 2004, was below the conversion price. As a result, there would be no premium over the principal amount, which is paid in cash, so no shares would be issued on conversion. As discussed below, a portion of the net proceeds from this offering were used to repurchase a portion of our outstanding 4.5% Convertible Senior Subordinated Notes and the remaining net proceeds have been and will be used for general corporate purposes.

On March 3, 2004, we issued $400,000 of our 1.5% convertible senior notes due 2024 (Old 1.5% Notes) to certain qualified institutional buyers. After expenses, we received net proceeds of approximately $390,500. Under certain circumstances, the Old 1.5% Notes are convertible, unless previously redeemed, into 41.85925 shares of our common stock per $1,000 of principal amount of the Old 1.5% Notes. This ratio results in a conversion price of approximately $23.89 per share. As of December 31, 2004, 16,744 shares of our common stock are reserved for issuance in connection with the conversion of the Old 1.5% Notes. We may redeem the Old 1.5% Notes on or after March 1, 2011. Beginning with the six-month period commencing on March 1, 2011, in addition to the stated interest of 1.5%, we will pay contingent interest of 0.36% of the market value of the Old 1.5% Notes if, during specified testing periods, the average trading price of the Old 1.5% Notes is 120% or more of the principal value. In addition, holders of the Old 1.5% Notes may require us to repurchase the notes at 100% of the principal amount on each of March 1, 2011, 2014, and 2019, and upon certain events.

Table of Contents

The Old 1.5% Notes can be converted into shares of our common stock prior to the stated maturity under the following circumstances:

- during any fiscal quarter if the closing sale price of our common stock for at least 20 consecutive trading days in the 30 consecutive trading-day period ending on the last trading day of the immediately preceding fiscal quarter exceeds 120% of the conversion price on that 30th trading day;
- during any five consecutive trading-day period immediately following any five consecutive trading-day period (Note Measurement Period) in which the average market price for the notes during that Note Measurement Period was less than 95% of the average conversion value for the notes during such period; provided, however, that, beginning on March 1, 2019, holders may not convert their notes if the closing sale price of our common stock on the trading day immediately preceding the day on which the notes are surrendered for conversion is greater than 100% of the conversion price but equal to or less than 120% of the conversion price;
- upon the occurrence of specified corporate transactions; or
- if we have called the notes for redemption.

Shares underlying the Old 1.5% Notes were included in our calculation of diluted earnings per share in the fourth quarter and for the year 2004 due to adoption of EITF No. 04-8 in the fourth quarter of 2004. EITF No. 04-8 requires us to apply the “if-converted” method to the Old 1.5% Notes and, if dilutive, include the common stock issuable on conversion in our calculation of diluted earnings per share regardless of whether the conditions to conversion have been met. See Note 16, Subsequent Events, for discussion of our exchange of the Old 1.5% Notes for new 1.5% convertible senior notes. As discussed below, a portion of the net proceeds from this offering were used to redeem our outstanding 5.5% Notes and the remaining net proceeds have been and will be used for general corporate purposes, including acquisitions of, and investments in, products, technologies and companies, capital expenditures and working capital. See Note 16, Subsequent Events, regarding our exchange of these notes after December 31, 2004.

The 4.5% Notes are convertible at any time prior to maturity, unless previously redeemed, into 31.21094 shares of our common stock per $1,000 of principal amount of the 4.5% Notes. This results in a conversion price of approximately $32.04 per share. As of December 31, 2004, 8,861 shares of our common stock are reserved for issuance in connection with the conversion of the outstanding 4.5% Notes. These shares were excluded from the calculation of diluted earnings per share because their impact was antidilutive. The 4.5% Notes are currently redeemable. Unamortized debt issuance costs related to the 4.5% Notes was $3,608 at December 31, 2004 and $8,816 at December 31, 2003, which is being amortized using the effective interest method to interest expense over the life of the 4.5% Notes. Using proceeds from our issuance of the 1.875% Notes, on December 22, 2004, we repurchased $250,000 of the 4.5% Notes at 98.5% of the aggregate principal amount plus accrued interest of $1,156. We paid $246,250 in cash to repurchase the notes and wrote off debt issuance costs in the amount of $3,209 in connection with the repurchase. This resulted in a gain on the repurchase of debt of $540. 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.

On May 18, 2004, we redeemed the 5.5% Notes in accordance with their terms at 102.357% of the aggregate principal amount outstanding of $249,000 plus accrued interest. We paid $254,869 in cash to redeem the notes and wrote off the redemption premium and debt issuance costs in the amount of $8,472 in connection with the redemption. Unamortized debt issuance costs related to the 5.5% Notes was

Table of Contents

$2,925 at December 31, 2003, which was 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.

Payments for the April 2, 2002, 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 $25,681 at December 31, 2004 and $55,368 at December 31, 2003. The current portion of this debt, net of the discount, was $25,681 at December 31, 2004. In addition, payments for the April 2, 2002, purchase of 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 $6,523 at December 31, 2004 and $5,868 at December 31, 2003. The current portion of this debt was $2,250 at December 31, 2004.

The present value of future minimum royalty payments due for the October 1, 2003, 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 $26,314 at December 31, 2004 and $49,003 at December 31, 2003, that was recorded as additional long-term debt in the accompanying consolidated balance sheets. The current portion of this debt, net of the discount, was $23,467 at December 31, 2004.

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 prime plus 0.25%. 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 $7,464 at December 31, 2004.

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, which was recorded in other income, net.

Certain of our international subsidiaries maintain relationships with foreign banks providing short-term lines of credit in the aggregate amount of approximately $39,400 at December 31, 2004, and $23,400 at December 31, 2003. Short-term borrowings totaled $18,825 at December 31, 2004, and $17,804 at December 31, 2003, and are included as “Loans payable” in the accompanying consolidated balance sheets. As of December 31, 2004, one of the foreign credit lines in the amount of $11,075 is secured by accounts receivables of $4,102.

Unless otherwise stated, our long-term debt is unsecured.

As of December 31, 2004, we had approximately $37,618 of non-cancelable raw material purchase obligations. A substantial portion of this material is for use in production of our gabapentin products. In the event the court determines that we infringed a valid patent of Warner-Lambert in our sales of gabapentin, we would be prevented from further sales of gabapentin (See Note 13, Commitments and Contingencies).

Table of Contents

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| 1.5% Convertible Senior Notes due 2024 | $ 380,076 | $ — |
| 1.875% Convertible Senior Notes due 2024 | 328,022 | — |
| 4.5% Convertible Senior Subordinated Notes due 2008 | 287,273 | 538,924 |
| 5.5% Convertible Senior Subordinated Notes due 2007 | — | 255,701 |
| QVAR® related payables | 25,681 | 55,368 |
| European respiratory business related payables | 26,314 | 49,003 |
| Mortgage note | 14,427 | 14,857 |
| Other subsidiaries' debt | 39,644 | 11,814 |
| Total | $1,101,437 | $925,667 |

Fair value of the 1.5%, 1.875%, 4.5% and 5.5% Notes is based on available quoted closing 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 $60,145 for 2005, $15,422 for 2006, $6,351 for 2007, $299,575 for 2008, $3,121 for 2009 and $733,374 thereafter.

