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 **IMPAX**  
LABORATORIES, INC.



## 2003 Milestones

### Quarter 1

- Final FDA approval for Loratadine/Pseudoephedrine sulfate, 5mg/120mg Extended Release Tablets (generic of Claritin® -D 12 Hour)
- Final FDA approval for Riluzole 50mg Tablets (generic of Rilutek®)
- Favorable patent ruling in district court for IMPAX's Fenofibrate Capsules, Micronized (generic of Tricor® Capsules)
- Record revenues of \$11,425,000, up more than 232% over 2002

### Quarter 2

- Merck & Co. withdrew patent infringement lawsuit related to IMPAX's Carbidopa and Levodopa Extended release Tablets (generic of Sinemet® CR)
- Final FDA approval for Pyridostigmine Bromide 60 mg Tablets (generic of Mestinon®)
- FDA accepted ANDA for Bupropion Hydrochloride 200 mg Tablets (generic of Wellbutrin SR®)
- Completed \$25 million private placement
- Record revenues of \$14,067,000, up more than 173% over 2002

### Quarter 3

- Strategic agreement entered into with Andrx and Teva related to Bupropion HCl 100mg and 150mg Extended Release Tablets
- Favorable ruling received from Court of Appeals for the Federal Circuit upholding lower court decision in patent litigation relating to IMPAX's Loratadine products (generics of Claritin® Reditab, Claritin D 12 and Claritin D 24)
- Patent # 6,602,521 issued by US Patent and Trademark Office for our Multiplex Drug Delivery Systems (MDDS)
- Final ANDA approval for:
  - Flavoxate Hydrochloride 100 mg tablets (generic of Urispas®)
  - Chloroquine Phosphate (generic of Aralen®)
  - Loratadine Orally Disintegrating Tablets 10 mg (generic of Claritin Reditabs)
- Tentative ANDA approval for Oxycodone Hydrochloride Controlled Release Tablets, 80 mg (generic of Oxycontin®)
- FDA accepted ANDA filing for Oxybutynin Chloride Tablets, 15 mg (generic of Ditropan® XL)
- Record revenues of \$16,497,000, up more than 119% over 2002

#### Quarter 4

- Settlement and license agreement entered into with Schering-Plough related to IMPAX's generic version of Claritin-D 24-Hour Tablets resolving all outstanding patent litigation
- Final ANDA approval for Fenofibrate Capsules, Micronized (generic of Tricor Capsules)
- Tentative ANDA approval for Oxycodone Hydrochloride Controlled Release Tablets, 10, 20 and 40 mg (generic of OxyContin)
- FDA accepted ANDA filing for Mixed Amphetamine Salts 30 mg Capsules (generic of Adderall® XR)
- IMPAX stock added to the NASDAQ Biotechnology Index® (NASDAQ: NBI)
- Record revenues of \$16,829,000, up more than 100% over 2002

## Year 2003

- **Nine ANDA approvals received, 7 final, 2 tentative**
- **Eight new applications filed with the FDA, including two INDs**
- **\$58,818,000 in revenues, up more than 139% over 2002**

# Shareholder's Letter



Fellow shareholders, employees and friends:

It is with great pleasure that we report on the ongoing progress and recent accomplishments at our company. We achieved much during 2003, and 2004 is already off to a rousing start. Behind this success are our talented and dedicated employees driven by a highly focused business strategy.

Our three-pronged strategy calls for the use of our oral drug delivery technologies and formulation expertise to develop generic controlled-release pharmaceuticals. The next prong deals with development of specialty generic products that have one or more barriers to entry. The third prong calls for us to apply our formulation and development expertise to known molecules to develop branded pharmaceuticals that offer benefits over existing products, primarily targeting treatments of central nervous system disorders. Our pipeline of products under development, numerous filings with the U.S. Food and Drug Administration (FDA) and growing number of commercial products provide confirmation of our strategy.

Already in 2004, we have received news from the FDA of final approval of our ANDA for a generic version of Claritin®-D 24-Hour (Loratadine and Pseudoephedrine Sulfate, 10mg/240mg) Extended Release Tablets; and tentative approvals of our ANDAs for Fenofibrate Tablets, generic for Tricor® and Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride 60mg/120mg Extended Release Tablets, generic for Allegra®-D. Also, FDA has approved our Abbreviated New Drug Application (ANDA) for Bupropion Hydrochloride, 100 mg, (generic of Wellbutrin® SR) and granted tentative approval of the 150 mg strength. Following on the heels of that news, we received a decision from the Court of Appeals for the Federal Circuit upholding the lower court's decision that our formulation of Bupropion Extended Release Tablets did not infringe GSK's patents.

In an attempt to bring these products to the market more quickly, last summer we entered into an Exclusivity Transfer Agreement with Andrx Corporation and a subsidiary of Teva Pharmaceutical Industries Ltd. relating to these products. Pursuant to the 12 product Strategic Alliance Agreement entered into in 2001 with Teva, they have U.S. marketing rights to our versions of these products. At this writing, we are working closely with our partners to launch these products.

While clearly these recent events are very exciting, 2003 was an excellent year for our development program. Our goal for 2003 was to file at least six applications with the FDA. We were able to file eight — matching our filing rate for the prior three years. During the year we received nine ANDA approvals, our highest ever. These included four final ANDA approvals for specialty generic drugs where we believe there could be limited competition, three ANDA approvals for Paragraph IV filings as well as tentative approval for two ANDA filings. On March 5, 2004, we had 19 applications pending at the FDA, including six tentatively approved, which addressed approximately \$6.8 billion in U.S. branded product sales.

During 2003, we also made great progress with the third prong of our strategy, our branded product development program. We now have filed two Investigational New Drug (IND) applications with the FDA for neurology products. Our plans eventually call for us to develop our own sales force to market our branded products, with a focus on neurologists.

Our increase in revenues reflects the progress we have made in moving our pipeline through development, legal and regulatory channels and into the market. Total revenues for 2003 were \$58.8 million, up more than 139% over 2002.

We continue to see progress in moving our development projects through the various processes and reviews necessary to bring them to the market. We look forward to success in 2004 and beyond.

Sincerely,

A handwritten signature in black ink that reads 'Charles Hsiao'.

Charles Hsiao, Ph.D.  
Chairman

A handwritten signature in black ink that reads 'Barry R. Edwards'.

Barry R. Edwards  
Chief Executive Officer

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

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**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2003**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 33-99310-NY**

**IMPAX LABORATORIES, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**65-0403311**  
(IRS Employer  
Identification No.)

**30831 Huntwood Avenue**  
**Hayward, CA**  
(Address of principal executive offices)

**94544**  
(Zip Code)

**(510) 476-2000**  
(Registrant's telephone number, including area code)

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

**Securities registered pursuant to Section 12(g) of the Act:**  
**Common Stock, \$0.01 par value per share**

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 registrant is an accelerated filer (as defined in Rule 12b-2 of the Act.) Yes  No

As of June 30, 2003, the aggregate market value of the Common Stock held by non-affiliates of the registrant (based on the closing price for the Common Stock on the Nasdaq Stock Market on June 30, 2003) was approximately \$382,664,594.<sup>(1)</sup> As of February 27, 2004, there were 57,932,707 shares of the registrant's Common Stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

The information called for by Part III is incorporated by reference to specified portions of the Registrant's definitive Proxy Statement to be issued in conjunction with the Registrant's 2004 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the Registrant's fiscal year ended December 31, 2003.

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<sup>(1)</sup>The aggregate market value of the voting stock set forth equals the number of shares of the Company's common stock outstanding reduced by the amount of common stock held by officers, directors and shareholders owning 10% or more of the Company's common stock, multiplied by \$11.94 the last reported sale price for the Company's common stock on June 30, 2003, the last business day of the registrant's most recently completed second fiscal quarter. The information provided shall in no way be construed as an admission that any officer, director or 10% shareholder in the Company may be deemed an affiliate of the Company or that he is the beneficial owner of the shares reported as being held by him, and any such inference is hereby disclaimed. The information provided herein is included solely for record keeping purposes of the Securities and Exchange Commission.

# IMPAX LABORATORIES, INC.

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# PART I

## Forward-Looking Statements

To the extent any statements made in this report contain information that is not historical, these statements are forward-looking in nature and express the beliefs, expectations or opinions of management. For example, words such as “may,” “will,” “should,” “estimates,” “predicts” “potential,” “continue,” “strategy,” “believes,” “anticipates,” “plans,” “expects,” “intends,” and similar expressions are intended to identify forward-looking statements. Such statements are based on current expectations and involve a number of known and unknown risks and uncertainties that could cause IMPAX’s future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Such risks and uncertainties include, but are not limited to, IMPAX’s ability to obtain sufficient capital to fund its operations, the difficulty of predicting Food and Drug Administration (“FDA”) filings and approvals, consumer acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, IMPAX’s ability to successfully develop and commercialize pharmaceutical products, IMPAX’s reliance on key strategic alliances, the uncertainty of patent litigation, the availability of raw materials, the regulatory environment, dependence on patent and other protection for innovative products, exposure to product liability claims, fluctuations in operating results and other risks detailed from time to time in IMPAX’s filings with the Securities and Exchange Commission. Forward-looking statements speak only as to the date on which they are made, and IMPAX undertakes no obligation to update publicly or revise any forward-looking statement, regardless of whether new information becomes available, future developments occur or otherwise.

## ITEM 1. BUSINESS

### Introduction

Impax Laboratories, Inc. (“we,” “us,” “our,” “the Company” or “IMPAX”) is a technology based, specialty pharmaceutical company focused on the development and commercialization of generic and brand name pharmaceuticals, utilizing our controlled-release and other in-house development and formulation expertise. In the generic pharmaceuticals market, we focus our efforts on controlled-release generic versions of selected brand name pharmaceuticals across a broad range of therapeutic areas. We are also developing specialty generic pharmaceuticals which we believe present one or more competitive barriers to entry, such as difficulty in raw materials sourcing, complex formulation or development characteristics, or special handling requirements. In the brand name pharmaceuticals market, we are developing products for the treatment of central nervous system, or CNS disorders. Our initial brand name product portfolio consists of development-stage projects to which we are applying our formulation and development expertise to develop differentiated, modified, or controlled-release versions of currently marketed drug substances. We intend to expand our brand name products portfolio primarily through internal development and, in addition, through licensing and acquisition.

IMPAX markets its prescription products through its Global Pharmaceuticals division and intends to market its branded products through its Impax Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed and may develop additional marketing partnerships to fully leverage its technology platform. Prior to December 14, 1999, the Company was known as Global Pharmaceutical Corporation (“Global”). On December 14, 1999, Impax Pharmaceuticals, Inc., a privately held drug delivery company, was merged into the Company and the Company changed its name to Impax Laboratories, Inc. For accounting purposes, however, the acquisition has been treated as the recapitalization of Impax Pharmaceuticals, Inc., with Impax Pharmaceuticals, Inc. deemed the acquirer of Global in a reverse acquisition.

IMPAX is a Delaware corporation with corporate headquarters located at 30831 Huntwood Avenue, Hayward, California. In addition, the Company maintains six other properties in Pennsylvania and California. For further details, see “Item 2. Properties.”

IMPAX, the Impax logo, the Global logo, METHITEST, and LIPRAM are trademarks of IMPAX. All other trademarks used or referred to in this report are the property of their respective owners. The following table includes the various trademarks used in this report and, to our knowledge, the owner of each trademark.

TRADEMARK	OWNER
Adderall® XR	Shire Pharmaceuticals Group PLC
Allegra-D®	Aventis S.A.
Alavert™	Wyeth Consumer Products
Aralen®	Sanofi Winthrop Pharmaceutical

TRADEMARK	OWNER
Betapace®	Berlex Laboratories
Brethine®	aaPharma
Claritin-D®	Schering-Plough Corp.
Claritin® Reditabs®	Schering-Plough Corp.
Creon®	Solvay Pharmaceuticals
Ditropan XL®	Alza Corporation
Dynacin®	Medicis
Flumadine®	Forest Laboratories, Inc.
Florinef®	King Pharmaceuticals
Mestinon®	ICN Pharmaceuticals
Minocin®	Wyeth Consumer Products
Nexium®	AstraZeneca PLC
Norflex®	3M Pharmaceuticals
OxyContin®	Purdue Pharma L.P.
Pancrease®	McNeil Laboratories
Prilosec®	AstraZeneca PLC
Rilutek®	Aventis S.A.
Sinemet®	Merck & Co.
Triaminic® AllerChews™	Novartis
Tricor®	Abbott Laboratories
Ultrase®	Axcan Scandipharm
Urispas®	Ortho-McNeil Pharmaceutical, Inc.
Wellbutrin® and Wellbutrin SR®	GlaxoSmithKline
Zyban®	GlaxoSmithKline

Unless otherwise indicated, all of the sales data in this report is based on information obtained from NDCHealth Corporation (“NDCHealth”) regarding U.S. sales, all channels for the twelve months ended December 31, 2003.

As of March 5, 2004, we had 60 generic products approved or pending approval by the U.S. Food and Drug Administration (FDA), or under development, targeting over \$23.0 billion in U.S. yearly product sales. The following summarizes our product development activities:

- 17 abbreviated new drug applications (which we refer to as ANDAs) approved by the FDA, which include generic versions of brand name pharmaceuticals such as Brethine, Florinef, Minocin, Claritin-D 12-hour, Claritin-D 24-hour, Wellbutrin SR and Prilosec. All of our approved drugs in total target a market of over \$2.4 billion in U.S. yearly product sales.
- 19 applications pending at the FDA, including six tentatively approved, that address approximately \$6.8 billion in U.S. yearly product sales. Fourteen of these filings were made under Paragraph IV of the Hatch-Waxman Amendments, including generic versions of OxyContin, Allegra D and Tricor, among others.
- 24 other products in various stages of development for which applications have not yet been filed. These products are for generic versions of brand name pharmaceuticals that had U.S. yearly product sales of approximately \$13.8 billion.

### Growth Strategy

We expect our future growth to come from the following:

- Aggressively File ANDAs We intend to continue to develop our portfolio of generic pharmaceuticals through the filing of ANDAs. Our product development strategy is based on a combination of speed to filing and a legal

strategy primarily predicated upon non-infringement of established brand name pharmaceuticals. In selecting our product candidates, we focus on pharmaceuticals that we believe will have potential for high sales volume, limited competition, or are technically challenging.

- Strategically Expand the Sales and Distribution of Our Products We entered into a strategic alliance with a subsidiary of Teva covering twelve of our controlled-release generic pharmaceutical products. Also, we entered into an Exclusivity Transfer Agreement with Andrx and a subsidiary of Teva pertaining to bioequivalent versions of Wellbutrin SR and Zyban. In addition, we have entered into agreements granting Novartis, Wyeth, and Schering-Plough marketing rights to market over-the-counter (referred to as OTC) versions of our generic Claritin (loratadine) products. We will depend on our strategic alliances with Teva, Andrx, Novartis, Wyeth, and Schering-Plough to achieve market penetration and generate revenues for those products covered by the alliances. We may seek additional strategic alliances with these and other partners for the expanded marketing and distribution of our products.
- Leverage Our Technology and Development Strengths We intend to continue to leverage our technology and development strengths, including our patented oral controlled-release drug delivery technologies. We have developed nine different proprietary controlled-release delivery technologies that can be utilized in a variety of oral dosage forms and drug release rates. We believe that these technologies are flexible and can be applied to a variety of pharmaceutical products, both generic and brand name.
- Continue to Develop Our Brand Name Products We are focusing our efforts on the development of products for the treatment of CNS disorders. Our strategy is to build this portfolio primarily through internal development, in-licensing, and acquisition. We intend to utilize our formulation and development expertise, as well as our drug delivery technologies, to develop differentiated, modified, or controlled-release variations of currently marketed drug substances that we will market as brand name products.