**(8) Restructuring Costs:**

During 2004, we incurred $1,374 of restructuring costs, primarily employee termination benefits, related to restructuring in the United Kingdom and Peru.

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.

Table of Contents

The components of the restructuring costs, spending and other activity, as well as the remaining restructuring reserve balances at December 31, 2004, 2003 and 2002 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.

| | Employee Termination Benefits | Plant Closures | Total |
|---|---|---|---|
| Balance at January 1, 2002 | $ 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 |
| 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 |
| Balance at December 31, 2003 | 1,727 | 242 | 1,969 |
| Accrual of restructuring costs | 1,374 | — | 1,374 |
| Cash payments during 2004 | (1,517) | (150) | (1,667) |
| Non-cash activity | (1,223) | (92) | (1,315) |
| Balance at December 31, 2004 | $ 361 | $ — | $ 361 |

**(9) Income Taxes:**

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Current: | | | |
| United States Federal | $ 25,845 | $ 7,148 | $34,635 |
| State | 521 | 2,764 | 2,267 |
| Puerto Rico and the U.S. Virgin Islands | 423 | (1,010) | 854 |
| Foreign | 13,761 | 19,558 | 22,096 |
| Deferred | | | |
| United States | 987 | 19,894 | (7,491) |
| Foreign | (17,780) | (2,795) | (619) |
| Total | $ 23,757 | $45,559 | $51,742 |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| United States | $ 83,408 | $ 87,938 | $ 83,539 |
| Puerto Rico and the U.S. Virgin Islands | 15,313 | 19,417 | 11,693 |
| Foreign | 123,103 | 37,063 | 74,267 |
| Total | 221,824 | $144,418 | $169,499 |

Table of Contents

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, | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Tax using statutory United States Federal tax rate at 35% | $ 77,638 | $50,547 | $ 59,324 |
| Effect of state income taxes | 958 | 1,797 | 1,474 |
| Lab Chile merger benefit | (33,548) | — | — |
| Change in valuation allowance on deferred tax assets (principally related to Chilean merger benefit) | 9,349 | (2,611) | (3,565) |
| Foreign tax rate differential | (31,939) | (3,555) | (10,131) |
| Effect of Puerto Rico taxes and tollgate | 423 | (1,010) | 854 |
| Puerto Rico and U.S. possessions tax incentives | (5,272) | (6,057) | (3,881) |
| Foreign operating losses not benefited | 13,400 | 9,692 | 5,615 |
| Tax claims, tax reserves, and other matters | (8,577) | (2,700) | — |
| Other | 1,325 | (544) | 2,052 |
| Total | $ 23,757 | $45,559 | $ 51,742 |

The tax provision for the year ended December 31, 2004, was less than the United States statutory rate primarily due to lower tax rates applicable to certain of our foreign operations and to the tax benefits resulting from the October 1, 2004, merger of two of our Chilean subsidiaries. The tax benefit from the merger resulted from a step-up in the tax basis of the assets existing at the time of the merger, as permitted under local tax regulations. The tax benefit associated with the merger is estimated to be $27,027, net of a valuation allowance of $6,521. The $2,911 net decrease in our estimate of the tax benefit from the prior quarter was due to a $199 decrease in the gross deferred tax asset and a $2,712 increase in the valuation allowance for the recovery period beyond five years, primarily from revision of the estimated amounts at which various issues connected with the merger are expected to be settled. The revised net benefit reflects our best estimate of the amount expected to be realized upon settlement of all merger-related issues. It is reasonably possible that an additional loss, in the range of $0 to $3,000 could occur upon audit of the merger and related returns. In accordance with SFAS No. 5, *Accounting for Contingencies*, this possible loss has not been accrued as it is not probable. The merger benefit was partially offset by $3,252 of additional United States and foreign taxes arising from the payment of an intercompany dividend. We recorded a valuation allowance against the Chilean merger deferred tax asset for the amount of the tax benefit that would be realizable beyond five years because we cannot reliably forecast beyond five years due to the political and economic uncertainties in Latin America. Also included in operating results is a net tax benefit of $5,749 resulting from the reversal of tax reserves in the amount of $8,577, relating to prior years' tax issues at three of our foreign subsidiaries, that on review were determined to no longer be necessary, partially offset by $2,828 of additional valuation allowance recorded against the deferred tax asset at another European subsidiary due to insufficient positive evidence that the deferred tax asset will be realized. 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.

Our income tax payable is less than the current tax provision by the amount of tax benefit we receive from compensation expense deductions associated with non-qualified stock option exercises. These payments will be reduced by $5,027 for our domestic operations and $747 for our foreign operations for the year ended December 31, 2004, were reduced by $1,930 for our domestic operations and $2,303 for our foreign operations for the year ended December 31, 2003, and were reduced by $1,411 for our domestic operations and $421 for our foreign operations the for the year ended December 31, 2002, representing the incremental impact of compensation expense deductions associated with non-qualified stock option exercises during those years. These amounts were credited to "Capital in excess of par value" in the accompanying consolidated balance sheets.

Table of Contents

As of December 31, 2004, the deferred tax benefit of $10,826 related to 2004 losses of foreign subsidiaries has been fully reserved through establishment of valuation allowances. On a cumulative basis, $48,829 of tax benefit from net operating loss (NOL) carryovers has been fully reserved through establishment of valuation allowances. The valuation allowance previously recorded against the foreign net deferred tax assets of $2,611 was reversed in 2003 due to management's expectation of increased taxable income in the coming year. The domestic net deferred tax asset was $80,445 at December 31, 2004 and $79,187 at December 31, 2003, and the aggregate net deferred tax asset in foreign countries was $23,903 at December 31, 2004 and $14,930 at December 31, 2003 and are included in "Other current assets" and "Other assets", respectively in the accompanying consolidated balance sheets. The domestic deferred tax asset had no valuation allowance at December 31, 2004 or 2003. The aggregate net foreign deferred tax asset does not reflect the benefit of fully reserved tax loss carryforwards. The 2004 amount, however, is net of a $6,521 valuation allowance established for the Chilean merger. 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.

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. A detail of the significant components of deferred tax assets (liabilities) in the accompanying consolidated balance sheets is as follows:

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Accounts receivable allowances | $ 69,571 | $ 66,542 |
| Reserves and accruals | 25,247 | 13,039 |
| Other | 9,528 | 7,161 |
| Amount included in "Other current assets" | 104,346 | 86,742 |
| Merger benefit, net | 12,295 | — |
| Tax credits | 3,110 | 1,600 |
| Net operating losses – United States | 3,730 | 4,790 |
| Net operating losses – foreign | 48,829 | 34,009 |
| Recognition of revenue | — | 219 |
| Carrying value of long-term assets | (3,068) | 1,340 |
| Other | 3,434 | 4,035 |
| Amount included in "Other assets" | 68,330 | 45,993 |
| Other, amount included in "Accrued expenses and other current liabilities" | (4,930) | (5,012) |
| Fixed assets basis difference | (7,615) | (1,631) |
| Tax on deferred installment gain | (5,567) | — |
| Bond original issue discount | (6,441) | — |
| Other | (11,572) | (17,124) |
| Other, amount included in "Other long-term liabilities" | (31,195) | (18,755) |
| Deferred tax asset | 136,551 | 108,968 |
| Valuation allowance for foreign operating losses | (48,829) | (34,009) |
| Net deferred tax asset | $ 87,722 | $ 74,959 |

Table of Contents

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 $423,395 as of December 31, 2004. Any United States tax amounts due would be reduced by allowable foreign tax credits.

Income from IVAX Pharmaceuticals' (IPI) 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 $4,720 in 2004, $6,217 in 2003 and $3,515 in 2002. Under the terms of the grant, IPI 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 $5,272 for 2004, $6,057 for 2003 and $3,881 for 2002, 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.

At December 31, 2004, 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:

| Expire | United States | Foreign |
|---|---|---|
| 2005 | $ — | $ 14,511 |
| 2006 | 3,028 | 10,571 |
| 2007 | 2,733 | 30,159 |
| 2008 | 4,896 | 19,588 |
| 2009 | — | 7,638 |
| 2010 | — | 13,190 |
| 2011 | — | 8,040 |
| 2012 | — | 5,933 |
| 2013 | — | 54 |
| Indefinite | — | 163,307 |
| Total | $ 10,657 | $272,991 |

Minority interest included in the accompanying consolidated statements of operations is net of a provision for income taxes of $7 in 2004, $29 in 2003 and $37 in 2002.

On October 22, 2004, the American Jobs Creation Act of 2004 was signed into law. Management has reviewed the provisions affecting the Company and has determined that it is not in the Company's best interest to repatriate any foreign earnings at this time. Such earnings will continue to be reinvested in our growing foreign operations. The principal reason for deciding against repatriation at a low tax rate is the absence of excess cash in our foreign subsidiaries. Repatriation would require local borrowing to fund the dividend payment, and such borrowing would be at a rate significantly higher than our current average borrowing rate. Management has also reviewed the provisions related to the reduced tax rate on domestic production activities. Since most of our products are manufactured outside the United States, this new tax provision is not expected to have a significant impact on the Company's tax position.

Table of Contents

**(10) 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 $3,377 in 2004, $2,010 in 2003 and $1,454 in 2002.

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, 2004, 562 employees were covered by this plan and 153 former members have retained entitlements to deferred benefits. As of December 31, 2003, 544 employees were covered by this plan and 145 former members have retained entitlements to deferred benefits.

Actuarial assumptions for the plan include: (a) 7.0% for the expected long-term rate of return on plan assets, (b) 4.9% for 2004, 5.25% for 2003 and 5.5% for 2002 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 for the years ended December 31, 2004 and 2003, were as follows:

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| **Net Periodic Pension Cost:** | | |
| Service cost | $ 1,831 | $ 2,028 |
| Interest cost | 927 | 846 |
| Expected return on plan assets | (971) | (675) |
| Amortization of actuarial gain | (85) | — |
| Amortization of transition obligation | 256 | 233 |
| Net periodic pension cost | $ 1,958 | $ 2,432 |

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Projected benefit obligation for service rendered to date | $(26,944) | $(21,296) |
| Plan assets at fair value, primarily mutual funds | 17,960 | 13,176 |
| Projected benefit obligation in excess of plan assets | (8,984) | (8,120) |
| Unrecognized net gain | (298) | (404) |
| Unrecognized net obligation | 7,261 | 7,007 |
| Accrued pension liability | $ (2,021) | $ (1,517) |

Table of Contents

A reconciliation of the pension benefit obligation is as follows:

| | December 31, 2004 | 2003 |
|---|---|---|
| **Pension Benefit Obligations:** | | |
| Start of year | $21,296 | $14,315 |
| Service cost | 1,831 | 2,028 |
| Employee contribution | 816 | 659 |
| Interest cost | 927 | 846 |
| Benefits paid | (445) | (242) |
| Unrecognized actuarial gain | 567 | 404 |
| Translation adjustment | 1,952 | 3,286 |
| At end of year | $26,944 | $21,296 |

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

| | December 31, 2004 | 2003 |
|---|---|---|
| **Fair Value of Pension Assets:** | | |
| Start of year | $13,176 | $ 8,262 |
| Employer contribution | 1,601 | 1,069 |
| Employee contribution | 816 | 659 |
| Actual return | 1,499 | 1,442 |
| Benefits paid | (445) | (242) |
| Translation adjustment | 1,313 | 1,986 |
| At end of year | $17,960 | $13,176 |

The accumulated benefit obligation was $20,910, of which $20,759 was vested, at December 31, 2004, and $15,310, of which $10,514 was vested, at December 31, 2003.

The weighted-average asset allocations, by asset category, are as follows:

| | December 31, 2004 | 2003 |
|---|---|---|
| **Asset Category:** | | |
| Equity securities | 73.4% | 74.9% |
| Debt securities | 18.2 | 15.5 |
| Real estate | 4.2 | 3.3 |
| Cash | 4.2 | 6.3 |
| Total | 100.0% | 100.0% |

The basis used to determine the overall expected rate of return on assets was an assumption that the investment return on debt securities would be 4.9% in line with the discount rate used, a 3.0% equity risk premium was assumed giving an expected equity return of 7.9%. It was assumed that real estate would return 1.0% less than equities. Combining these assumptions with the target asset allocation of the plan gives an expected return rate of approximately 7.0%. The investment policy is to invest in line with the typical ‘discretionary’ balanced fund in the Irish marketplace. This implies asset class weightings along the following lines: equities (60% - 80%), fixed interest (15% - 35%), property (0% - 15%) and cash (0% - 10%).

We expect to contribute $1,843 to the pension plan in 2005. The benefit payments, which reflect expected future service, expected to be paid are approximately $33 in 2005, $38 in 2006, $47 in 2007, $57 in 2008, $69 in 2009, and $1,168 for the five years thereafter.

Table of Contents

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.

Net pension expenses for the United Kingdom plan were $482 for 2003.

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

| | December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Projected benefit obligation for service rendered to date | $(15,642) | $(15,985) |
| Plan assets at fair value, primarily mutual funds | 15,642 | 15,985 |
| Projected benefit obligation in excess of plan assets | — | — |
| Unrecognized net obligation | 4,231 | 3,939 |
| Prior service cost | (5,031) | (4,684) |
| Accrued pension liability | $ (800) | $ (745) |

In addition, we have defined benefit employee pension plans at two other European subsidiaries covering approximately 21 employees.