#### *Competitive Strengths*

- Product Pipeline. We have filed eight new applications in each of the last three calendar years and expect to submit at least six more this year. We have built a robust pipeline that, as of March 5, 2004, consists of 19 applications pending at the FDA and another 24 products in various stages of development.
- Controlled-Release Delivery Technology. By focusing on the development of commercial projects rather than purely on technology, we have developed a wide range of drug delivery technologies that we have applied to 16 projects either approved or pending approval by the FDA. We believe that we can use these technologies to improve the formulation of a number of existing immediate-release drugs.
- Ability to Gain FDA Approval. We have developed, filed and received final approvals from the FDA for seventeen ANDAs. We had a total of eight approvals in 2002 (including five tentative approvals) and nine approvals in 2003 (including two tentative approvals).
- Strategic Marketing Partners. Our over-the-counter, or OTC, marketing partners, Novartis, Wyeth and Schering-Plough, give us access to the OTC non-sedating antihistamine market for our generic loratadine products. Our marketing partner, Teva, provides us access to the market for our generic prescription products.

#### **Background**

##### ***Controlled-Release Technology***

According to NDCHealth, product sales for the oral controlled-release segment of the U.S. prescription drug market were approximately \$32.9 billion for the year ended December 31, 2003. Controlled-release pharmaceuticals are designed to reduce the frequency of drug administration, improve the effectiveness of the drug treatment, ensure greater patient compliance with the treatment regimen, and reduce side effects or increase drug stability by releasing drug dosages at specific times and in specific locations in the body.

Oral administration represents the most common form of drug delivery, owing to its convenience and ease of use. Many orally-administered immediate-release drug products deliver the majority of their drug components within one to three hours, requiring administration every four to six hours. As a result, patient non-compliance is a significant problem for many immediate-release drug products.

Oral controlled-release technology attempts to circumvent the need for multiple dosing by extending the release of the active drug so that the drug maintains its therapeutic usefulness over a longer period of time. The basic tenet of this technology is to envelop the active ingredient in a system that modulates release, thereby minimizing the peak-and-trough levels of the drug in the blood, typically seen with immediate-release formulations. Lowering the peak levels of drugs in the blood may reduce adverse side effects associated with certain drugs.

Controlled-release drug delivery technologies can also be effective product-life-cycle management tools. For example, as a product nears the end of its patent life, conversion to controlled-release dosing or a different route of administration could provide an extension to the patent or marketing exclusivity period. Many pharmaceutical and specialty pharmaceutical companies have successfully utilized controlled-release technology to develop product line extensions.

### ***Generic Pharmaceuticals Market***

In the last five years, generic pharmaceutical companies have enjoyed significant growth, due largely to a number of macroeconomic and legislative trends. Factors impacting growth in the generic pharmaceuticals market include, but are not limited to:

- **ANDA Approvals** – ANDA approvals have increased significantly in the last eight years. Since 1997, the FDA has approved approximately 309 ANDAs per year with 373 approved in 2003. During the last ten years, the median approval time for ANDAs has been reduced from approximately 24.2 months to approximately 17.3 months.
- **Payor Support for Generic Drugs** – Managed care organizations and government-sponsored health care programs are increasingly encouraging the use of generic drugs as a means to control health care costs. As a result, the market share of generic drugs as a percent of total U.S. prescription units dispensed has been increased since the passage of the Hatch-Waxman Amendments. According to the Generic Pharmaceutical Association, or GPhA, generics accounted for 51% of all prescriptions dispensed in 2002. This percentage has increased significantly since 1994 when approximately 36% of the prescriptions in the United States were filled with generics.
- **Significant Patent Expirations on Brand Name Products** – A significant number of brand name products with annual sales over \$100 million are expected to come off patent in the next few years. This represents significant opportunity for generic drug companies. The GPhA estimates that, over the next 3 years, \$35 billion of brand name drugs will lose patent protection and, by 2010, \$48 billion will lose this protection.

### **Technology**

We have developed nine different proprietary controlled-release delivery technologies that can be utilized with a variety of oral dosage forms and drugs. In addition, we have other non-proprietary drug delivery technologies that can also be utilized for a variety of commercial product opportunities. We believe that these technologies are flexible and can be applied to develop a variety of pharmaceutical products, both generic and branded.

Our product development strategy is centered on both proprietary and non-proprietary drug delivery technology and capabilities. We have developed several proprietary drug delivery technologies covering the formulation of dosage forms with controlled-release and multiple modes of release rates. We have obtained six U.S. patents, have filed 15 applications, and expect to file up to 8 additional U.S. patent applications and various foreign patent applications relating to our drug delivery technologies. We also have several other proprietary controlled-release technologies that are not patented or for which we have not filed a patent application, and are working to develop additional new technologies for which we may seek patent protection. Some of our proprietary technologies are described below.

Our drug delivery technologies utilize a variety of polymers and other materials to encapsulate or entrap the active drug compound and to release the drug at varying rates and/or at predetermined locations in the gastrointestinal tract. In developing an appropriate drug delivery technology for a particular drug candidate, we consider such factors as:

- desired release rate for the drug;
- physicochemical properties of the drug;
- physiology of the gastrointestinal tract and manner in which the drug will be absorbed during passage through the gastrointestinal tract;

- effect of food on the absorption rate and transit time of the drug; and
- in-vivo/in-vitro correlation.

The following summarizes some of our drug delivery technologies:

<u>Drug Delivery Technology</u>	<u>Description</u>
Concentric Multiple-Particulate Delivery System (CMDS)	Many of today’s controlled-release technologies are designed for the release of only one active ingredient with one rate of release. This release profile may not be adequate for drugs in certain therapeutic categories. Our CMDS technology is designed to control the release rate of multiple active ingredients in a multi-particulate dosage form. This technology allows us to overcome one of the technical challenges in the development of multi-particulate dosage forms – achieving acceptable uniformity and reproducibility of a product with a variety of active ingredients. Our CMDS technology is designed to allow for the release of each of the active ingredients through an encapsulated form at predetermined time intervals and desired levels on a consistent basis. The U.S. Patent and Trademark Office (“USPTO”) has granted us a patent for CMDS; U.S. Patent No. 5,885,616.
Timed Multiple-Action Delivery System (TMDS)	Similar to CMDS, this system controls release rates for multiple ingredients within a single tablet in a programmed manner. Our TMDS technology allows for the release of more than one active ingredient in a single tablet formulation to be released in multiple profiles over time. The USPTO has granted us a patent for TMDS; U.S. Patent No. 6,372,254.
Dividable Multiple-Action Delivery System (DMDS)	Our proprietary DMDS system is an extension of our CMDS and TMDS technologies. It is designed to provide greater dosing flexibility which improves product efficacy and reduces side effects. Traditional controlled-release tablets often lose their “controlled” mechanism of delivery once broken. Our DMDS technology allows the tablet to be broken in half so that each respective portion of the tablet will achieve exactly the same release profile as the whole tablet. This technology allows the patient and physician to adjust the dosing regimen according to the clinical needs without compromising efficacy. The USPTO has granted us a patent for DMDS; U.S. Patent No. 6,602,521.
Programmed Multiple-action Delivery System (PMDS)	Our PMDS technology is designed to provide for the multi-phasic delivery of any active ingredient in a more controlled fashion as compared to typical controlled release technologies. Our PMDS technology is designed to allow for the release of the active ingredient at predetermined time intervals and desired levels on a consistent basis. This technology allows us to overcome one of the technical challenges in the development of multi-particulate dosage forms – achieving acceptable uniformity and reproducibility of a product with a variety of release rates. It is designed to provide greater dosing flexibility that improves product efficacy and may reduce side effects. We have filed a patent application for PMDS with the USPTO.
Multi-Ingredient Multiple-Action Delivery System (MMDS)	Similar to PMDS, this system provides multi-phasic delivery of two or more different active ingredients within a single tablet. Our MMDS technology allows for the release of more than one active ingredient in a single tablet formulation to be released in multiple profiles over time in a more controlled fashion as compared to typical controlled release technologies. We expect to file a patent application for MMDS with

the USPTO.

Particle Dispersion Systems (PDS)

One of the challenges in the formulation of an insoluble drug is to achieve satisfactory bioavailability in humans. Our proprietary PDS system provides a drug delivery system for the oral administration of water insoluble inactive ingredients. The USPTO has granted us a patent for PDS: U.S. Patent No. 6,531,158.

Pharmaceutical Stabilization System (PSS)

Our PSS system is designed to create an acidic micro-environment for drugs which require an acidic environment to achieve optimal stability. We achieve this environment through the addition of an organic acid using several salts which retard the degradation of, and therefore stabilize, certain active ingredients. The USPTO has granted us a patent for PSS: U.S. Patent No. 6,333,332.

Rapid Dissolving Delivery System (RDDS)

With increasingly active lifestyles and an aging population, allowing patients to swallow a tablet without using water has gained popularity during the past decade. Our Rapid Dissolving Delivery System enables us to manufacture a rapid dissolving tablet and meet this growing patient need. We expect to file a patent application for RDDS with the USPTO.

Multiplex Drug Delivery System (MDDS)

A multiplex drug delivery system suitable for oral administration, containing at least two distinct drug dosage packages which exhibit equivalent dissolution profiles for an active agent when compared to one another and when compared to that of the entire multiplex drug delivery unit, and substantially enveloped by a scored film coating that allows the separation of the multiplex drug delivery system into individual drug dosage packages can provide a convenient and cost-effective drug delivery unit, particularly for patients with a regimen of prescribed dosages that varies during their treatment period. Patent for MDDS: U.S. Patent No. 6,602,521.

**Products and Product Development**

We currently market thirty-one generic pharmaceuticals that represent dosage variations of thirteen different pharmaceutical compounds. Our existing customer base includes large pharmaceutical wholesalers, warehousing chain drug stores, mass merchandisers, and mail-order pharmacies. We do not currently market any brand name pharmaceuticals.

As of March 5, 2004, we had nineteen applications pending at the Food and Drug Administration (“FDA”), including six tentatively approved, that address approximately \$6.8 billion in U.S. product sales for the twelve months ended December 31, 2003. Fourteen of these filings were made under Paragraph IV of the Hatch-Waxman Amendments. We have approximately twenty-four other products in various stages of development for which applications have not yet been filed. These products are for generic versions of brand name pharmaceuticals that had U.S. sales of approximately \$13.8 billion for the twelve months ended December 31, 2003.

The following table lists the nine ANDAs which the FDA approved during 2003 (U.S. market size in millions):

<u>PROJECT</u>	<u>TYPE</u>	<u>U.S. MARKET SIZE</u>
Riluzole Tablets	Specialty Generic	\$ 32
Pyridostigmine Bromide Tablets	Specialty Generic	\$ 17
Flavoxate Hydrochloride Tablets	Specialty Generic	\$ 7
Chloroquine Phosphate Tablets	Specialty Generic	\$ 3
Loratadine Orally Disintegrating Tablets	Specialty Generic	\$ 39
Fenofibrate Capsules	Specialty Generic	\$ 3

Loratadine and Pseudoephedrine Sulfate 5/ 120 mg 12-Hr Extended Release Tablets	Controlled-Release Generic	\$ 29
Oxycodone Hydrochloride 80mg ER Tablets (Tentative)	Controlled-Release	\$ 634
Oxycodone Hydrochloride 10, 20 & 40mg ER Tablets (Tentative)	Controlled-Release	\$ 1,182

The following table provides the status as of March 5, 2004 of our controlled-release and specialty generic projects (U.S. market size in millions):

	CONTROLLED-RELEASE GENERICS		SPECIALTY GENERICS		TOTAL GENERIC PROJECTS	
	Number of Projects	US Market Size	Number of Projects	US Market Size	Number of Projects	US Market Size
Our Development Pipeline: .....						
Pending, Disclosed .....	10	\$ 4,825	1	\$ 591	11	\$ 5,416
Pending, Undisclosed .....	3	1,082	5	300	8	1,382
Total Projects Pending at FDA .....	13	\$ 5,907	6	\$ 891	19	\$ 6,798
Projects Under Development .....	17	13,628	7	150	24	13,778
Total Development Pipeline .....	30	\$ 19,535	13	\$ 1,041	43	\$ 20,576

The following table provides the summary of our Paragraph IV Filings from 1999 through 2003 (18 projects) (U.S. market size in millions):

PROJECT	GENERIC OF	FILE ORDER*	MARKET SIZE	FILED
Omeprazole 10, 20 & 40 mg DR	Prilosec	5th of 10 total	\$1,823	4Q99
Bupropion 100, 150 mg ER	Wellbutrin SR	3rd of 5 total	\$1,632	2Q00
Bupropion 150 mg ER	Zyban	2nd of 4 total	\$73	2Q00
Fenofibrate 67, 134 & 200 mg	Tricor Capsules	2nd of 2 total	\$3	2Q00
Loratadine/PSE 10/240 mg ER	Claritin-D 24 hr	2nd of 2 total	\$39	3Q00
Loratadine ODT 10 mg	Claritin Reditab	3rd of 3 total	\$39	4Q00
Loratadine/PSE 5/120 mg ER	Claritin-D 12 hr	1st of 2 total	\$29	4Q00
Fexofenadine/PSE 60/120 mg ER	Allegra-D	2nd of 3 total	\$459	4Q01
Oxycodone 80 mg ER	OxyContin	3rd of 3 total	\$634	4Q01
Oxycodone 10,20 & 40 mg ER	OxyContin	3rd of 3 total	\$1,182	2Q02
Fenofibrate 54 & 160 mg	Tricor Tablets	2nd of 4 total	\$591	3Q02
Carbidopa/Levodopa ER	Sinemet CR	2nd of 2 total	\$81	4Q02
Undisclosed	—	—	—	4Q02
Undisclosed	—	—	—	4Q02
Bupropion 200 mg ER	Wellbutrin SR	1st of 2 total	\$265	1Q03
Oxybutynin 5,10 & 15 mg ER	Ditropan XL	2nd of 2 total	\$362	2Q03
S.E. Amphetamine 30 mg ER	Adderall XR	2nd of 2 total	\$151	3Q03
Undisclosed	—	—	—	4Q03

\* Estimate based on publicly available data.

### ***Controlled-release generic pharmaceuticals***

We apply our controlled-release drug delivery technologies and formulation skills to develop bioequivalent versions of selected brand name pharmaceuticals. We generally employ our technologies and formulation expertise to develop products

that will reproduce the brand name product's physiological characteristics but not infringe upon the patents relating to the brand name product. In applying our expertise to controlled-release products, we focus our efforts on generic versions of brand name pharmaceuticals that have technically challenging drug delivery mechanisms. As of March 5, 2004, we had six ANDAs approved and thirteen ANDAs under review by the FDA for controlled-release generic pharmaceuticals. Twelve of our pending ANDA filings for controlled-release generic pharmaceuticals contain certifications under Paragraph IV of the Hatch-Waxman Amendments. If we believe our product will not infringe the innovator's patents, and/or that such patents are invalid or unenforceable, we are required to submit a certification to that effect in our filing of an ANDA. This certification is known as a "Paragraph IV Certification."