**(11) Shareholders' Equity:**

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

| Plan Category | (a) Number of securities to be issued upon exercise of outstanding options, warrants and rights | (b) Weighted-average exercise price of outstanding options, warrants and rights | (c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---|---|---|---|
| Equity compensation plan approved by security holders: | | | |
| 2004 Plan | 91 | $ 18.29 | 12,409 |
| 1994 Plan | 12,047 | 13.48 | — |
| Equity compensation plans not approved by security holders: | | | |
| 1997 Plan | 16,384 | 15.64 | 1,915 |
| 1985 Plan | — | | — |
| Total | 28,522 | $ 14.74 | 14,324 |

Table of Contents

We administer and have stock options outstanding under our 2004 Incentive Compensation Plan (2004 Plan), 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 15, 2004, IVAX' shareholders approved the establishment of the 2004 Plan to permit the issuance of options to employees, non-employee directors and consultants to purchase up to 31,250 shares of our common stock and 36,621 related common stock purchase rights. Shares available for grants or payments of awards are limited to the lesser of 12,500 shares, plus an annual increase of 2% of the then outstanding shares of common stock of IVAX, calculated on the first day of each fiscal year commencing January 1, 2005, or 31,250 shares. On July 28, 2003, our Board of Directors approved an increase to 28,750 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 16,406 shares of our common stock. The 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.

On December 20, 2004, our Compensation Committee accelerated the vesting of all of our unvested stock options awarded to officers and employees under the 1994 Plan, the 1997 Plan and the 2004 Plan which had an exercise price greater than $15.39, the closing price of our common stock on the American Stock Exchange on December 20, 2004. As a result of the acceleration, options to acquire approximately 8,167 shares of our common stock (representing approximately 29% of the total outstanding options), which otherwise would have vested from time to time over the next 46 months, became immediately exercisable. Approximately 65% of the accelerated options would have vested over the next 15 months. If we had already adopted the fair value method, the acceleration of the options would have increased compensation expense $38,835 in 2004 and would have decreased compensation expense $18,307 in 2005, $9,981 in 2006, $8,994 in 2007 and $1,982 in 2008.

Our Compensation Committee's decision to accelerate the vesting of these options was in response to the issuance by the FASB of SFAS No. 123 (revised 2004), *Share-Based Payment*. By accelerating the vesting of these options, we believe it will potentially result in our not being required to recognize any compensation expense in the current year or in future periods associated with these options.

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

| | 2004 | | 2003 | | 2002 | |
|---|---|---|---|---|---|---|
| | 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 | 24,721 | $ 13.28 | 23,800 | $ 13.92 | 20,945 | $ 13.58 |
| Granted | 6,966 | 18.44 | 5,245 | 9.48 | 4,842 | 14.22 |
| Exercised | (1,936) | 9.63 | (2,138) | 8.03 | (851) | 6.18 |
| Terminated/exchanged | (1,229) | 14.53 | (2,186) | 16.24 | (1,136) | 16.52 |
| Balance at end of year | 28,522 | 14.74 | 24,721 | 13.28 | 23,800 | 13.92 |
| Exercisable at December 31, | 24,865 | $ 15.53 | 12,666 | $ 12.74 | 10,964 | $ 10.46 |

Table of Contents

The following table summarizes information about fixed stock options outstanding at December 31, 2004 (number of shares in thousands):

| Range of Exercise Prices | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| | Number Outstanding at 12/31/04 | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable at 12/31/04 | Weighted Average Exercise Price |
| $ 0.00-$ 6.30 | 3,359 | 0.9 | $ 4.03 | 3,359 | $ 4.03 |
| $ 6.31-$ 9.46 | 4,178 | 5.9 | 8.75 | 1,134 | 8.61 |
| $ 9.47-$12.61 | 3,575 | 3.8 | 11.43 | 3,262 | 11.56 |
| $12.62-$15.76 | 4,842 | 4.7 | 15.15 | 4,542 | 15.21 |
| $15.77-$18.91 | 6,480 | 6.8 | 18.35 | 6,480 | 18.35 |
| $18.92-$22.06 | 2,803 | 3.3 | 20.68 | 2,803 | 20.68 |
| $22.07-$25.22 | 2,656 | 4.9 | 23.03 | 2,656 | 23.03 |
| $25.23-$28.37 | 382 | 2.5 | 27.47 | 382 | 27.47 |
| $28.38-$31.52 | 247 | 3.8 | 30.54 | 247 | 30.54 |
| | 28,522 | 4.6 | $ 14.74 | 24,865 | $ 15.53 |

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 6,563, subject to future increases as stated in the plan, is reserved for issuance. 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 12,500 shares of common stock or a like-valued amount of our convertible debentures, bringing the total authorized for repurchase to 84,375 shares. From December 31, 1997, through December 31, 2004, we repurchased 67,905 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.

In 2004, we did not repurchase shares of our common stock. We repurchased (including shares repurchased via the physical settlement method disclosed below) 875 shares of our common stock in 2003 at a total cost, including commissions, of $8,997 and 4,853 shares in 2002 for $59,391.

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 from “Capital in excess of par value” into a separate temporary equity account “Put options.”

During 2002, in connection with our share repurchase program, five put options that we issued in 2001 were exercised for 1,500 shares by the holders at strike prices ranging from $15.20 to $25.82. We elected the physical settlement method upon the exercise of two put options for 625 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 875 shares and issued 1,214 shares of our common stock in settlement of the obligation. Upon exercise of the put options, 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.

Table of Contents

Warrants – Frost Gamma Limited Partnership (FGLP), beneficially owned by our Chairman and CEO, has a warrant to purchase 1,172 shares of our common stock at an exercise price of $7.68 per share that was issued in connection with a $50,000 promissory note issued to FGLP on November 18, 1999, and repaid on June 30, 2000. Proceeds of the note were used to purchase our common stock under our share repurchase program and the exercise price of the warrant was equal to the price paid for the repurchased shares. The warrant is exercisable through November 17, 2006. As of December 31, 2004, our common stock reserved for on the warrants is 1,172 shares.

Shelf Registration – We filed a shelf registration statement on Form S-4, which was declared effective in March 2001, registering up to a total of 23,438 shares of common stock that can be issued in connection with the acquisition of businesses, assets or securities. 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 46,151 shares of our common stock under our shelf registration statements in connection with the acquisition of businesses, assets or securities.

We filed a universal shelf registration statement on Form S-3, which was declared effective in March 2001, registering the sale of up to $400,000 of any combination of debt securities or common stock. 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 $382,500.

Stock Split – On July 15, 2004, our Board of Directors approved a five-for-four stock split in the form of a 25% dividend paid in common stock on August 24, 2004, to shareholders of record on August 10, 2004. To reflect the stock split, common stock was increased and capital in excess of par value was decreased by $5,006.

Diagnostics Warrants – As of December 31, 2004, 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 (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, 2004, options for 2,090 shares of common stock were outstanding under these plans and as of December 31, 2003, options for 1,918 shares of common stock were outstanding.

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, 2004, we held approximately 20,000 shares of the total 27,020 IVAX Diagnostics common shares outstanding, or 74% ownership.

Table of Contents

Convertible Debt – See Note 7, Debt, for comments regarding convertible senior subordinated notes.

Dividends – We did not pay dividends during the years ended December 31, 2004, 2003 and 2002.

**(12) 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*, and EITF No. 04-10, *Determining Whether to Aggregate Operating Segments That Do Not Meet the Quantitative Thresholds,* 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.

Table of Contents

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

| | North America | Europe | Latin America | Corporate and Other | Total IVAX |
|---|---|---|---|---|---|
| **2004** | | | | | |
| External net sales | $850,839 | $551,697 | $312,900 | $ 53,137 | $1,768,573 |
| Intersegment sales | 4,667 | 86,805 | — | (91,472) | — |
| Other revenues | 4,164 | 65,540 | 2,914 | (3,773) | 68,845 |
| Net revenues | 859,670 | 704,042 | 315,814 | (42,108) | 1,837,418 |
| Asset impairment and restructuring | — | 1,119 | 392 | (137) | 1,374 |
| Operating income (loss) | 140,245 | 76,572 | 65,214 | (30,164) | 251,867 |
| Interest income | 3 | 1,238 | 1,259 | 3,045 | 5,545 |
| Interest expense | (182) | (1,762) | (1,194) | (38,286) | (41,424) |
| Other income (expense), net | 6,904 | (3,432) | 533 | 657 | 4,662 |
| Equity earnings of affiliates | — | 738 | (10) | 446 | 1,174 |
| Tax provision (benefit) | 52,028 | 9,746 | (12,540) | (25,477) | 23,757 |
| Income (loss) from continuing operations before minority interest | 94,942 | 63,608 | 78,342 | (38,825) | 198,067 |
| **2003** | | | | | |
| External net sales | $625,523 | $440,259 | $251,067 | $ 52,053 | $1,368,902 |
| Intersegment sales | 2,289 | 66,645 | — | (68,934) | — |
| 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), net | 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 |
| **2002** | | | | | |
| External net sales | $476,085 | $371,987 | $227,933 | $ 44,713 | $1,120,718 |
| Intersegment 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), net | 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 (loss) from continuing operations before minority interest | 84,511 | 21,376 | 27,199 | (15,329) | 117,757 |

Table of Contents

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 |
|---|---|---|---|---|---|
| 2004 | $352,529 | $678,546 | $522,195 | $117,605 | $1,670,875 |
| 2003 | 339,353 | 432,668 | 466,329 | 126,884 | 1,365,234 |
| 2002 | 310,422 | 306,361 | 423,576 | 108,589 | 1,148,948 |

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:

| | Additions to Long-Lived Assets | | | Depreciation/Amortization | | |
|---|---|---|---|---|---|---|
| Region | 2004 | 2003 | 2002 | 2004 | 2003 | 2002 |
| North America | $ 41,383 | $ 37,914 | $116,900 | $30,459 | $28,416 | $21,845 |
| Europe | 179,985 | 124,442 | 68,784 | 38,929 | 36,948 | 26,252 |
| Latin America | 41,656 | 8,466 | 14,996 | 9,036 | 7,896 | 7,711 |

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, Chile and Poland. 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:

| | | United States | United Kingdom | Chile | Poland | Other | Total |
|---|---|---|---|---|---|---|---|
| **Geographic Areas:** | | | | | | | |
| Net revenues | 2004 | $906,814 | $290,636 | $ 89,965 | $ 21,847 | $528,156 | $1,837,418 |
| | 2003 | 700,283 | 232,517 | 75,560 | 1,837 | 410,142 | 1,420,339 |
| | 2002 | 570,676 | 218,097 | 81,630 | 1,475 | 325,366 | 1,197,244 |
| Long-lived assets | 2004 | $468,712 | $238,914 | $280,215 | $218,422 | $464,612 | $1,670,875 |
| | 2003 | 465,956 | 226,466 | 265,069 | 375 | 407,368 | 1,365,234 |
| | 2002 | 417,696 | 192,729 | 220,080 | 326 | 318,117 | 1,148,948 |

Table of Contents

**Net Revenues by Therapeutic Category and Product Type:**

| | Net Revenues | | |
|---|---|---|---|
| | 2004 | 2003 | 2002 |
| Therapeutic category: | | | |
| Respiratory | | | |
| Proprietary and branded | $ 236,090 | $ 194,483 | $ 154,610 |
| Generic pharmaceutical | 135,396 | 121,551 | 97,321 |
| Total Respiratory | 371,486 | 316,034 | 251,931 |
| Other | | | |
| Proprietary and branded | 384,313 | 345,024 | 375,997 |
| Generic pharmaceutical | 1,081,619 | 759,281 | 569,316 |
| Total Other | 1,465,932 | 1,104,305 | 945,313 |
| Total product type: | | | |
| Proprietary and branded | 620,403 | 539,507 | 530,607 |
| Generic pharmaceutical | 1,217,015 | 880,832 | 666,637 |
| Total | $1,837,418 | $1,420,339 | $1,197,244 |

No single customer accounted for 10% or more of our consolidated net revenues for any of the three years ended December 31, 2004. Other revenues included in net revenues in the accompanying consolidated statements of operations consist of license fees, royalties, and development service fees and milestones.

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 |
| Acquisitions | — | 153,925 | 14,196 | — | 168,121 |
| Foreign exchange and other | — | 13,677 | 11,365 | (50) | 24,992 |
| December 31, 2004 | $ 1,472 | $249,455 | $ 384,557 | $ 47,294 | $ 682,778 |

Table of Contents

**(13) 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 $10,144 in 2004, $8,039 in 2003 and $7,755 in 2002. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2004 and 2003, were not material. Certain of our leases contain escalation clauses and renewal options. The future minimum lease payments under non-cancelable operating leases with initial or remaining terms of one year or more at December 31, 2004, were as follows:

| | |
|---|---|
| 2005 | $10,122 |
| 2006 | 8,258 |
| 2007 | 7,105 |
| 2008 | 6,076 |
| 2009 | 5,169 |
| Thereafter | 6,456 |
| Total minimum lease payments | $43,186 |

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 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 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. 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. On September 15, 2003, the United States Court of Appeals for the Eleventh Circuit reversed the order. On September 20, 2001, the District Court entered an order certifying the direct purchaser class and in early 2002, IPI entered into a settlement with the direct purchaser class. In November 2003, the appellate court also issued a ruling de-certifying the class. On remand and following class discovery, the District Court entered an order on June 23, 2004, denying the Direct Purchaser Plaintiffs' renewed motion for class certification. In light of these orders, on August 31, 2004, we elected to terminate the Settlement Agreement with the direct purchasers and requested the return of the settlement payment less

Table of Contents

notice and Settlement Fund administrative fees. On February 16, 2005, IPI announced to the Court its willingness to re-enter into the settlement with the direct purchasers on substantially the same terms as the previous settlement, provided that the court certifies a settlement class of direct purchasers that is not materially different from the previously de-certified direct purchaser class. On February 25, 2005, the Court indicated its preliminary approval of a settlement containing these terms and provisions, and has scheduled a hearing for April 15, 2005 to determine whether to grant final approval of this settlement. To date, sixteen 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 5,546 cases and has been dismissed from approximately 5,184 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. As of September 1, 2004, claims made against us for the first time may not be afforded insurance 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