If the FDA accepts our ANDA for filing, we must send a notice to the patent and NDA holder that we have filed an ANDA with a Paragraph IV Certification explaining the basis for our belief that the patent is not infringed and/or is invalid or unenforceable. The patent holder may then initiate a legal challenge to the filing of our ANDA within 45 days after receipt of the Paragraph IV Certification. If a legal challenge is initiated, the FDA is automatically prevented from approving the ANDA until the earlier of 30 months after the date the Paragraph IV Certification is given to the patent and NDA holder, expiration of the patent or patents involved in the certification, or when the infringement case is decided in our favor. Filings made under the Hatch-Waxman Amendments often result in the initiation of litigation by the patent holder and NDA holder.

We have submitted ANDAs for generic versions of the brand name controlled-release products listed below, all of which are filed with a Paragraph IV Certification. We will not be able to market any of these products prior to the earlier of the expiration of the 30-month waiting period or our obtaining a favorable resolution of the patent litigation, or the expiration of any generic marketing exclusivity period and, in any case, FDA approval of our ANDA. For additional information regarding the patent litigation for these products, see "Item 3 – Legal Proceedings."

*Prilosec  
(Omeprazole)* In March 2000, the FDA accepted for filing our ANDA submission for a bioequivalent version of Prilosec, which is used for the treatment of ulcers and gastro esophageal reflux disease, and is currently being marketed by AstraZeneca PLC. AstraZeneca has commenced patent litigation against us with respect to this product in May 2000. Our ANDA was granted final approval for the 10 mg and 20 mg strengths, and tentative approval for the 40 mg strength, by the FDA on November 10, 2002.

*Wellbutrin SR  
(Bupropion HCl)  
Zyban  
(Bupropion HCl)* In June 2000, the FDA accepted for filing our ANDA submissions for bioequivalent versions of Wellbutrin SR, which is used to treat depression, and for a bioequivalent version of Zyban. The branded products are currently being marketed by GlaxoSmithKline PLC ("Glaxo"). Glaxo commenced patent infringement litigation against us with respect to these products in November 2000, and in August 2002, the U.S. District Court, Northern District of California, issued an order granting IMPAX's Motion for Summary Judgment of Non-Infringement. This ruling was appealed by Glaxo. We filed an ANDA with the FDA for a bioequivalent version of Wellbutrin SR 200 mg in March 2003. In January 2004 the Court of Appeals for the Federal Circuit in Washington, D.C. upheld the lower court decision. Glaxo filed a request for rehearing en banc. In January 2004, our ANDA for our bioequivalent version of Wellbutrin SR was granted final approval for the 100 mg strength while the 150 mg strength was granted tentative approval by the FDA.

*Allegra-D  
(Fexofenadine  
HCl and  
Pseudoephedrine  
HCl)* In December 2001, the FDA accepted for filing our ANDA submission for a bioequivalent version of Allegra-D, which is used for the relief of symptoms associated with seasonal rhinitis in adults and children 12 years of age and older, and is currently marketed by Aventis Pharmaceuticals. Aventis commenced patent litigation against us with respect to this product in March 2002. The FDA granted tentative approval to our ANDA in February 2004.

*OxyContin  
(Oxycodone HCl)* In December 2001, the FDA accepted for filing our ANDA submission for a bioequivalent version of the 80 mg strength of OxyContin, which is used for the management of moderate to severe pain and is currently marketed by Purdue Pharmaceuticals, L.P. ("Purdue"). Purdue commenced patent litigation against us with respect to this product in April 2002 and the litigation is still ongoing. In June 2002, the FDA accepted for filing our ANDA submission for a bioequivalent version of the 40 mg strength of OxyContin. This application was subsequently amended to add the 10 mg and 20 mg strengths. In September 2003, the FDA granted us tentative approval for the 80 mg strength and in December 2003 granted us tentative approval for the 10, 20 and 40 mg strengths.

<i>Ditropan XL (Oxybutynin Chloride)</i>	In May 2003, the FDA accepted for filing our ANDA submission for a bioequivalent version of Ditropan XL, which is used for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, and is currently being marketed by Alza Corporation, a Johnson & Johnson unit. This application was subsequently amended to add the 5 mg and 10 mg strengths. Alza commenced patent litigation against us with respect to this product in September 2003.
<i>Adderall XR (Mixed Salts of a Single-Entity Amphetamine Product)</i>	In September 2003, the FDA accepted for filing our ANDA submission for a bioequivalent version of Adderall XR 30 mg Capsules. Shire Pharmaceuticals Group PLC markets the product for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD). Shire commenced patent litigation against us with respect to this product in December 2003.

We have also submitted ANDAs related to three additional products, the details of which have not been publicly disclosed, with U.S. market size of approximately \$1.1 billion for the twelve months ended December 31, 2003.

We were first to have an ANDA that included a Paragraph IV Certification accepted for filing by the FDA for the bioequivalent version of Claritin-D 12-hour. The developer of a bioequivalent product who is the first to have its ANDA containing a Paragraph IV Certification for any bioequivalent drug accepted for filing by the FDA is awarded a 180-day period of marketing exclusivity against other companies that subsequently file Paragraph IV Certifications. When the FDA approved our ANDA in January 2003, our bioequivalent version of Claritin-D 12-hour was granted the 180-day period of marketing exclusivity. This exclusivity period ran from commencement of the first commercial marketing of the product in January 2003. We believe we may have been the first to file with respect to at least one of our other pending applications with Paragraph IV Certifications. There can be no certainty, however, until FDA grants final approval of the ANDA(s).

In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24-hour Extended Release Tablets for the OTC market under the Alavert brand. IMPAX is responsible for developing and manufacturing the products, while Wyeth is responsible for their marketing and sale. The structure of the agreement includes payment upon achievement of milestones and royalties paid to IMPAX on Wyeth's sales on a quarterly basis. We commenced shipments to Wyeth in March 2003, and Wyeth launched this product in May 2003 as Alavert D-12.

In June 2002, we signed a non-exclusive Licensing, Contract Manufacturing and Supply Agreement with Schering-Plough relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets for the OTC market under the Claritin-D 12-Hour brand. The structure of the agreement included milestone payments by Schering-Plough and agreed-upon sales prices. We commenced shipments to Schering-Plough at the end of January 2003, and Schering-Plough launched our product as its OTC Claritin-D 12-hour in March 2003.

In addition to the products for which we have submitted applications, we have seventeen other controlled-release ANDA eligible products in various stages of development. The total U.S. market size of these products was approximately \$13.6 billion in the twelve months ended December 31, 2003. We are continually evaluating these and other potential product candidates. In selecting our target product candidates, we focus on pharmaceuticals which we believe will have potential for high sales volume, are technically challenging, and may be suitable for filing under Paragraph IV Certification.

### ***Other generic pharmaceuticals***

We are also developing other generic pharmaceuticals that present one or more competitive barriers to entry, such as difficulty in raw material sourcing, complex formulation or development characteristics, or special handling requirements.

As of March 5, 2004, we had six applications pending at the FDA for specialty generic pharmaceuticals, two of which were made under Paragraph IV of the Hatch-Waxman Amendments. These applications are for products that are generic versions of brand name pharmaceuticals whose total U.S. market size was approximately \$891 million for the twelve months ended December 31, 2003. We have an additional seven other products under development relating to brand name products that had approximately \$150 million in total U.S. sales for the twelve months ended December 31, 2003.

We have submitted ANDAs for generic versions of the following brand name products, the first one of which was filed with a Paragraph IV Certification. We will not be able to market any of these products prior to the earlier of the expiration of the 30-month waiting period or our obtaining a favorable resolution of the patent litigation, or the expiration of any generic

marketing exclusivity period and, in any case, FDA approval of our ANDA. For additional information regarding the patent litigation for these products, see “Item 3 – Legal Proceedings.”

*Tricor Tablets (Fenofibrate)* In December 2002, the FDA accepted for filing our ANDA submission for a bioequivalent version of Tricor 160 mg Tablets, which is used for the treatment of very high serum triglyceride levels, currently marketed by Abbott. Abbott commenced patent infringement litigation against us with respect to this product in January 2003. The application was later amended to include the 54 mg strength. We are currently scheduled to proceed to trial in June 2005. We received tentative approval of this ANDA in March 2004.

*Rilutek Tablets (Riluzole)* In May 2001, the FDA accepted for filing our ANDA submission for a bioequivalent version of Rilutek Tablets, which is used in the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease. In June 2002, we received tentative FDA approval of this ANDA due to the Orphan Drug Exclusivity for Rilutek that extended through December 2002. In June 2002, we filed a declaratory judgment action seeking a Judicial Declaration of Invalidity against Aventis regarding U.S. Patent No. 5,527,814 that had only recently been listed by Aventis in the FDA “Orange Book.” FDA granted us tentative approval for this application in July 2002. In December 2002, the U.S. District Court of Wilmington, Delaware, granted the Preliminary Injunction Motion brought by Aventis in October 2002 to forestall our entry into this market. We received final FDA approval of this ANDA in January 2003. A trial was held in October 2003 and we are currently awaiting a decision from the court.

We have also submitted applications relating to five additional products, the details of which have not been publicly disclosed, with U.S. market size of approximately \$300 million for the twelve months ended December 31, 2003.

In December 2001, we entered into a license and supply agreement granting to Novartis exclusive rights to market our OTC Loratadine Orally Disintegrating Tablets (generic of Claritin Reditabs) product in the pediatric market. Under the terms of the agreement, IMPAX is responsible for developing and manufacturing the product, while Novartis is responsible for its marketing and sale. The structure of the agreement includes milestone payments and a royalty on Novartis’ sales. Novartis launched this product in February 2004 as Triaminic AllerChews.

### ***Brand name pharmaceuticals***

In the brand name pharmaceuticals market, we are focusing our efforts on the development of products for the treatment of Central Nervous System (“CNS”) disorders. Our strategy is to build this portfolio primarily through internal development and through licensing and acquisition. We intend to utilize our formulation and development expertise as well as our drug delivery technologies in the formulation of off-patent drug substances as differentiated, modified, or controlled-release pharmaceutical products that we will market as brand name products. Barry R. Edwards, our Chief Executive Officer, Larry Hsu, Ph.D., our President, and Nigel Fleming, Ph.D., a Director, all have experience in developing and/or marketing products for the treatment of CNS disorders.

According to NDCHealth, CNS is the largest therapeutic category in the U.S. with 2003 retail sales of \$41 billion, or 18.8% of the \$218 billion U.S. retail drug market. CNS drug sales grew 8.1% in 2003 versus a sales growth of 3.9% for the entire industry.

CNS disorders include ailments such as Alzheimer’s disease, attention deficit hyperactivity, depression, epilepsy, migraines, multiple sclerosis, Parkinson’s disease, and schizophrenia. There are approximately 8,300 neurologists, of which, historically, a concentrated number are responsible for writing the majority of neurological CNS prescriptions.

We have four CNS projects under development. We are currently evaluating up to eleven additional brand name projects.

These potential products may require us to file additional Investigational New Drug applications (“IND”s) with the FDA before commencing clinical trials, and New Drug Applications (“NDA”s) in order to obtain FDA approval. In 2003, we filed two INDs with the FDA. We believe that developing 505(b)(2) type NDAs for these brand name products provides us with strategic advantages, including a significant reduction in the cost and time to develop these products. We believe that the development risks for these products are reduced compared to new chemical entities because the FDA has previously evaluated and approved the chemical entities being utilized in these products. We believe we may be eligible for FDA marketing exclusivity rights for certain products which we develop in our brand name drug development programs.

## ***Competition***

The pharmaceutical industry is highly competitive and is affected by new technologies, new developments, government regulations, health care legislation, availability of financing, and other factors. Many of our competitors have longer operating histories and greater financial, research and development, marketing, and other resources than us. We are in competition with numerous other entities that currently operate, or intend to operate, in the pharmaceutical industry, including companies that are engaged in the development of controlled-release drug delivery technologies and products, and other manufacturers that may decide to undertake in-house development of these products. Due to our focus on relatively hard-to-replicate controlled-release products, competition is often limited to those competitors who possess the appropriate drug delivery technology.

The principal competitive factors in the generic pharmaceutical market include:

- the ability to introduce generic versions of products promptly after a patent expires;
- price;
- quality of products;
- customer service (including maintenance of inventories for timely delivery);
- breadth of product line; and
- the ability to identify and market niche products.

In the brand name pharmaceutical market, we expect to compete with large pharmaceutical companies, other drug delivery companies, and other specialty pharmaceutical companies that have focused on CNS disorders.

## **Sales and Marketing**

### ***Customers***

Our existing customer base includes pharmaceutical wholesalers, warehousing chain drug stores, mass merchandisers and mail-order pharmacies. We market our generic products through personal sales calls, direct advertising and promotion, as well as trade journal advertising and attendance at major trade shows and conferences. In addition, we market our OTC products through strategic alliances with Novartis, Wyeth and Schering-Plough. We have four major customers, Amerisource-Bergen, Cardinal Health, McKesson, and Schering-Plough that accounted for approximately 64% of total sales for the year ended December 31, 2003.

### ***Controlled-release and other generics***

In June 2001, we entered into a strategic alliance agreement with a subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva") for twelve controlled-release generic products. The agreement granted Teva exclusive U.S. prescription marketing rights for six of our products pending approval at the FDA, and six products under development at the time the agreement was signed. Teva elected to commercialize a competing product to one of the products, which it developed internally. Pursuant to the agreement, we have elected to participate in the development and commercialization of Teva's competing product and share in the gross margin of such product. The agreement allows us to enter into agreements with other companies relating to the development, supply and marketing of these products for the OTC market.

Our current prescription products are marketed through our Global Pharmaceuticals division while OTC products are marketed through strategic partners. We also intend to market future generic products through the Global Pharmaceuticals division and strategic partners. We depend on our strategic alliances for market penetration and revenue generation for products covered by those alliances. IMPAX may seek additional alliances for expanded marketing and distribution of our products.

The Global Pharmaceuticals division markets solid oral prescription pharmaceuticals primarily to the generic sector of the pharmaceutical market. Our existing customer base includes pharmaceutical wholesalers, warehousing chain drug stores, mass merchandisers, and mail-order pharmacies. The sale of the generic line requires a small, targeted sales and marketing group. We market our generic products through personal sales calls, direct advertising and promotion, trade journal advertising, and attendance at major trade shows and conferences.

We intend to concentrate our generic sales and marketing efforts on large distribution partners because their national presence can provide access to a greater number of customers and patients. These supply chain partners traditionally support the sales process and help generate product demand.

We believe our customer base, with respect to our existing generic products, provides us with an established distribution base into which we can sell our new products if and when FDA approvals are received.

### ***Brand name products***

We anticipate that brand name products will be marketed through our Impax Pharmaceuticals division. Our brand name sales strategy consists of targeting the high-volume prescribing physicians, first on a selective regional basis, and then expanding the sales force nationally, as required. There are approximately 8,300 neurologists, of which, historically, a concentrated number are responsible for writing the majority of neurologists' CNS prescriptions. We believe this concentration will allow us to maintain a relatively small sales and marketing group for CNS products. We currently do not market any brand name products.