A number of counties in the State of New York and the City of New York City have filed complaints against IVAX and IPI and other pharmaceutical companies alleging a scheme to overcharge for prescription drugs paid for by Medicaid, a portion of which is paid for by these New York municipalities. IVAX and IPI have been named as defendants in actions filed by the County of Suffolk, the County of Westchester, the County of Nassau, the County of Onondaga, and the City of New York and in each of these cases, the plaintiff seeks the recovery of unspecified damages, including restitution, treble and punitive damages, civil penalties, interest and attorneys fees. Each of these actions was filed in the United States District Court for the applicable district in New York and, thereafter, was either transferred to the United States District Court for the District of Massachusetts as part of the Pharmaceutical Industry Average Wholesale Price Multi-District Litigation, MDL 1456 (MDL), or is in the process of being transferred to the MDL. The County of Suffolk vs. Abbott Laboratories, Inc. et al. action (Suffolk Action) has been treated as the lead case. In the Suffolk Action the court dismissed IVAX and IPI from the complaint by order dated October 26, 2004. Notwithstanding this dismissal, the County of Suffolk has indicated an intent to file an amended complaint naming IVAX and IPI as defendants. By stipulation of the parties, the remaining New York City and New York county actions are being held in abeyance pending a final ruling on the motions to dismiss the Suffolk Action. We intend to vigorously defend ourselves in these actions.

IVAX and IPI were named as defendants, along with other generic drug manufacturers, in The Commonwealth of Massachusetts vs. Mylan Laboratories, et al., filed in the United States District Court for the District of Massachusetts (Massachusetts Action). The Massachusetts Action alleges that through

Table of Contents

fraudulent and deceptive schemes thirteen manufacturers of generic pharmaceuticals caused Massachusetts to overpay pharmacies by inflating the wholesale acquisition cost of drugs. The state seeks unspecified damages, including injunctive relief, restitution, treble damages, civil penalties, interest, attorney fees and investigation and litigation costs. The case is pending before the same judge that is handling the MDL. The defendants in the Massachusetts Action moved to dismiss the complaint and by order dated February 4, 2005, the Court denied the motion in part, granted the motion in part, and deferred ruling in part. An additional ruling on the motion is expected. We intend to vigorously defend ourselves in this action.

A number of states have filed actions against IVAX and IPI and other pharmaceutical companies alleging schemes to overcharge for prescription drugs paid for by Medicaid. IVAX and IPI have been named as defendants in the following actions filed by the State of Wisconsin, the Commonwealth of Kentucky, the State of Alabama, and the State of Illinois. IVAX and IPI were added as defendants in State of Wisconsin vs. Abbott Laboratories, Inc., et al., Circuit Court of Dane County, Case No. 04 CV 1709 on November 1, 2004. IVAX and IPI were named as defendants in Commonwealth of Kentucky vs. Alpharma, Inc., Franklin Circuit Court, Case No. 04-CI-1487 on November 4, 2004. IVAX and IPI were named as defendants in State of Alabama vs. Abbott Laboratories, Inc., et al., Circuit Court of Montgomery County, Case No. CV-2005-219 on January 26, 2005. IVAX and IPI were named as defendants in The people of the State of Illinois vs. Abbott Laboratories, Inc., Circuit Court of Cook County, Case No. 05CH02474 on February 7, 2005. In each of these actions, the States seek unspecified damages, including treble and punitive damages, interest, civil penalties and attorneys fees. We intend to vigorously defend ourselves in these actions.

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 AWP. IPI has also received correspondence from the States of Nevada, Kentucky, Florida, and Illinois, on behalf of itself and eight 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. 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. On July 20, 2004, the OAG for the State of Florida issued subpoenas to IPI and five other pharmaceutical companies requesting materials to assist in its 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, the Serious Fraud Office expects to conclude its investigation and anticipates bringing charges by October 2005. There is no indication at this time regarding which companies may be charged.

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

Table of Contents

approximate aggregate amount of 27,527 Pounds Sterling (approximately $52,800 at the December 31, 2004, 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 31,438 Pounds Sterling (approximately $60,301 at the December 31, 2004, currency exchange rate), plus interest and costs.

In July 2004, 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 ranitidine in the United Kingdom between 1996 and 2000. This claim seeks damages against all defendants in the approximate amount of 69,252 Pounds Sterling (approximately $132,832 at the December 31, 2004, currency exchange rate), plus interest and costs.

Commercial Matters

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 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 the 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 filed a motion to dismiss the action in its entirety. On January 4, 2005, the District Court entered an order dismissing the Second Amended Complaint with prejudice and entered judgment in favor of all the named defendants. It is unclear whether the plaintiff intends to appeal this decision.

Patent Litigation

IPI filed ANDA's under paragraph IV of Hatch-Waxman Act to market and sell various strengths of generic gabapentin capsules and tablets, a product marketed by Warner-Lambert under the trademark Neurontin®. As a result of the filing of these ANDAs, Warner Lambert Company, Pfizer and Godecke Aktiengesellschaft filed three separate suits against us and our affiliates for patent infringement. These three consolidated actions are now pending in the United States District Court for the District of New Jersey. Civil Action No. 00-6073 was filed December 14, 2000, Civil Action No. 01-0193 was filed January 12, 2001 and Civil Action No. 01-1537 was filed February 3, 2001. The three suits have been consolidated in a multidistrict litigation in the District of New Jersey with several other cases brought by plaintiffs against other companies seeking to market generic gabapentin. We, along with the other defendants in the consolidated actions, moved for summary judgment of non-infringement and invalidity of Warner-Lambert's patents on various grounds. Oral argument on these motions were held in November 2004. In August 2004, based on our decision to begin commercial sales of non-AB-rated gabapentin tablets, Warner-Lambert sought a temporary restraining order and a preliminary injunction in an effort to prevent us from doing so. Warner-Lambert's request was denied, and we commenced commercial sale of our non-AB-rated gabapentin tablets on August 18, 2004. We also intend

Table of Contents

to commence commercial sales of the AB-rated gabapentin capsules and tablets shortly prior to the expiration of applicable Hatch-Waxman exclusivity periods as a result of a settlement reached with the generic manufacturer awarded the exclusivity by the FDA. While we expect to be successful in our defense, in the event the court determines that we infringed a valid patent of Warner-Lambert's in our sales of gabapentin, it will result in an injunction against us preventing further sales and substantial damages which could exceed our profit or selling price for these products.

Environmental Matters

On July 16, 2003, API Industries, Inc. (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 API purchase agreement, 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. On April 27, 2004, the EPA requested API to further address certain groundwater contaminant issues, including monitoring and sampling, relating to the presence of IPE in its facility. On June 14, 2004, API responded to the EPA's April 27, 2004, letter and submitted a revised SWMU Plan. On November 8, 2004, API received the EPA's approval of the SWMU Plan Revision 3.0 dated November 2, 2004. API will now engage in the necessary efforts to conduct the actions delineated in the referenced approved plan.