### **Strategic Alliances**

#### ***Strategic Alliance with Teva***

In June 2001, we entered into a Strategic Alliance Agreement with a subsidiary of Teva for twelve controlled-release generic pharmaceutical products. According to Teva, which is headquartered in Israel, Teva is among the top 30 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Close to 90% of Teva's sales are in North America and Europe. Teva develops, manufactures, and markets generic and brand name pharmaceuticals and active pharmaceutical ingredients.

The agreement granted Teva exclusive U.S. prescription marketing rights for six of our products pending approval at the FDA and six products under development at the time the agreement was signed. The six products for which ANDAs were already filed at the time of the agreement were Omeprazole 10 mg, 20 mg, and 40 mg Delayed Released Capsules (generic of Prilosec), Bupropion Hydrochloride 100 mg and 150 mg Extended Release Tablets (generic of Wellbutrin SR), Bupropion Hydrochloride 150 mg Extended Release Tablets (generic of Zyban), Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets (generic of Claritin-D 12-Hour) and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24 hour Extended Release Tablets (generic of Claritin-D 24-hour) and Loratadine Orally Disintegrating Tablets (generic of Claritin Reditabs). Of the six products under development, four have since been filed with the FDA. Teva elected to commercialize a competing product to one of the four products filed since June 2001, which it developed internally. Pursuant to the agreement, we have elected to participate in the development and commercialization of Teva's competing product and share in the gross margins of such product. Teva also had an option to acquire exclusive marketing rights in the rest of North America, South America, the European Union, and Israel for these products. We will be responsible for supplying Teva with all of its requirements for these products and will share with Teva in the gross margins from its sale of the products. We will depend on our strategic alliance with Teva to achieve market penetration for these products and to generate product revenues for us. Teva's exclusive marketing right for each product will run for a period of ten years in each country from the date of Teva's first sale of that product. Unless either party provides appropriate notice, this ten-year period will automatically be extended for two additional years.

As part of the strategic alliance agreement, Teva will share some of our costs relating to the twelve products. For the six products which were pending approval at the FDA in June 2001, Teva will pay 50% of the attorneys' fees and costs of obtaining FDA approval, including the fees and costs for the patent infringement litigation instituted by brand name pharmaceutical manufacturers in excess of the \$7.0 million covered by our patent litigation insurer. For three other products, for which we have since filed ANDAs with the FDA, Teva will pay 45% of all fees, costs, expenses, damages or awards, including attorneys' fees, related to patent infringement claims with respect to these products. For the remaining three products, Teva will pay 50% of these fees, costs, expenses, damages or awards.

We also agreed to sell to Teva an aggregate of \$15.0 million worth of our common stock in four equal installments, with the last sale occurring on June 15, 2002. Teva purchased a total of 1,462,083 shares of our common stock. The price of the common stock was equal to the average closing sale price of our common stock measured over a ten-trading-day period ending two days prior to the date when Teva acquired the common stock. However, on the date Teva completes its first sale of any one of six products specified in our alliance agreement, we may repurchase from Teva 16.66% (243,583) of these shares for an aggregate of \$1.00.

In addition, in consideration for the potential transfer of the marketing rights, we received \$22.0 million from Teva which assisted in the construction and improvement of our Hayward, California facilities and the development of the twelve products specified in our Strategic Alliance Agreement. The \$22 million was reflected on the balance sheet as a refundable deposit. The refundable deposit was provided in the form of a loan. Pursuant to the agreement, accrued and future interest on the refundable deposit was forgiven during 2002 as a result of our receipt of tentative or final approvals for at least three

of our products. In addition, Teva forgave portions of this loan as we achieved certain milestones relating to the development and launch dates of the products described in our strategic alliance agreement. In addition, by requiring us to repay only 50% of the portion of the loan related to certain missed milestones, Teva chose to continue to have exclusive marketing rights for those products. At our option, we could repay Teva any amounts we owed them as part of the loan in cash or in shares of our common stock. The price of the common stock for purposes of repaying any amounts owed under the loan was the average closing sale price of our common stock measured over a ten-trading-day period ending two days prior to repayment.

In September 2003, we issued 888,918 shares of our common stock to Teva, paying \$13.5 million of the original \$22.0 million refundable deposit. In December 2003, Teva exercised its option to retain marketing exclusivity for certain products and, accordingly, reduced the refundable deposit by \$3.5 million to \$5.0 million.

In January 2004, Teva's exercise of the marketing exclusivity option for certain products reduced the refundable deposit to \$2.5 million. On January 15, 2004, we satisfied the remaining \$2.5 million refundable deposit obligation to Teva by issuing 160,951 shares of our common stock to Teva. As of February 27, 2004, to our knowledge, Teva owns 2,511,952 shares of our common stock, or approximately 4.3% of the outstanding common stock.

### ***Strategic Alliance with Andrx and Teva***

In July 2003, we entered into an Exclusivity Transfer Agreement with Andrx and a subsidiary of Teva pertaining to pending ANDAs for bioequivalent versions of Wellbutrin SR and Zyban (Bupropion Hydrochloride) 100 mg and 150 mg Extended Release Tablets filed by Andrx, as well as by us. Pursuant to our existing strategic alliance agreement with Teva, Teva has U.S. marketing rights to our versions of these products. These two strengths of Wellbutrin SR and Zyban, marketed by GlaxoSmithKline, had U.S. sales of over \$1.74 billion for the twelve-month period ended December 31, 2003 according to NDCHealth.

The parties to the agreement believe that the Andrx ANDAs for the products are entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity. Under the Exclusivity Transfer Agreement, Andrx will continue to seek approval of its ANDAs. The agreement provides, among other things, that if Andrx is unable to launch its own products within a defined period of time, and we are able to market our products, Andrx will enable us to launch our own products through Teva, with the parties sharing certain payments with Andrx relating to the sale of the products for a 180-day period. Should Andrx launch its own products prior to our product launch, it will share with us certain payments for a 180-day period.

### ***OTC Alliances***

In December 2001, we entered into a License and Supply Agreement granting to Novartis exclusive rights to market our OTC Loratadine Orally Disintegrating Tablets (generic Claritin Reditabs) for the pediatric market. Under the terms of the agreement, IMPAX is responsible for developing and manufacturing the product, while Novartis is responsible for its marketing and sale. The structure of the agreement includes payment upon achievement of milestones and royalties paid on Novartis' sales to IMPAX on a quarterly basis. Novartis launched this product in February 2004 as Triaminic AllerChews.

In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24-hour Extended Release Tablets for the OTC market under the Alavert brand. IMPAX is responsible for developing and manufacturing the products, while Wyeth is responsible for their marketing and sale. The structure of the agreement includes payment upon achievement of milestones and royalties paid to IMPAX on Wyeth's sales on a quarterly basis. Wyeth launched this product in May 2003 as Alavert D-12.

In June 2002, we signed a non-exclusive Licensing, Contract Manufacturing and Supply Agreement with Schering-Plough relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets for the OTC market under the Claritin-D 12-hour brand. The structure of the agreement included milestone payments by Schering-Plough and agreed upon sales prices. Shipments to Schering-Plough commenced at the end of January 2003. Schering-Plough launched our product as its OTC Claritin-D 12-hour in March 2003.

## **MANUFACTURING**

We manufacture our finished dosage form products at our Hayward, California, Building 2 facility and then package, warehouse and distribute the products from our Philadelphia facility. This strategy allows us to use the lower operating cost and larger Philadelphia facility for packaging and warehousing, which requires significant space, while focusing Building 2 on tablet and capsule manufacturing, which requires less space. The facility currently manufactures Loratadine and

Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets, Orphenadrine Citrate 100 mg Extended Release Tablets, Sotalol Hydrochloride 80 mg, 120 mg, 160 mg, and 240 mg Tablets, METHITEST(Methyltestosterone) Tablets, Minocycline Hydrochloride 50 mg, 75 mg, and 100 mg Capsules, Fludrocortisone Acetate Tablets 0.1 mg, Terbutaline Sulfate 2.5 mg and 5.0 mg Tablets, Rimantadine Hydrochloride 100 mg Tablets, Flavoxate HCl Tablets 0.1 mg, Chloroquine Phosphate Tablets 250 mg, and Pyridostigmine Bromide Tablets 60 mg. We are also currently manufacturing additional products in anticipation of future product launches. We began full-scale manufacturing in this facility in June 2002 and believe we have sufficient capacity to produce new products in the future. During the fourth quarter of 2003, we were using about 60% of our estimated annual production capacity of up to approximately 1.0 to 1.5 billion tablets and capsules.

Our research and development activities are situated in Hayward, California, Building 1. Research and development expenses for the years ended December 31, 2003, 2002, and 2001 were \$16,938,000, \$15,549,000 and \$10,972,000, respectively. We believe this proximity allows for a more efficient transfer and scale-up of products from research and development to manufacturing. Currently, Building 1 serves as our research and development center and analytical development laboratory, and has a pilot plant that can accommodate most of our current development work. This facility will also provide space for the expansion of our development resources in future years. Our Building 5 in Hayward, California houses production materials for our California operations.

Currently, our Philadelphia facility packages and distributes the ten pancreatic enzyme products that comprise our LIPRAM family of products, in addition to the products manufactured in Hayward and by others. A third party, Eurand America, Inc., for whom we distribute these products under an exclusive license/distribution agreement, manufactures the LIPRAM family of products.

## **RAW MATERIALS**

The active chemical raw materials, essential to IMPAX's business, are generally readily available from multiple sources in the U.S. and throughout the world. Certain raw materials used in the manufacture of our products are, however, available from limited sources and, in some cases, a single source. Any curtailment in the availability of such raw materials could result in production or other delays and, in the case of products for which only one raw material supplier exists or has been approved by the FDA, could result in material loss of sales with consequent adverse effects on our business and results of operations. Also, because raw material sources for pharmaceutical products must generally be identified and approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs, and loss of sales and customers. IMPAX obtains a portion of its raw materials from foreign suppliers, and its arrangements with such suppliers are subject to, among other risks, FDA approval, governmental clearances, export duties, political instability, and restrictions on the transfers of funds.

In addition, recent changes in patent laws in foreign jurisdictions may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable U.S. or foreign patents. Any inability to obtain raw materials on a timely basis, or any significant price increases that can not be passed on to customers, could have a material adverse effect on us.

To date, IMPAX has not experienced any significant delays from lack of raw material availability. However, significant delays may occur in the future.

## **QUALITY CONTROL**

In connection with the manufacture of drugs, the FDA requires testing procedures to monitor the quality of the product, as well as the consistency of its formulation. We maintain a quality control laboratory that performs, among other things, analytical tests and measurements required to control and release raw materials, in-process materials, and finished products, and to routinely test marketed products to ensure they remain within specifications.

Quality monitoring and testing programs and procedures have been established by us in our effort to assure that all critical activities associated with the production, control, and distribution of our drug products will be carefully controlled and evaluated throughout the process. By following a series of systematically organized steps and procedures, we seek to assure that established quality standards will be achieved and built into the product.

Our policy is to continually seek to meet the highest quality standards, with the goal of thereby assuring the quality, purity, safety, and efficacy of each of our drug products. We believe that adherence to high operational quality standards will also promote more efficient utilization of personnel, materials, and production capacity.

## REGULATION

The manufacturing, distribution, processing, formulation, packaging, labeling and advertising of our products are subject to extensive regulation by federal agencies, including the FDA, the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Consumer Product Safety Commission and the Environmental Protection Agency (EPA), among others. We are also subject to state and local laws, regulations and agencies in California, Pennsylvania, and elsewhere. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), the Prescription Drug Marketing Act of 1987 (“PDMA”), the Controlled Substances Act, the Generic Drug Enforcement Act of 1992, and other federal statutes and regulations govern or influence the manufacture, labeling, testing, storage, record-keeping, approval, advertising and promotion of our products. Noncompliance with applicable requirements can result in recalls, seizure of products, injunctions, suspension of production, refusal of the government to enter into supply contracts or to approve drug applications, civil and criminal fines, criminal prosecution, and disgorgement of profits.

FDA approval is required before any “new drug,” as defined in Section 201(p) of the FFDCA, may be distributed in interstate commerce. A drug that is the generic equivalent of a previously approved prescription drug (referred to as the “reference listed drug”) also requires FDA approval. Many OTC drugs also require FDA pre-approval if the OTC drug is not covered by, or does not conform to, the conditions specified in an applicable OTC Drug Product Monograph and is therefore considered a new drug.

All facilities engaged in the manufacture, packaging, labeling and repackaging of drug products must be registered with the FDA and are subject to FDA inspection to ensure that drug products are manufactured in accordance with current Good Manufacturing Practices. For fiscal year 2004, annual establishment fees for facilities that produce products subject to NDAs are approximately \$226,800, and product listing fees are approximately \$36,080 per product.

Generally, two types of applications are used to obtain FDA approval of a “new drug:”

*New Drug Application (NDA)* – For drug products with an active ingredient or ingredients or indications not previously approved by the FDA, a prospective manufacturer must submit a complete application containing the results of a clinical study or studies supporting the drug product’s safety and efficacy. These studies may take anywhere from two to five years, or more. An NDA may also be submitted through Section 505(b)(2) for a drug with a previously approved active ingredient if the drug will be used to treat an indication for which the drug was not previously approved, if the method of delivery is changed, or if the abbreviated procedure discussed below is not available. Currently, FDA approval of an NDA, on average, is estimated to take approximately 12 to 15 months following submission to the FDA. During fiscal year 2004, user fees to file an NDA are approximately \$573,500.

*Abbreviated New Drug Application (ANDA)* – The Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, established an abbreviated new drug application procedure for obtaining FDA approval of generic versions of certain drugs. An ANDA is similar to an NDA except that the FDA waives the requirement that the applicant conduct and submit to the FDA clinical studies to demonstrate the safety and effectiveness of the drug. Instead, for drugs that contain the same active ingredient and are of the same route of administration, dosage form, strength and indication(s) as drugs already approved for use in the United States, the FDA ordinarily only requires bioavailability data demonstrating that the generic formulation is bioequivalent to the previously approved reference listed drug, indicating that the rate of absorption and the levels of concentration of the generic drug in the body do not show a significant difference from those of the previously approved reference listed drug product. According to information published by the FDA, the FDA currently takes approximately 18 to 20 months on average to approve an ANDA following the date of its first submission to the FDA. Currently, the FFDCA does not require applicants to pay user fees for ANDAs.

Patent certification requirements for generic drugs could also result in significant delays in obtaining FDA approvals. First, where patents covering a reference listed drug are alleged to be invalid, unenforceable, or not infringed by an ANDA applicant, the holder or holders of the brand name drug patents may institute patent infringement litigation and obtain a stay of up to 30 months of approval of an ANDA, and for ANDA’s of products whose patent information was listed before August 2003, potentially multiple 30 month stays. Second, the first company to submit an ANDA for a given drug, which the FDA accepts for filing, and which certifies that an unexpired patent covering the reference listed brand name drug is invalid, unenforceable, or will not be infringed by its product, can be awarded 180 days of market exclusivity following approval of its ANDA during which the FDA may not approve any other ANDAs for that drug product.