On November 3, 2004, API received a Notice of Deficiency whereby the EPA states that it is the agency's position that one of the incinerators at the company's plant must be decontaminated and closed pursuant to 40 CFR § 264.351. EPA bases its position on the company's failure to present a Notice of Intent to Comply (NIC) with MACT for such incinerator (due in 1999). API agreed to submit a revised Closure Plan for EPA's review and approval and a revised RCRA Part B application reflecting this closure was filed on February 15, 2005. At this time we are waiting for the agency's response.

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.

Table of Contents

**(14) Quarterly Financial Information (Unaudited):**

The following tables summarize selected quarterly data of IVAX for the years ended December 31, 2004 and 2003:

| | First Quarter | Second Quarter (1) | Third Quarter (2) | Fourth Quarter (3) | Full Year |
|---|---|---|---|---|---|
| **2004** | | | | | |
| Net revenues | $425,191 | $ 463,962 | $ 439,086 | $ 509,179 | $1,837,418 |
| Gross profit | 199,406 | 224,554 | 190,556 | 237,777 | 852,293 |
| Income from continuing operations | 42,341 | 48,098 | 44,378 | 63,210 | 198,027 |
| Net income | 42,341 | 48,098 | 44,378 | 63,210 | 198,027 |
| Basic earnings per common share: | | | | | |
| Continuing operations | 0.17 | 0.19 | 0.18 | 0.25 | 0.79 |
| Net earnings | 0.17 | 0.19 | 0.18 | 0.25 | 0.79 |
| Diluted earnings per common share: | | | | | |
| Continuing operations (4) | 0.16 | 0.18 | 0.17 | 0.24 | 0.75 |
| Net earnings (4) | 0.16 | 0.18 | 0.17 | 0.24 | 0.75 |
| **2003** | | | | | |
| 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 | 0.12 | 0.08 | 0.09 | 0.12 | 0.41 |
| Discontinued operations | — | 0.09 | — | — | 0.09 |
| Net earnings | 0.12 | 0.17 | 0.09 | 0.12 | 0.50 |
| Diluted earnings per common share: | | | | | |
| Continuing operations | 0.12 | 0.08 | 0.09 | 0.12 | 0.40 |
| Discontinued operations | — | 0.09 | — | — | 0.09 |
| Net earnings | 0.12 | 0.17 | 0.09 | 0.12 | 0.49 |

(1) Our net revenues and gross profit benefited by approximately $6,700, $4,254 net of tax, during the second quarter of 2004, due to positive resolution of potential service level claims. The potential service level claims related to contractual penalties payable in the event we were unable to fulfill specific purchase orders within defined parameters. Service level penalty amounts were accrued based on our interpretation of the contracts and claims history. These amounts were reversed following a determination that the amounts were not owed based upon agreements with the customers. This change increased our diluted earnings per share by $0.02.

(2) Our net revenues and gross profit benefited by approximately $2,300, $1,461 net of tax, during the third quarter of 2004, due to the positive resolution of additional potential service level claims. The potential service level claims related to contractual penalties payable in the event we were unable to fulfill specific purchase orders within defined parameters. Service level penalty amounts were accrued based on our interpretation of the contracts and claims history. These amounts were reversed following a determination that the amounts were not owed based upon agreements with the customers. In addition, our tax provision and net income for the third quarter of 2004, benefited by net changes of $4,197 related to the merger of two of our Chilean subsidiaries and by $7,033 from the reversal of tax reserves, relating to prior years' tax issues, that on review were determined to no longer be necessary, partially offset by $2,828 of additional valuation allowance recorded against a deferred tax asset in Europe. The total impact of these changes increased net income by $9,863, or $0.04 per diluted share, for the three months ended September 30, 2004. During the three months ended September 30, 2003, as a result of an improvement in our return and customer inventory experience our estimates of returns and other allowances and inventory obsolescence decreased resulting in increased net revenues of $10,170, reduced cost of sales of $2,457, increased net income of $7,943 and increased diluted earnings per share by $0.03.

(3) During the fourth quarter of 2004, our estimates of the reserve for shelf-stock adjustments decreased compared to the third quarter of 2004, by $8,400 due to delayed competition for one product and by $3,000 due primarily to agreement with a customer during the fourth quarter of 2004 that no shelf stock adjustment was required for

Table of Contents

previously purchased product. In addition, our estimate of the tax benefit to be received from the merger of two of our Chilean subsidiaries decreased by $2,911 compared to the estimate as of September 30, 2004, due to revision of the estimated amounts at which various issues connected with the merger are expected to be settled. These changes during the fourth quarter did not impact the results for the year ended December 31, 2004. Also, our tax provision during the fourth quarter and year of 2004 benefited by the reversal of a $1,544 tax reserve relating to a prior year foreign exposure that was resolved during the fourth quarter of 2004. These changes increased our net revenues by $11,400, increased our tax provision by $5,471 and increased net income by $5,929, or $0.02 per diluted share, during the fourth quarter of 2004. During the fourth quarter of 2003, as a result of our recent return and customer inventory experience, doubtful accounts and analysis of 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 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.

(4) On September 30, 2004, the EITF reached a consensus on Issue No. 04-8, *The Effect of Contingently Convertible Debt on Diluted Earnings per Share,* concluding that contingently convertible debt instruments should be included in diluted earnings per share computations (if dilutive) regardless of whether the market price trigger (or other contingent feature) has been met. This consensus is effective for reporting periods ending after December 15, 2004, and requires prior period earnings per share amounts presented for comparative purposes to be restated utilizing a transition method. The transition method agreed upon by the EITF is a modified restatement approach that results in a company applying the consensus to the terms of the security at the adoption date. As such, if the terms of the security are changed prior to the adoption date, it is the changed terms to which the consensus is applied. We adopted the consensus in the fourth quarter of 2004. The impact of adoption has reduced our reported diluted earnings per share for each of the three month periods ended March 31, 2004, June 30, 2004, and December 31, 2004, by $0.01 per share and for the year ended December 31, 2004 by $0.03 per share and there was no impact on the prior years reported diluted earnings per share.

**(15) Related Party Transactions:**

Whitman Education Group, Inc. (Whitman) leased office space from us in Miami, Florida. Whitman leased approximately 11,567 square feet from January 1, 2004 through March 30, 2004 and 6,102 square feet from April 1, 2004 through June 15, 2004 at an annual adjusted rate of $173, 11,567 square feet during 2003 at an annual rate of $292 and 13,849 square feet during 2002 at an annual rate of $290. Whitman was acquired by an unaffiliated entity, Career Education Corporation on July 1, 2003. Following the acquisition, the lease was terminated and Whitman vacated the facility on June 15, 2004. The total rental income, including furniture received and termination payments, was $171 in 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 $2,436 in 2004, $2,504 in 2003 and $2,702 in 2002 to PharmAir Corporation for use of an airplane. PharmAir Corporation is indirectly, beneficially owned by our Chairman and Chief Executive Officer.

During 2004, a wholly-owned subsidiary of IVAX entered into a Promotion Agreement (Promotion Agreement) with Aero Pharmaceuticals, Inc. (Aero), pursuant to which certain sales representatives of Aero will promote designated products of IVAX. Under the terms of the agreement, we paid Aero a promotion fee of $683 for the year ended December 31, 2004. The Promotion Agreement has an 18-month term, subject to our right to terminate the Promotion Agreement on 30 days notice prior to each of April 8, 2005, October 8, 2005 and January 8, 2006. Mr. Richard Frost, the Chairman and a principal shareholder

Table of Contents

of Aero, is the nephew of Dr. Phillip Frost, Chairman and Chief Executive Officer of IVAX. Dr. Frost has no stock ownership or other financial interest in Aero.

**(16) Subsequent Events:**

On February 2, 2005, we completed the cash tender offer for an additional 24.89 shares of Polfa Kutno for approximately $2,744 increasing our ownership percentage to 99.25%.

During February 2005, a wholly-owned subsidiary of IVAX entered into two agreements with InnovaPharm, Inc. The first is a Services Agreement for Prescription Pharmaceutical Products (Prescription Agreement), pursuant to which InnovaPharm will provide services and perform certain regulatory functions in Canada with respect to certain designated products. Under the terms of the agreement, we will pay InnovaPharm a fee based on a percentage of net sales for these services. The term of the Prescription Agreement began upon execution of the agreement and continues through June 30, 2007 with automatic two-year renewals, subject to our right to terminate the Prescription Agreement on 120 days notice prior to each anniversary of the agreement's execution date. The second agreement is a Services Agreement for OTC Products (OTC Agreement), pursuant to which InnovaPharm will serve as an exclusive sales representative in Canada for the promotion of certain designated OTC products. Under the terms of the agreement, we will pay InnovaPharm a fee based on a percentage of net sales for these services. The OTC Agreement has a three-year term, with one-year renewals upon written consent of the parties. Mr. Tarik Henein, the President and a principal shareholder of InnovaPharm, is the son of Dr. Rafick Henein, President and Chief Executive Officer of IVAX Pharmaceuticals, Inc. Dr. Henein has no stock ownership or other financial interest in InnovaPharm.

On February 15, 2005, we entered into an agreement to acquire Phoenix Scientific, Inc. (Phoenix), a generic veterinary pharmaceutical manufacturing company. The closing of the acquisition transaction is subject to certain customary conditions including clearance under the Hart-Scott-Rodino Antitrust Improvement Act and is expected to occur during the second quarter of 2005. Under the terms of the agreement, we will pay a combination of $75,000 in common stock and $196,850 in cash. We plan to acquire Phoenix to expand our growth in our existing veterinary operations.

In response to the adoption of the EITF consensus discussed above under Recently Issued Accounting Standards, on February 23, 2005, we completed an exchange offer pursuant to which we offered to exchange each $1,000 principal amount of our (Old 1.5% Notes) that was validly tendered and accepted for exchange for $1,000 principal amount of our New 1.5% Notes; and a one-time cash payment equal to $2.50 per $1,000 principal amount of such Old 1.5% Notes validly tendered and accepted for exchange. The New 1.5% Notes are substantially identical to the Old 1.5% Notes except that the New 1.5% Notes contain a "net share settlement" feature under which we committed to pay up to the principal amount of the New 1.5% Notes in cash upon conversion. By committing to pay up to the principal amount of the New 1.5% Notes in cash upon conversion, we believe we will be able to account for the New 1.5% Notes under the "treasury stock" method, which is generally expected to be less dilutive to earnings per share than the "if-converted" method prescribed by EITF Issue No. 04-8. The "treasury stock" method only requires inclusion of the shares to be delivered upon conversion if our common stock is trading at a price in excess of the conversion price based on the average trading price during the preceding quarter and then only to the extent the conversion value is greater than the principal amount of the New 1.5% Notes. We generally expect that since fewer shares will be included in the number of fully diluted shares outstanding under the New 1.5% Notes based on this calculation than would be included for the Old 1.5% Notes under the "if-converted" method when dilutive, our diluted earnings per share will be greater. We accepted for exchange $399,000 of our Old 1.5% Notes for exchange in the exchange offer and, as a result only $1,000 principal amount of the Old 1.5% Notes currently remain outstanding.

Table of Contents

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of IVAX Corporation

We have audited the consolidated financial statements of IVAX Corporation as of December 31, 2004 and 2003, and for each of the three years in the period ended December 31, 2004, and have issued our report thereon dated March 9, 2005. Our audits also included Schedule II—Valuation and Qualifying Accounts for each of the three years in the period ended December 31, 2004, 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.

In our opinion, the financial statement schedule as of December 31, 2004 and 2003, and for each of the three years in the period ended December 31, 2004, 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
Certified Public Accountants

Miami, Florida
March 9, 2005

Table of Contents

SCHEDULE II

**IVAX CORPORATION AND SUBSIDIARIES**
**VALUATION AND QUALIFYING ACCOUNTS**
**THREE YEARS ENDED DECEMBER 31, 2004**
(in thousands)

ALLOWANCE FOR DOUBTFUL ACCOUNTS

| Description | Balance at Beginning of Year | Charged to Cost and Expenses | Net Deductions | Other | Balance at End of Year |
|---|---|---|---|---|---|
| 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 |
| Year ended December 31, 2004 | $ 17,675 | 2,627 | (4,744) | 3,654 | $ 19,212 |

INVENTORY RESERVES

| Description | Balance at Beginning of Year | Charged to Cost and Expenses | Net Deductions | Other | Balance at End of Year |
|---|---|---|---|---|---|
| Year ended December 31, 2002 | $ 5,494 | 1,873 | (325) | 770 | $ 7,812 |
| Year ended December 31, 2003 | $ 7,812 | 2,948 | (468) | 1,469 | $ 11,761 |
| Year ended December 31, 2004 | $ 11,761 | 506 | (789) | 92 | $ 11,570 |

ENVIRONMENTAL ACCRUALS

| Description | Balance at Beginning of Year | Charged to Cost and Expenses | Net Deductions | Other | Balance at End of Year |
|---|---|---|---|---|---|
| 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 |
| Year ended December 31, 2004 | $ 1,178 | 2,599 | (1,119) | — | $ 2,658 |

Table of Contents

## EXHIBIT INDEX

| EXHIBIT NUMBER | DESCRIPTION OF DOCUMENT |
|---|---|
| 3.1 | Restated Articles of Incorporation. |
| 10.14 | Warrant to Purchase Shares of Common Stock of IVAX Corporation dated November 29, 2002 between IVAX Corporation and Frost Gamma Limited Partnership. |
| 21 | Subsidiaries of IVAX Corporation. |
| 23.1 | Consent of Independent Registered Public Accounting Firm. |
| 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. |