On November 20, 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) was enacted. Title X of the MMA amended provisions of the Hatch-Waxman Amendments relating to the 30-month stay of the FDA approval following institution of patent infringement litigation in response to notice of a Paragraph IV Certification, the content and timing of notices to NDA and patent holders made when an ANDA applicant submits an ANDA with a

Paragraph IV Certification, and the 180-day exclusivity to the first generic applicant filing an ANDA with a Paragraph IV Certification. The major change in the law pursuant to the MMA is to eliminate, in most cases, multiple 30-month stays for ANDAs. The law also clarifies when the 30-month stay is terminated, how, when, and what notice is given to the NDA and patent holder to the filing of an ANDA with a Paragraph IV certification, what triggers 180-day exclusivity and how it is forfeited, and which applicant is entitled to 180-day exclusivity when more than one patent is challenged.

While the Hatch-Waxman Amendments codify the ANDA mechanism for generic drugs, they also foster pharmaceutical innovation through incentives that include market exclusivity and patent term extension. First, the Hatch-Waxman Amendments provide two distinct market exclusivity provisions that either preclude the submission or delay the approval of an abbreviated drug application for a drug product. A five-year marketing exclusivity period is provided for new chemical compounds, and a three-year marketing exclusivity period is provided for approved applications containing new clinical investigations essential to an approval, such as a new indication for use or new delivery technologies or new dosage forms. The three-year marketing exclusivity period would be applicable to, among other things, the development of a novel drug delivery system, as well as a new use. In addition, companies can obtain six additional months of exclusivity if they perform pediatric studies of a reference listed drug product. The marketing exclusivity provisions apply equally to patented and non-patented drug products.

Second, the Hatch-Waxman Amendments provide for patent term extensions to compensate for patent protection lost due to time taken in conducting FDA required clinical studies and during FDA review of NDAs. Patent term extension may not exceed five additional years, nor may the total period of patent protection following FDA marketing approval be extended beyond 14 years. In addition, by virtue of the Uruguay Round Agreements Act of 1994 that ratified the General Agreement on Tariffs and Trade ("GATT"), certain brand name drug patent terms have been extended to 20 years from the date of filing of the pertinent patent application (which can be longer than the former patent term of 17 years from date of issuance of a patent). These extensions can further delay ANDA effective dates. Patent term extensions may delay the ability of IMPAX to use its proprietary technology in the future to market new extended release products, file section 505(b)(2) NDAs referencing approved products (see below), and file ANDAs based on reference listed drugs when those approved products or listed drugs have acquired patent term extensions.

With respect to any drug with active ingredients not previously approved by the FDA, a prospective manufacturer must submit a full NDA, including complete reports of pre-clinical, clinical, and other studies to prove that product's safety and efficacy for its intended use or uses. An NDA may also need to be submitted for a drug with a previously approved active ingredient if, among other things, the drug will be used to treat an indication for which the drug was not previously approved, if the method of delivery is changed, or if the abbreviated procedure discussed above is otherwise not available. A manufacturer intending to conduct clinical trials for a new drug compound as part of an NDA is required first to submit an Investigational New Drug ("IND") application to the FDA containing information relating to pre-clinical and planned clinical studies. The full NDA process is expensive and time consuming. Controlled or extended-release versions of approved immediate-release drugs will require the filing of an NDA. The FDA will not accept ANDAs when the delivery system or duration of drug availability differs significantly from the reference listed drug. However, the FDCA provides for NDA submissions that may rely in whole or in part on publicly available clinical data on safety and efficacy under section 505(b)(2) of the FDCA. We may be able to rely on the existing safety and efficacy data for a chemical entity in filing NDAs for extended-release products when the data exists for an approved immediate-release version of that chemical entity. However, the FDA may not accept our applications under section 505(b)(2), or that the existing data may not be available or useful. Utilizing the section 505(b)(2) NDA process is uncertain because we have not had significant experience with it. Additionally, under the Prescription Drug User Fee Act of 1992, as amended by the Prescription Drug User Fee Amendments of 2002, all NDAs require the payment of a substantial fee upon filing, and other establishment and product fees must be paid annually after approval. These fees increase on an annual government fiscal year basis. No assurances exist that, if approval of an NDA is required, the approval can be obtained in a timely manner, if at all.

PDMA, which amends various sections of the FDCA, requires, among other things, state licensing of wholesale distributors of prescription drugs under federal guidelines that include minimum standards for storage, handling, and recordkeeping. It also sets forth civil and criminal fines and penalties for violations of these and other provisions. Failure to comply with the wholesale distribution provisions and other requirements of the PDMA could have a materially adverse effect on IMPAX's financial condition, results of operations, and cash flows.

Among the requirements for new drug approval is the requirement that the prospective manufacturer's facility, production methods and recordkeeping practices, among other factors, conform to FDA regulations on current Good Manufacturing Practices. The current Good Manufacturing Practices regulations must be followed at all times when the approved drug is manufactured. In complying with the standards set forth in the current Good Manufacturing Practices regulations, the manufacturer must expend time, money and effort in the areas of production and quality control to ensure full technical and regulatory compliance. Failure to comply can result in possible FDA actions, such as the suspension of manufacturing,

seizure of finished drug products, injunctions, consent orders, payment of civil and criminal fines, civil and criminal penalties, and disgorgement of profits. Federal, state and local laws of general applicability, such as laws regulating working conditions, also govern us.

The Generic Drug Enforcement Act of 1992 establishes penalties for wrongdoing in connection with the development or submission of an ANDA. In general, FDA is authorized to temporarily bar companies, or temporarily or permanently bar individuals, from submitting or assisting in the submission of an ANDA, and to temporarily deny approval and suspend applications to market off-patent drugs under certain circumstances. In addition to debarment, FDA has numerous discretionary disciplinary powers, including the authority to withdraw approval of an ANDA or to approve an ANDA under certain circumstances and to suspend the distribution of all drugs approved or developed in connection with certain wrongful conduct.

We are subject to the Maximum Allowable Cost (“MAC”) Regulations which limit reimbursements for certain generic prescription drugs under Medicare, Medicaid, and other programs to the lowest price at which these drugs are generally available. In many instances, only generic prescription drugs fall within the MAC Regulations’ limits. Generally, the pricing and promotion of, method of reimbursement and fixing of reimbursement levels for, and the reporting to Federal and state agencies relating to drug products is under active review by federal, state and local governmental entities, as well as by private third-party reimbursers, and individuals under whistleblower statutes. At present, the Justice Department and U.S. Attorneys Offices and State Attorneys General have initiated investigations, reviews, and litigation into industry-wide pharmaceutical pricing and promotional practices, and whistleblowers have filed *qui tam suits*. We cannot predict the results of those reviews, investigations, and litigation or their impact on our business.

Virtually every state, as well as the District of Columbia, has enacted legislation permitting the substitution of equivalent generic prescription drugs for brand name drugs where authorized or not prohibited by the prescribing physician, and currently 13 states mandate generic substitution in Medicaid programs.

In addition, numerous state and federal requirements exist for a variety of controlled substances which may be part of our product formulations. For example, the DEA regulates narcotics. The DEA, which has similar authority to the FDA and may also pursue monetary penalties, and other federal and state regulatory agencies have far-reaching authority.

The State of California requires that any manufacturer, wholesaler, retailer or other entity in California that sells, transfers or otherwise furnishes certain so-called precursor substances must have a permit issued by the California Department of Justice, Bureau of Narcotic Enforcement (BNE). The substances covered by this requirement include ephedrine, pseudoephedrine, norpseudoephedrine and phenylpropanolamine, among others. The BNE has authority to issue, suspend and revoke precursor permits. According to the California Health and Safety Code, a permit may be denied, revoked or suspended for various reasons, including: (i) failure to maintain effective controls against diversion of precursors to unauthorized persons or entities; (ii) failure to comply with the Health and Safety Code provisions relating to precursor substances, or any regulations adopted thereunder; (iii) commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions or duties of the permit holder; or (iv) if any individual owner, manager, agent, representative or employee of the permit applicant/permit holder willfully violates any federal, state or local criminal statute, rule, or ordinance relating to the manufacture, maintenance, disposal, sale, transfer or furnishing of any precursor substances. The California Health and Safety Code further requires that the theft or loss of any precursor substance discovered by a permit holder be reported in writing to the BNE within three days after discovery.

Compliance with the complex and extensive regulatory requirements is difficult and expensive. If we fail to comply with the numerous federal, state and local rules and regulations, our current or future operations could be curtailed and our business and financial results could be materially harmed.

## **ENVIRONMENTAL LAWS**

We are subject to comprehensive federal, state and local environmental laws and regulations that govern, among other things, air polluting emissions, waste water discharges, solid and hazardous waste disposal, and the remediation of contamination associated with current or past generation handling and disposal activities, including the past practices of corporations as to which we are the successor. We are subject periodically to environmental compliance reviews by various environmental regulatory agencies.

A Phase I environmental study was conducted with respect to our Philadelphia plant and operations in 1993 and all environmental compliance issues that were identified at that time, including the discovery of asbestos in certain areas of the plant and the existence of underground oil storage tanks, have been resolved. We periodically monitor compliance with

applicable environmental laws. There can be no assurance that future changes in environmental laws or regulations, administrative actions or enforcement actions, or remediation obligations arising under environmental laws will not have a material adverse effect on IMPAX's financial condition, results of operations, or cash flows.

## EMPLOYEES

As of February 27, 2004, we employed approximately 453 full-time employees. Of these employees, approximately 214 are in operations, 95 are in research and development, 94 work in the quality area, 41 are in administration, and 9 work in sales and marketing. In addition, as of February 27, 2004, we employed approximately 98 temporary employees. Of these employees, approximately 91 are in operations, 6 in the quality area, and 1 in research and development. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are subject to collective bargaining agreements with labor unions, and we believe our employee relations are good.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth certain information with respect to executive officers of the Company.

Name	Age*	Position
Charles Hsiao	60	Chairman and Director
Barry R. Edwards	47	Chief Executive Officer and Director
Larry Hsu	55	President and Director
Cornel C. Spiegler	59	Chief Financial Officer and Corporate Secretary
May Chu	54	Vice President, Quality Affairs
David S. Doll	45	Senior Vice President, Sales and Marketing

\*As of February 27, 2004

Charles Hsiao, Ph.D. has been our Chairman and Director since December 1999. Dr. Hsiao was our Co-Chief Executive Officer from December 1999 through December 31, 2003. Dr. Hsiao co-founded Impax Pharmaceuticals, Inc., and has served as Chairman, Chief Executive Officer and a Director since its inception in 1995. Dr. Hsiao co-founded IVAX Corporation in 1986 with two partners. By October 1994, when he left the Vice-Chairman position at IVAX, this company had become the world's largest generic pharmaceutical company with approximately 7,000 employees and \$1.0 billion in worldwide sales. Dr. Hsiao's technical expertise is in the area of formulation and development of oral controlled-release dosage form. Dr. Hsiao obtained his Ph.D. in pharmaceuticals from University of Illinois.

Barry R. Edwards has been our Chief Executive Officer since January 2004 and Director since January 1999. Mr. Edwards was our Co-Chief Executive Officer from December 1999 until December 2003. From January 1999 until December 1999, Mr. Edwards served as President and Chief Executive Officer of Global. From 1996 to 1998, Mr. Edwards was Vice President, Marketing and Business Development for Teva Pharmaceuticals USA, a manufacturer of generic drugs. From 1991 to 1996, Mr. Edwards served as Executive Director of Gate Pharmaceuticals, a brand marketing division of Teva Pharmaceuticals USA. Prior to 1991, Mr. Edwards held a number of management functions in strategic planning, corporate development, business development, and marketing at Teva Pharmaceuticals USA.

Larry Hsu, Ph.D. has been our President and Director since December 1999, and served as Chief Operating Officer from December 1999 through January 2003. Dr. Hsu co-founded Impax Pharmaceuticals, Inc. and served as its President, Chief Operating Officer and a Director since 1995. From 1980 to 1995, Dr. Hsu worked at Abbott Laboratories. During the last four years at Abbott, Dr. Hsu was the Director of Product Development in charge of formulation development, process engineering, clinical lot manufacturing, and production technical support of all dosage forms, managing a staff of approximately 250 people. Dr. Hsu obtained his Ph.D. in pharmaceuticals from University of Michigan.

Cornel C. Spiegler has been Chief Financial Officer and Corporate Secretary since September 1995. From 1989 to 1995, Mr. Spiegler was Chief Financial Officer and Senior Vice President of United Research Laboratories, Inc. and Mutual Pharmaceutical Company, Inc., companies engaged in the generic pharmaceutical industry. From 1973 to 1989, Mr. Spiegler held a number of financial and operational management functions, including Vice President and Controller of Fischer and Porter, Inc., a manufacturer of process control equipment. From 1970 to 1973, Mr. Spiegler was employed by the accounting firm of Arthur Andersen and Co. Mr. Spiegler is a certified public accountant and has an MBA from Temple University.

May Chu, M.S., has been Vice President, Quality Affairs since December 1999. Ms. Chu joined Impax Pharmaceuticals, Inc. in 1996 as Director of Research and Development, Analytical and Quality Assurance. From 1985 to 1996, Ms. Chu was

employed at Watson Laboratories in the areas of Research and Development and Quality Assurance. Prior to joining Watson, she worked at Rachele Laboratories for seven years as a research chemist.

David S. Doll has been Senior Vice President, Sales and Marketing since March 2001. From June 1993 until March 2001, Mr. Doll served in a number of management functions at Merck & Co., Inc., such as Senior Director, Managed Care; General Manager, West Point Pharma; and Director of Marketing, West Point Pharma. From December 1984 until June 1993, Mr. Doll held a number of sales and marketing management positions at Lemmon Company, a division of Teva. Mr. Doll has an MBA in Pharmaceutical Marketing from Saint Joseph's University.

## **ADDITIONAL INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. So long as we are subject to the SEC's reporting requirements, we will continue to furnish the reports and other required information to the SEC.

You may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operations of the Public Reference Room. Our SEC filings are also available on the SEC's Internet site (<http://www.sec.gov>).

The Company's common stock is traded on the NASDAQ National Market under the symbol "IPXL." You may also read reports, proxy statements and other information we file at the offices of the National Association of Securities Dealers, Inc., 1735 K Street, N.W., Washington, DC 20006.

Our Internet address is [www.impaxlabs.com](http://www.impaxlabs.com). We make available, free of charge on 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 or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

In addition, we will provide, at no cost, paper or electronic copies of our reports and other filings made with the SEC (except for exhibits) upon request. Requests should be directed to Corporate Secretary, Impax Laboratories, Inc., 30831 Huntwood Avenue, Hayward, CA 94544.

The information on the websites listed above is not, and should not be, considered part of this annual report on Form 10-K and is not incorporated by reference in this document. These websites are, and are only intended to be, inactive textual references.

## **ITEM 2. PROPERTIES**

We currently have seven facilities, as follows:

### Building 1 – Hayward, California

This 35,125 square foot building is our corporate headquarters and primary research and development center. Of the total 35,125 square feet, approximately 4,500 square feet are used for the research and development laboratory and pilot plant, 4,500 square feet are used for the analytical laboratories, 11,700 square feet are used for the administrative functions, and 14,425 square feet are used for warehousing. We purchased this previously leased property in June 2001 for \$3,800,000. The land and building serve as partial collateral for a Cathay Bank loan.

### Building 2 – Hayward, California

This 50,400 square foot building serves as our primary manufacturing center and includes a 25,000 square foot manufacturing area, a 9,000 square foot analytical laboratory, a 7,400 square foot office and administration area, and a 9,000 square foot warehouse. The facility was totally rebuilt inside to accommodate the manufacturing and testing of pharmaceutical products. This work was completed in June 2002 and is fully operational. This facility also includes a two and one-half acre unimproved lot for future expansion. We purchased this previously leased property in November 2001 for \$4,900,000. The land and building serve as partial collateral for a Cathay Bank loan.

### Building 3 – Hayward, California

This 14,400 square foot facility includes some of our administrative functions, accounting, information technology, and human resources, and is adjacent to our Building 1. The facility includes approximately 10,400 square feet of office and administration area, and 4,000 square feet of warehouse area. This facility is subject to a lease with a term from November 2002 through December 2005.

#### Building 4 – Philadelphia, Pennsylvania

This 113,000 square foot facility is our primary commercial center for sales and marketing, packaging, warehousing, and distribution of the Company's products.

We own this facility that consists of a three-story brick, interconnected building. The interior of the building has been renovated and modernized since 1993 and includes new dust collection and environmental control units for humidity and temperature control. The land and the building serve as partial collateral for two Pennsylvania Industrial Development Authority ("PIDA") loans.

We also own an adjacent property of 1.04 acres, of which 0.50 acres are paved for parking.

#### Building 5 – Hayward, California

This 61,800 square foot building is used for warehousing production materials. The lease period for this building is from October 2003 through October 2005.

#### Building 6 – Pleasanton, California

This 3,280 square foot facility will be used for research and development of new products. The lease period is from February 2004 through February 2007.

#### Building 7 – New Britain, Pennsylvania

This 44,000 square foot facility will be primarily used for sales and marketing, and additional warehousing space. The lease period for this facility is from April 2004 through April 2009.

In all our facilities we maintain an extensive equipment base, much of which is new or recently reconditioned and automated, including equipment for the packaging and manufacturing of compressed tablets, coated tablets, and capsules. The packaging equipment includes fillers, cottoners, cappers, and labelers. The manufacturing and research and development equipment includes mixers and blenders for capsules and tablets, automated capsule fillers, tablet presses, particle reduction, sifting equipment, and tablet coaters. We also maintain two well-equipped, modern laboratories used to perform all the required physical and chemical testing for the products. The Company also maintains a broad variety of material handling and cleaning, maintenance, and support equipment. The Company owns substantially all of its manufacturing equipment and believes that its equipment is well maintained and suitable for its requirements.

We maintain property and casualty and business interruption insurance in amounts we believe are sufficient and consistent with practices for companies of comparable size and business.

### **ITEM 3. LEGAL PROCEEDINGS**

#### **PATENT LITIGATION**

There has been substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use, and sale of new products that are the subject of conflicting patent rights. One or more patents cover most of the brand name controlled-release products for which we are developing generic versions. Under the Hatch-Waxman Amendments, when a drug developer files an ANDA for a generic drug, and the developer believes that an unexpired patent which has been listed with the FDA as covering that brand name product will not be infringed by the developer's product or is invalid or unenforceable, the developer must so certify to the FDA. That certification must also be provided to the patent holder, who may challenge the developer's certification of non-infringement, invalidity or unenforceability by filing a suit for patent infringement within 45 days of the patent holder's receipt of such certification. If the patent holder files suit, the FDA can review and approve the ANDA, but is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered, or 30 months from the date the certification was received, whichever is sooner. Should a patent holder commence a lawsuit with respect to an alleged patent infringement by us, the uncertainties inherent in

patent litigation make the outcome of such litigation difficult to predict. The delay in obtaining FDA approval to market our product candidates as a result of litigation, as well as the expense of such litigation, whether or not we are successful, could have a material adverse effect on our results of operations and financial position. In addition, there can be no assurance that any patent litigation will be resolved prior to the 30-month period. As a result, even if the FDA were to approve a product upon expiration of the 30-month period, we may not commence marketing that product if patent litigation is still pending.

Lawsuits have been filed against us in connection with fourteen of our Paragraph IV filings. The outcome of such litigation is difficult to predict because of the uncertainties inherent in patent litigation.

### **AstraZeneca AB et al. v. IMPAX: The Omeprazole Cases**

In May 2000, AstraZeneca AB and four of its related companies filed suit against IMPAX in the U.S. District Court in Wilmington, Delaware claiming that IMPAX's submission of an ANDA for Omeprazole Delayed Release Capsules, 10 mg and 20 mg, constitutes infringement of six U.S. patents relating to AstraZeneca's Prilosec product. The action seeks an order enjoining IMPAX from marketing Omeprazole Delayed Release Capsules, 10 mg and 20 mg until February 4, 2014, and awarding costs and attorney fees. There is no claim for damages.

In February 2001, AstraZeneca and the same related companies filed the same suit against IMPAX in the same federal court in Delaware for infringement, based upon IMPAX's amendment to its ANDA adding 40 mg strength Omeprazole Delayed Release Capsules.

AstraZeneca filed essentially the same lawsuits against nine other generic pharmaceutical companies (Andrx, Genpharm, Cheminor, Kremers, LEK, Eon, Mylan, Apotex, and Zenith). Due to the number of these cases, a multidistrict litigation proceeding, *In re Omeprazole 10 mg, 20 mg, and 40 mg Delayed Released Capsules Patent Litigation*, MDL-1291, has been established to coordinate pre-trial proceedings. Both lawsuits filed by AstraZeneca against IMPAX have been transferred to the multidistrict litigation.

Early in the multidistrict litigation, the trial court ruled that one of the six patents-in-suit was not infringed by the sale of a generic omeprazole product and that certain other patents were invalid. These rulings effectively eliminated four patents from the trial of these infringement cases, although AstraZeneca may appeal these rulings as part of the overall appeal process in the case.

On October 11, 2002, after a trial involving Andrx, Genpharm, Cheminor, and Kremers, the trial judge handling the multidistrict litigation ruled on AstraZeneca's complaints that three of these four defendants (First Wave Defendants) infringed the remaining patents-in-suit. The trial judge ruled that three of the First Wave defendants, Andrx, Genpharm, and Cheminor, infringed the remaining two patents asserted by AstraZeneca in its complaints, and that those patents are valid until 2007. In the same ruling, the trial court ruled that the remaining First Wave Defendant, Kremers, did not infringe either of the remaining two patents. This defendant's formulation differed from the formulation used by the other First Wave Defendants in several respects. In mid-December 2003, the U.S. Court of Appeals for the Federal Circuit affirmed the October 2002 ruling in all respects. Subsequent petitions for rehearing have been denied.

The formulation that IMPAX would employ in manufacturing its generic equivalent of omeprazole has not been publicly announced. IMPAX's formulation has elements that resemble those of other First Wave Defendants, but it also has elements that differ. Although the ruling by the trial court in the multidistrict litigation has a significant effect on the course of AstraZeneca's litigation against IMPAX, application of the trial court's opinion is not certain. IMPAX believes that it has defenses to AstraZeneca's claims of infringement, but the opinion rendered by the trial court in the First Wave cases makes the outcome of AstraZeneca's litigation against IMPAX uncertain.

Two of the remaining six defendants (Second Wave Defendants) filed Motions for Summary Judgment of Non-Infringement, based upon the October 2002 ruling. The trial court has deferred ruling on those motions until discovery is completed.

In December 2003, the trial court entered a new scheduling order governing pre-trial proceedings relating to the Second Wave Defendants, including IMPAX. The schedule for completion of the litigation in the Second Wave, including AstraZeneca's litigation against IMPAX, now provides that all fact discovery (with certain exceptions) is complete. AstraZeneca's expert reports on issues as to which it bears the burden of proof, including issues of alleged infringement, were produced on February 17, 2004. IMPAX's responsive expert reports will be due in July 2004. Any rebuttal reports by AstraZeneca will be required to be produced by mid-August 2004. Depositions of the parties' experts are expected to occur thereafter and to be completed by mid-September 2004. Motions for Summary Judgment and responses must be filed and fully briefed by mid-November 2004. Given the delays which have thus far occurred in the litigation and the number of

experts already designated by the parties, it is uncertain whether the expert depositions can be completed in the time allotted by the present schedule.

Under the scheduling order, any further Motions for Summary Judgment must be filed by early Fall, and they will be heard by the trial court after briefing is completed in November 2004. IMPAX may file Motions for Summary Judgment, including a Motion for Summary Judgment of Non-Infringement, following the close of all discovery. If the case is not resolved by summary judgment, the case involving IMPAX will be returned to the U.S. District Court in Delaware for trial. It is likely, given the proceedings in the First Wave cases, that the case against IMPAX will be transferred back to New York for a consolidated trial before the same judge who decided the First Wave cases. Trial will commence as soon as practicable thereafter. If IMPAX does not file a Motion for Summary Judgment, or if such a Motion is denied, the court will schedule a date for trial. IMPAX intends to vigorously defend the action brought by AstraZeneca.

In August 2003, the court issued an order dismissing four of the patents-in-suit, three with prejudice. On September 30, 2003, as a result of the court's dismissal, AstraZeneca served each of the Second Wave Defendants, including IMPAX, with an amended complaint. In October 2003, IMPAX filed an answer to the amended complaint in which we asserted a new counterclaim with antitrust allegations. The counterclaim will be severed, and proceedings relating to it will be stayed until after trial of the patent infringement case.

### **Abbott Laboratories et al. v. IMPAX: The Fenofibrate Capsule Cases**

In August 2000, Abbott Laboratories and Fournier Industrie et Santee and a related company, filed suit against IMPAX in the U.S. District Court in Chicago, Illinois claiming that IMPAX's submission of an ANDA for Fenofibrate (Micronized) Capsules, 67 mg, constitutes infringement of a U.S. patent owned by Fournier and exclusively licensed to Abbott, relating to Abbott's Tricor product. In December 2000, Abbott and Fournier filed a second action against IMPAX in the same court making the same claims against IMPAX's 200 mg Fenofibrate (Micronized) Capsules. A third action was filed for IMPAX's 134 mg Fenofibrate (Micronized) Capsules in March 2001. All three actions seek an injunction preventing IMPAX from marketing its Fenofibrate Capsules until January 19, 2009, and an award of damages for any commercial manufacture, use, or sale of IMPAX's Fenofibrate Capsules, together with costs and attorney fees.

Abbott and Fournier have filed essentially the same lawsuits against Novopharm/Teva also in the U.S. District Court in Chicago.

IMPAX responded to the complaints by filing an answer asserting that its proposed generic fenofibrate product does not infringe the patent-in-suit and by asserting that the patent-in-suit is invalid and not enforceable against IMPAX.

In March 2002, Novopharm's Motion for Summary Judgment of Non-Infringement was granted. The grounds for finding non-infringement by Novopharm were applicable to IMPAX. IMPAX filed its own Motion for Summary Judgment of Non-Infringement. In March 2003, the Court of Appeals for the Federal Circuit affirmed the grant of Novopharm's Motion for Summary Judgment of Non-Infringement. Shortly thereafter, IMPAX's Motion for Summary Judgment of Non-Infringement was granted by the District Court and, as of February 27, 2004, no appeal has been taken.

Abbott's and Fournier's petition requesting a rehearing before the Federal Circuit in its appeal in the Novopharm case was denied, and on July 11, 2003, the complaint was dismissed with prejudice.

### **GlaxoSmithKline (Glaxo) v. IMPAX: The Bupropion Cases**

Glaxo filed a Complaint (Case No. 00-04403) against IMPAX in the U.S. District Court for the Northern District of California on November 3, 2000 alleging infringement of U.S. Patent No. 5,427,798 covering Wellbutrin SR and Zyban. On November 7, 2000, IMPAX filed its Answer to the Complaint which included defenses to the infringement claim, and counterclaimed for patent invalidity. Glaxo has filed suit against Andrx, Watson, Eon (only with regard to Wellbutrin SR) and Excel for similar ANDA filings.

IMPAX filed a Summary Judgment Motion, based upon prosecution history estoppel grounds. The parties completed the briefing on this issue and oral argument was held on November 19, 2001. At the request of the Court, in July 2002, both sides submitted briefs on the impact of the recent Supreme Court decision in *Festo v. Shoketsu Kinzoku Kogyo Kabushi Co., et al.* (which we refer to as the *Festo* decision) to the pending Motion for Summary Judgment. IMPAX brought an additional Motion for Summary Judgment in early August 2002, requesting that the court apply another court's decision which limited the scope of the Glaxo '798 patent.

On August 21, 2002, IMPAX's Motions for Summary Judgment were granted. Glaxo has appealed this decision to the Court of Appeals for the Federal Circuit and that appeal was fully briefed on January 22, 2003. Oral argument was heard on June 2, 2003 and the District Court's decision in favor of IMPAX was affirmed by the Court of Appeals on January 29, 2004. Glaxo has filed a request for rehearing or rehearing en banc.

Previously, Glaxo had decided to settle its Bupropion Hydrochloride 100 mg and 150 mg Extended Release Tablets litigation with Watson Pharmaceuticals on terms that are confidential.

### **Schering-Plough Corporation v. IMPAX: The Loratadine Cases**

On January 2, 2001, Schering-Plough Corporation ("Schering-Plough") sued IMPAX in the U.S. District Court for the District of New Jersey (Case No. 01-0009), alleging that IMPAX's proposed Loratadine and Pseudoephedrine Sulfate 24-hour Extended Release Tablets, containing 10 mgs of loratadine and 240 mgs of pseudoephedrine sulfate, infringe U.S. Patent Nos. 4,659,716 (the "'716 patent") and 5,314,697 (the "'697 patent"). Schering-Plough has sought to enjoin IMPAX from obtaining FDA approval to market its 24-hour extended release tablets until the '697 patent expires in 2012. Schering-Plough has also sought monetary damages should IMPAX use, sell or offer to sell its loratadine product prior to the expiration of the '697 patent. IMPAX filed its Answer to the Complaint on February 1, 2001, and IMPAX has denied that it infringes any valid and/or enforceable claim of the '716 or '697 patent.

On January 18, 2001, Schering-Plough sued IMPAX in the U.S. District Court for the District of New Jersey (Case No. 01-0279), alleging that IMPAX's proposed orally-disintegrating loratadine tablets ("ODT") infringe claims of the '716 patent. Schering-Plough has sought to enjoin IMPAX from obtaining approval to market its ODT products until the '716 patent expires in 2004. Schering-Plough has also sought monetary damages should IMPAX use, sell, or offer to sell its loratadine product prior to the expiration of the '716 patent. IMPAX filed its Answer to the Complaint on February 27, 2001, and has denied that it infringes any valid or enforceable claim of the '716 patent.

On February 1, 2001, Schering-Plough sued IMPAX in the U.S. District Court for the District of New Jersey (Case No. 01-0520), alleging that IMPAX's proposed Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets, containing 5 mgs of loratadine and 120 mgs of pseudoephedrine sulfate, infringe claims of the '716 patent. Schering-Plough has sought to enjoin IMPAX from obtaining approval to market its 12-hour extended release tablets until the '716 patent expires in 2004. Schering-Plough has also sought monetary damages should IMPAX use, sell, or offer to sell its loratadine product prior to the expiration of the '716 patent. IMPAX filed its Answer to the Complaint on February 27, 2001 and has denied that it infringes any valid or enforceable claim of the '716 patent.

These three cases have been consolidated for the purposes of discovery with seven other cases in the District of New Jersey in which Schering-Plough sued other corporations who have sought FDA approval to market generic loratadine products.

Fact discovery and expert discovery on issues related to the '716 patent have ended. In accordance with the schedule set by the Court, the parties filed Initial Dispositive Motions on issues related to the '716 patent on October 31, 2001, and these motions were fully briefed in December 2001. Oral argument on two of the Dispositive Motions took place on June 26, 2002. On August 8, 2002, the Court granted Defendants' Motion for Summary Judgment that certain claims of the '716 Patent are invalid. Schering-Plough appealed the decision to the U.S. Court of Appeals for the Federal Circuit. On August 1, 2003, the Court of Appeals for the Federal Circuit in Washington, D.C. upheld the lower court decision that ruled against certain claims by Schering-Plough of the '716 patent in litigation relating to the antihistamine product Claritin (loratadine). On August 15, 2003, Schering-Plough filed a combined petition for panel rehearing and rehearing en banc. The Federal Circuit requested a brief from Appellees in response to Schering's petition which was filed on September 30, 2003. On October 28, 2003, the Court of Appeals denied Schering's petition for panel rehearing and rehearing en banc.

On October 27, 2003, the Company announced that it had entered into a Settlement and License Agreement with Schering-Plough Corporation related to IMPAX's generic version of Claritin-D 24-hour (Loratadine and Pseudoephedrine Sulfate, 10 mg/240 mg) Extended Release Tablets. This agreement resolved all of the remaining outstanding patent litigation between the parties on this product.

### **Aventis Pharmaceuticals Inc., et al. v. IMPAX: The Fexofenadine Cases**

On March 25, 2002, Aventis Pharmaceuticals Inc., Merrell Pharmaceuticals Inc., and Carderm Capital L.P. (collectively referred to as Aventis) sued IMPAX in the U.S. District Court for the District of New Jersey (Civil Action No. 02-CV-1322) alleging that IMPAX's proposed fexofenadine and pseudoephedrine hydrochloride tablets, containing 60 mg of fexofenadine and 120 mg of pseudoephedrine hydrochloride, infringe U.S. Patent Nos. 6,039,974; 6,037,353; 5,738,872; 6,187,791; 5,855,912; and 6,113,942. On November 7, 2002, Aventis filed an amended complaint, which added an allegation that

IMPAX's Fexofenadine and Pseudoephedrine Hydrochloride 60 mg/120 mg Extended Release Tablet product infringes U.S. Patent No. 6,399,632. Aventis seeks an injunction preventing IMPAX from marketing its Fexofenadine and Pseudoephedrine Hydrochloride 60 mg/120 mg Extended Release Tablet product until the patents-in-suit have expired, and an award of damages for any commercial manufacture, use, or sale of IMPAX's Fexofenadine and Pseudoephedrine Hydrochloride 60 mg/120 mg Extended Release Tablet product, together with costs and attorneys' fees.

Because of the pending procedural motions, discovery is in its early stages. IMPAX believes that it has defenses to the claims made by Aventis based on noninfringement and invalidity. The court has scheduled trial for September 2004.

Aventis has also filed a suit against Barr Laboratories, Inc., Mylan Pharmaceuticals, Inc., Dr. Reddy's Pharmaceuticals and Teva Pharmaceuticals USA, Inc. in New Jersey asserting the same patent infringement against these defendants' proposed Fexofenadine and Pseudoephedrine or Fexofenadine products. The IMPAX case has been consolidated for trial with the Barr, Mylan, Dr. Reddy and Teva cases.

On July 23, 2003, IMPAX filed Summary Judgment motions for non-infringement of U.S. Patent Nos. 6,039,974, 6,113,942, and 5,855,912; and for non-infringement and invalidity of U.S. Patent No. 5,738,872. Opposition papers were filed on August 11, 2003. Reply papers were filed on September 24, 2003. On October 24, 2003, IMPAX filed a brief discussing the impact of the recent Festo decision on their Motions for Summary Judgment of non-infringement. Oral argument for the Summary Judgment Motion regarding the '912, '942, and '974 patents was heard on November 3, 2003. Oral argument for the Summary Judgment Motion regarding the '872 patent was heard on December 8, 2003. IMPAX is currently awaiting a decision on these motions.

#### **Purdue Pharma L.P. et al. v IMPAX: The Oxycodone Cases**

On April 11, 2002, Purdue Pharma and related companies filed a complaint in the U.S. District Court for the Southern District of New York alleging that IMPAX's submission of ANDA No. 76-318 for 80 mg OxyContin Tablets infringes three patents owned by Purdue. The Purdue patents are U.S. Patent Nos. 4,861,598, 4,970,075 and 5,266,331; all directed to controlled release opioid formulations. On September 19, 2002, Purdue filed a second Infringement Complaint regarding IMPAX's 40 mg OxyContin generic product. On October 9, 2002, Purdue filed a third Infringement Complaint regarding IMPAX's 10 mg and 20 mg OxyContin generic products. IMPAX filed its answer and counterclaims in each case on October 3, 2003. On November 25, 2003, Purdue submitted their reply to our counterclaims. Purdue is seeking, among other things, a court order preventing IMPAX from manufacturing, using or selling any drug product that infringes the subject Purdue patents. IMPAX had disputed jurisdiction of the New York courts and brought an action for a Declaratory Judgment of Patent Invalidity in Delaware. The New York court recently denied IMPAX's Motion to Dismiss and the Delaware action was dismissed.

Purdue previously sued Boehringer Ingelheim/Roxane, Endo and Teva on the same patents. One or more of these defendants may resolve the invalidity issues surrounding the Purdue patents prior to IMPAX' case going to trial. The Boehringer Ingelheim/Roxane suit is stayed. The Endo action was tried in June 2003 and post trial briefs have been filed. In January 2004, the judge in the Endo action ruled that the three patents in suit, the same patents that Purdue had asserted against IMPAX, are unenforceable because they were inequitably procured and enjoined their enforcement. There can be no assurances that such ruling will not be challenged or, if sustained upon challenge, that the rulings in IMPAX's cases will be consistent with such rulings.

#### **IMPAX v. Aventis Pharmaceuticals, Inc.: The Riluzole Case**

In June 2002, IMPAX filed suit against Aventis Pharmaceuticals, Inc. in the U.S. District Court in Wilmington, Delaware, seeking a declaration that the filing of an ANDA to engage in a commercial manufacture and/or sale of Riluzole 50 mg Tablets for treatment of patients with amyotrophic lateral sclerosis (ALS) does not infringe claims of Aventis' U.S. Patent No. 5,527,814 ('814 patent) and a declaration that this patent is invalid.

In response to IMPAX's complaint, Aventis filed counterclaims for direct infringement and inducement of infringement of the '814 patent. In December 2002, the district court granted Aventis' Motion for Preliminary Injunction and enjoined IMPAX from infringing, contributory infringing, or inducing any other person to infringe Claims 1, 4 or 5 of the '814 patent by selling, offering for sale, distributing, marketing or exporting from the United States any pharmaceutical product or compound containing riluzole or salt thereof for the treatment of ALS.

The trial was completed on October 30, 2003, and post-trial briefing was completed in December 2003. IMPAX is pursuing its assertions that claims of the '814 patent are invalid in view of prior art and are unenforceable in view of inequitable conduct committed during the prosecution of the patent before the USPTO.

On January 30, 2004, the court denied IMPAX's Motion for Summary Judgment on inequitable conduct and, on February 5, 2004, the court denied IMPAX's Motion for Summary Judgment on non-infringement of certain claims. As of February 27, 2004, the court did not issue its trial rulings and did not rule on the third pre-trial Motion for Summary Judgment based on invalidity of the patent-in-suit.

If IMPAX is not ultimately successful in proving invalidity or unenforceability, there is a substantial likelihood that the court will enter a Permanent Injunction enjoining IMPAX from marketing Riluzole 50 mg Tablets for the treatment of ALS in the United States until the expiration of the '814 patent (June 18, 2013). If IMPAX is ultimately successful in proving either defense, the Preliminary Injunction would be set aside and IMPAX would be permitted to market its Riluzole 50 mg Tablet product for the treatment of ALS in the United States.

#### **Abbott Laboratories v. IMPAX: The Fenofibrate Tablet Cases**

In January 2003, Abbott Laboratories and Fournier Industrie et Sante and a related company filed suit against IMPAX in the U.S. District Court in Wilmington, Delaware claiming that IMPAX's submission of an ANDA for Fenofibrate Tablets, 160 mg, constitutes infringement of two U.S. patents owned by Fournier and exclusively licensed to Abbott, relating Abbott's Tricor tablet product.

In March 2003, Abbott and Fournier filed a second action against IMPAX in the same court making the same claims against IMPAX's 54 mg Fenofibrate Tablets. These cases were consolidated in April 2003.

Abbott and Fournier have filed essentially the same lawsuits against Teva, also in the U.S. District Court in Wilmington, Delaware.

In September 2003, Abbott and Fournier filed a third action against IMPAX in the U.S. District Court in Wilmington, Delaware, claiming that IMPAX's submission of its ANDA for 54 and 160 mg Fenofibrate Tablets constitutes infringement of a third patent recently issued to Fournier and exclusively licensed to Abbott. This action was also consolidated with the two previously consolidated actions in December 2003. In January 2004, Abbott and Fournier filed a fourth action relating to IMPAX's 54 mg and 160 mg Fenofibrate Tablets based upon a claim of infringement of a fourth patent. All four cases were consolidated in March 2004. Discovery in the consolidated cases closes in June 2004 and the trial is currently set for June 2005. IMPAX has responded to all four complaints by asserting that its proposed generic Fenofibrate Tablet products do not infringe the patents-in-suit and by asserting that the patents-in-suit are invalid.

All four actions seek an injunction preventing IMPAX from marketing its Fenofibrate Tablet products until the expiration of the patents (January 9, 2018) and an award of damages for any commercial manufacture, use, or sale of IMPAX's Fenofibrate Tablet product, together with costs and attorney fees.

#### **Merck & Co., Inc. v. IMPAX: The Carbidopa and Levodopa Case**

On February 24, 2003, Merck & Co., Inc. filed a lawsuit against IMPAX in the U.S. District Court in Delaware alleging patent infringement related to our filing of an ANDA for a generic version of Sinemet CR Tablets. On April 8, 2003, Merck & Co., Inc. withdrew its lawsuit alleging patent infringement related to our filing of the ANDA for a generic version of Sinemet CR Tablets

#### **Solvay Pharmaceuticals v. IMPAX: The Creon Case**

On April 11, 2003, Solvay Pharmaceuticals, Inc., manufacturer of the Creon line pancreatic enzyme products, brought suit against IMPAX in the U.S. District Court for the District of Minnesota claiming that IMPAX has engaged in false advertising, unfair competition, and unfair trade practices under federal and Minnesota law in connection with the Company's marketing and sale of its Lipram products. The suit seeks actual and consequential damages, including treble damages, attorneys' fees, injunctive relief and declaratory judgments that would prohibit the substitution of Lipram for prescriptions of Creon. On June 6, 2003, IMPAX filed a Motion for Dismissal of Plaintiff's Complaint, which seeks to dismiss each count of Solvay's complaint. Oral argument on that Motion was heard on November 7, 2003. On January 29, 2004, the U.S. District Court issued a ruling on IMPAX's Motion for Dismissal, dismissing two of the counts set forth in the Complaint, including the count which sought a declaratory judgment that Lipram may not lawfully be substituted for prescriptions of Creon. IMPAX believes it has defenses to Solvay's allegations and intends to pursue these defenses vigorously.

### **Alza Corporation v. IMPAX: The Oxybutynin Case**

On September 4, 2003, Alza Corporation (“Alza”) filed a lawsuit against IMPAX in the U.S. District Court for the Northern District of California alleging patent infringement of one patent related to IMPAX’s filing of an ANDA for a generic version of Ditropan XL (Oxybutynin Chloride) Tablets, 5 mg, 10 mg, and 15 mg. Alza seeks an injunction, a declaration of infringement, attorney’s fees and costs. On October 24, 2003, IMPAX filed its Answer to the Complaint, which included defenses to the infringement claim, and counterclaimed for patent non-infringement and invalidity.

On October 24, 2003, IMPAX filed a lawsuit against Alza in the U.S. District Court for the Northern District of California seeking a declaratory judgment that four Alza patents relating to IMPAX’s filing of an ANDA for a generic version of Ditropan XL (Oxybutynin Chloride) Tablets, 5 mg, 10 mg, and 15 mg (the “Product”) are invalid and/or not infringed by the commercial manufacture, use, offer for sale, sale, or importation of the IMPAX Product. On November 17, 2003, Alza moved to dismiss the Company’s complaint for lack of subject matter jurisdiction based on Alza’s argument that there is no case or controversy between the parties with respect to these four patents. That motion is pending.

### **Shire Laboratories Inc. v IMPAX: The Adderall Case**

On December 29, 2003, Shire Laboratories, Inc., a subsidiary of Shire Pharmaceuticals Group, PLC, filed a lawsuit against IMPAX in the U.S. District Court for the District of Delaware alleging patent infringement on U.S. Patent Nos. 6,322,819 and 6,605,300 related to filing of an ANDA to market a generic version of Adderall 30 mg capsules. IMPAX filed its answer was filed on January 20, 2004, denying infringement and contesting the validity of both patents. As of February 27, 2004, no trial date was scheduled.

## **OTHER LITIGATION**

### **State of California v. IMPAX**

On August 7, 2003, IMPAX received an Accusation from the BNE alleging that IMPAX failed to maintain adequate controls to safeguard precursors from theft or loss regarding our pseudoephedrine product in January 2003. IMPAX is currently reviewing this Accusation and has entered into discussions with the BNE to bring resolution to this matter. IMPAX has implemented a number of remedial measures aimed at improving the security and accountability of precursor substances used by IMPAX and regulated by the BNE. IMPAX hopes to resolve this matter prior to June 23, 2004, when a hearing has been scheduled with the BNE.

Other than the legal proceedings described above, we are not aware of any other material pending or threatened legal actions, private or governmental, against us. However, as we file additional applications with the FDA that contain Paragraph IV Certifications and develop new products, it is likely we will become involved in additional litigation related to those filings or products.

## **INSURANCE**

As part of our patent litigation strategy, we obtained two policies covering up to \$7 million of patent infringement liability insurance from American International Specialty Line Company (“AISLIC”), an affiliate of AIG International. This litigation insurance covers us against the costs associated with patent infringement claims made against us relating to seven of the ANDAs we filed under Paragraph IV of the Hatch-Waxman Amendments. Correspondence received from AISLIC indicated that, as of February 4, 2004, one of the policies had approximately \$19,770 remaining on the limit of liability and the second of the policies had reached its limit of liability. In addition, pursuant to the agreement with Teva, for the six products with ANDAs filed with the FDA at the time of the agreement, Teva will pay 50% of the attorneys’ fees and costs in excess of \$7.0 million. For three of the products with ANDAs filed with the FDA since the agreement was signed, Teva will pay 45% of the attorneys’ fees and costs, and for the remaining three products, Teva will pay 50% of the attorneys’ fees and costs.

While Teva has agreed to pay 45% to 50% of the attorneys’ fees and costs in excess of \$7.0 million related to the twelve products covered by our strategic alliance agreement with them, we will be responsible for the remaining expenses and costs for these products, and all of the costs associated with patent litigation for our other products and our future products.

We do not believe that this type of litigation insurance will be available to us on acceptable terms for our other current or future ANDAs. In those cases, our policy is to record such expenses as incurred.

Product liability claims by customers constitute a risk to all pharmaceutical manufacturers. We carry \$20 million of product liability insurance for our own manufactured products. This insurance may not be adequate to cover any product liability claims to which we may become subject.

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

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

## **PART II**

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

Our common stock is traded on the NASDAQ National Market under the symbol "IPXL." The following table sets forth the high and low sales prices for our common stock for the periods indicated below:

	<u>Price Range Per Share</u>	
	<u>High</u>	<u>Low</u>
<u>Year Ended December 31, 2003</u>		
Quarter ended March 31, 2003	\$5.45	\$3.01
Quarter ended June 30, 2003	\$12.55	\$4.51
Quarter ended September 30, 2003	\$16.49	\$10.74
Quarter ended December 31, 2003	\$15.00	\$11.57
<u>Year Ended December 31, 2002</u>		
Quarter ended March 31, 2002	\$13.72	\$6.70
Quarter ended June 30, 2002	\$8.38	\$6.90
Quarter ended September 30, 2002	\$7.10	\$3.15
Quarter ended December 31, 2002	\$6.11	\$2.75

As of March 2, 2004, there were approximately 126 holders of record and approximately 13,870 beneficial owners of our common stock.

We have never paid cash dividends on our common stock and have no present plans to do so in the foreseeable future. Our current policy is to retain all earnings, if any, for use in the operation of our business. The payment of future cash dividends, if any, will be at the discretion of the Board of Directors and will be dependent upon our earnings, financial condition, capital requirements and other factors as the Board of Directors may deem relevant. Our loan agreements and our strategic agreement with Teva prohibit the payment of dividends without the other party's consent.

On May 7, 2003, the Company completed a private placement of 4,394,081 shares of common stock and warrants to purchase 878,815 shares of common stock to a group of institutional investors for a purchase price of \$24.0 million. In addition, the investors purchased an additional 183,000 shares of common stock on May 16, 2003 for approximately \$1.0 million. Gross proceeds from the private placement were \$25.0 million. The net proceeds of \$23.3 million were used for general corporate purposes. The sales were exempt from registration pursuant to Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

If the Company issues shares of common stock or securities convertible into or exercisable for shares of common stock at a price less than \$5.462 per share prior to May 6, 2004, the Company is required to issue additional shares of common stock to the private placement purchasers equal to the additional number of shares such purchasers would have received at such lower price based on the consideration paid for the shares of common stock that such purchasers still hold from the private placement and any exercise of warrants purchased in the private placement.

Principal purchasers in the private placement (i.e., purchasers that purchased more than 1.0 million shares) are entitled to rights of first refusal with respect to certain offers and sales of the Company's securities prior to June 16, 2005.

The warrants are exercisable for a period of five years at an exercise price of \$7.421 per share. The warrants may also be exercised in a "cashless exercise." Both the warrant exercise price and the number of shares issuable upon exercise of the warrants are subject to adjustment for issuances of securities at prices below the exercise price of the warrant. If such lower

priced securities are issued prior to May 8, 2004, the exercise price will be adjusted to equal the price at which such securities were sold. If such lower priced securities are issued on or after May 8, 2004, the adjustment will be based on a weighted average formula. In addition, the exercise price and the number of securities issuable upon exercise are subject to adjustment for stock splits, stock dividends and certain other corporate events.

The securities sold in the private placement are entitled to registration rights. A Form S-3 registration statement registering the resale of the shares of common stock, the warrants and the shares of common stock underlying the warrants was filed with the Securities and Exchange Commission on June 6, 2003.

In September 2003, we issued 888,918 shares of common stock to Teva, paying \$13.5 million of the original \$22 million refundable deposit.

See Item 12 of this report for information on our equity compensation plans.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data as of and for each of the five years ended December 31, 2003, are derived from the financial statements of IMPAX. The data should be read together with IMPAX's financial statements and related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" which are included elsewhere in this report.

Statement of Operations Data (in thousands, except per share data)	For The Year Ended December 31,				
	1999 <sup>(1)</sup>	2000	2001	2002	2003
Net revenues <sup>(2)</sup> .....	\$1,240	\$10,170	\$6,591	\$24,515	\$58,818
Research and development .....	7,858 <sup>(3)</sup>	11,096	10,972	15,549	16,938
Total operating expenses .....	9,648	25,546	22,252	26,817	28,584
Operating loss .....	(9,333)	(25,092)	(25,330)	(20,794)	(13,178)
Net loss .....	(8,949)	(24,961)	(25,111)	(20,040)	(14,207)
Net loss per share (basic and diluted) .....	\$ (1.12)	\$ (0.91)	\$ (0.60)	\$ (0.42)	\$ (0.28)

In 2002, the Company adopted the non-amortization provisions of Statement of Financial Accounting Standards ("SFAS") No. 142. As a result of the adoption of SFAS No. 142, results of the years 2002 and 2003 do not include certain amounts of amortization of goodwill that are included in prior years' financial results. Included in total operating expenses for the years 1999, 2000 and 2001 is goodwill amortization, which was \$205,000, 4,604,000, and 3,888,000, respectively. See Note 2 to the Company's financial statements for additional information.

Balance Sheet Data	At December 31,				
	1999	2000	2001	2002	2003
Cash, cash equivalents and short-term investments .....	\$ 7,413	\$ 19,228	\$ 35,466	\$ 10,219	\$15,505
Restricted cash .....	—	—	—	10,000	10,000
Working capital .....	6,297	17,802	36,180	4,946	12,931
Total assets .....	61,705	67,128	97,612	104,403	132,706
Refundable deposit .....	—	—	22,876	22,000	5,000
Long term debt .....	—	1,345	6,868	9,105	8,854
Mandatorily redeemable convertible preferred stock .....	22,000	28,303	7,500	7,500	7,500
Accumulated deficit .....	(20,230)	(45,191)	(70,302)	(90,342)	(104,549)
Total stockholders' equity .....	30,278	30,754	52,448	41,064	66,108

<sup>(1)</sup> On December 14, 1999, Impax Pharmaceuticals, Inc. merged with and into Global Pharmaceuticals, Inc. For accounting purposes, the merger has been treated as a recapitalization of Impax Pharmaceuticals with Impax Pharmaceuticals deemed the acquirer of Global in a reverse acquisition. As a reverse acquisition, the historical operating results prior to the merger are those of Impax Pharmaceuticals and only include Global's operating results after the merger. The following unaudited pro forma information on results of operations assumes the companies had combined on January 1, 1999.

	Pro forma Year Ended <u>December 31, 1999*</u>
Operating revenue.....	\$ 9,446
Research and development.....	8,030
Operating loss .....	(15,608)
Net loss .....	(15,224)
Net loss per share (basic and diluted).....	\$ (0.71)

\*Excludes non-recurring charges related to acquisition of \$1,420 or \$(0.06) per share.

<sup>(2)</sup> We were considered a development stage company until December 14, 1999.

<sup>(3)</sup> Includes acquired in-process research and development of \$1,379.

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

### *Overview*

The net loss for the year ended December 31, 2003 was \$14,207,000 as compared to \$20,040,000 for the year ended December 31, 2002. The decrease in the net loss of \$5,833,000 was due to increased sales revenues, which partially offset increases in manufacturing expenses, research and development, and other operating expenses. The year-over-year sales increase was primarily due to the introduction of new products, such as the OTC Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets and Flavoxate Hydrochloride 100 mg Tablets, and higher sales of a number of existing products. During 2003, we continued to ramp-up production for new product introduction by purchasing additional equipment, and recruiting and training additional personnel. We also continued the investment in Research and Development. During 2003, we filed eight applications with the FDA and received nine ANDA approvals. We expect increased revenues in 2004, primarily due to new product introductions, contingent upon FDA approval of our ANDAs and positive resolution of patent litigations. We also expect that our investment in Research and Development area will continue to increase. During 2004, our general and administrative expenses are expected to increase, primarily due to higher professional fees and insurance premiums, and additional personnel.

### **Critical Accounting Policies**

In preparing the financial statements in conformity with accounting principles generally accepted in the United States of America, the Company's management must make decisions which impact the reported amounts and the related disclosures. Such decisions include the selection of the appropriate accounting principles to be applied and assumptions on which to base estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates, including those related to returns, rebates and chargebacks, inventory reserves, impaired assets and goodwill. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The Company's management believes the critical accounting policies described below are the most important to the fair presentation of the Company's financial condition and results. The policies require management's most significant judgments and estimates in the preparation of the Company's consolidated financial statements.

#### **1. Our critical accounting policies related to revenue recognition are as follows:**

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin ("SAB") 101 issued by the SEC in December 1999. We recognize revenue from the sale of products when the shipment of products is received and accepted by the customer. Provisions for estimated discounts, rebates, chargebacks, returns and other adjustments are provided for in the period the related sales are recorded. In December 2003, the Staff Accounting Bulletin (SAB) 104 was issued by the SEC. This bulletin revises and clarifies portions of Topic 13 of the Staff Accounting Bulletin to be consistent with current accounting and auditing guidance and SEC rules and regulations.

Emerging Issues Task Force (EITF) No. 00-21 supplemented SAB 101 for accounting for multiple element arrangements. The Company has entered into several strategic alliances that involve the delivery of multiple products

and services over an extended period of time. In multiple element arrangements, the Company must determine whether any or all of the elements of the arrangement can be separated from one another. If separation is possible, revenue is recognized for each deliverable when the revenue recognition criteria for the specific deliverable is achieved. If separation is not possible, revenue recognition is required to be spread over an extended period.

Under EITF No. 00-21, in an arrangement with multiple elements, the delivered item should be considered a separate unit of accounting if all of the following criteria are met:

- 1) the delivered item has value to the customer on a standalone basis;
- 2) there is objective and reliable evidence of the fair value of the undelivered item; and
- 3) if the arrangement included a general right of return, or whether delivery or performance of the undelivered item is considered probable.

The Company reviews all of the terms of its strategic alliances and follows the guidance from EITF No. 00-21 for multiple element arrangements.

## **2. Our critical accounting policy related to returns reserve is as follows:**

The sales return reserve is calculated using an historical lag period (that is, the time between when the product is sold and when it is ultimately returned as determined from the Company's system generated lag period report) and return rates, adjusted by estimates of the future return rates based on various assumptions which may include changes to internal policies and procedures, changes in business practices and commercial terms with customers, competitive position of each product, amount of inventory in the pipeline, the introduction of new products, and changes in market sales information.

Our returned goods policy requires prior authorization for the return, with corresponding credits being issued at the original invoice prices, less amounts previously granted to the customer for rebates and chargebacks. Products eligible for return must be expired and returned within one year following the expiration date of the product. Prior to 2002, we required returns of products within six months of expiration date. Because of the lengths of the lag period and volatility that may occur from quarter to quarter, we are currently using a rolling 21-month calculation to estimate our product return rate.

In addition to the rolling 21-month calculation, we review the level of pipeline inventory at major wholesalers to assess the reasonableness of our estimate of future returns. Although the pipeline inventory information may not always be accurate or timely, it represents another data point in estimating the sales returns reserve. If we believe that a wholesaler may have too much inventory on hand, a discussion with the wholesaler takes place and an action plan is developed to reduce inventory levels related to a particular product including, but not limited to, suspending new orders and redirecting the inventory to other distribution centers.

Further, in 2003, we have developed an order flagging mechanism based on historical purchases by individual customers. This new process allows the Company to evaluate any customer orders for quantities higher than historical purchases.

The Company believes that its estimated returns reserves were adequate at each balance sheet date since they were formed based on the information that was known and available, which were supported by the Company's historical experience when similar events occurred in the past, and management's overall knowledge of and experience in the generic pharmaceutical industry. In estimating its returns reserve, the Company looks to returns after the balance sheet date but prior to filing its financial statements to ensure that any unusual trends are considered.

At December 31, 2003 and 2002, our returns reserve was \$4.1 million and \$3.1 million, respectively.

## **3. Our critical accounting policy related to rebates and chargebacks is as follows:**

The sales rebates are calculated at the point of sale, based on pre-existing written customer agreements by product, and accrued on a monthly basis. Typically, these rebates are for a fixed percentage, as agreed to by the Company and the customer in writing, multiplied by the dollar volume purchased.

The vast majority of chargebacks are also calculated at the point of sale as the difference between the list price and contract price by product (with the wholesalers) and accrued on a monthly basis. Therefore, for these chargebacks, the amount is fixed and determinable at the point of sale. Additionally, a relatively small percentage of chargebacks are

estimated at the point of sale to the wholesaler as the difference between the wholesalers' contract price and the Company's contract price with retail pharmacies or buying groups. At December 31, 2003 and 2002, our reserves for rebates were \$2.7 million and \$1.5 million, respectively, and at December 31, 2003 and 2002, our reserves for chargebacks were \$4.1 million and \$1.4 million, respectively.

The Company believes it is important for the users of its financial statements to understand the key components, which reduce gross sales to net sales.

**4. Our critical accounting policy related to inventory is as follows:**

Inventory is stated at the lower of cost or market. Cost is determined using a standard cost method, which assumes a first-in, first-out (FIFO) flow of goods. Standard costs are revised annually, and significant variances between actual costs and standard costs are apportioned to inventory and cost of goods sold based upon inventory turnover. Historically, IMPAX considered product costs as inventory once the Company received FDA approval to market its ANDA related products. During 2003, the Company evaluated the risk of building commercial quantities as inventories of certain products that have not received FDA approval. For the first time, the Company decided to build and capitalize inventories in commercial quantities prior to receiving FDA approval. The Company, as do most companies in the generic pharmaceutical industry, may build inventories of certain ANDA related products that have not yet received FDA approval and/or satisfactory resolution of patent infringement litigation, when it believes that such action is appropriate to increase its commercial opportunity. Costs include materials, labor, quality control, and production overhead. Inventory is adjusted for short-dated, unmarketed inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required.

**5. Our critical accounting policy related to shelf stock reserve is as follows:**

A reserve is estimated at the point of sale for certain products for which it is probable that shelf-stock credits to customers for inventory remaining on their shelves following a decrease in the market price of these products will be granted. When estimating this reserve, we consider the competitive products, the estimated decline in market prices, and the amount of inventory in the pipeline. At December 31, 2003 and 2002, the shelf-stock reserve was \$232,000 and \$660,000, respectively.

**6. Our critical accounting policy related to impaired assets is as follows:**

The Company evaluates the carrying value of long-lived assets to be held and used, including definite lived intangible assets, on an annual basis, when events or changes in circumstances indicate that the carrying value may not be recoverable. The carrying value of a long-lived asset is considered impaired when the total projected undiscounted cash flows from such asset is separately identifiable and is less than its carrying value. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the projected cash flows discounted at a rate commensurate with the risk involved. Losses on long-lived assets to be disposed of are determined in a similar manner. As the Company's assumptions related to assets to be held and used are subject to change, additional write-downs may be required in the future.

**7. Our critical accounting policy related to goodwill is as follows:**

Prior to the adoption of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets," we amortized goodwill on a straight-line basis over its estimated useful life. The Company adopted the provisions of SFAS No. 142, effective January 1, 2002; no impairment was noted. Under the provisions of SFAS No. 142, the Company performs the annual review for impairment at the reporting unit level, which the Company has determined to be consistent with its business segment, that is, the entire Company.

Effective January 1, 2002, we evaluated the recoverability and measured the possible impairment of our goodwill under SFAS 142. The impairment test is a two-step process that begins with the estimation of the fair value of the reporting unit. The first step screens for potential impairment and the second step measures the amount of the impairment, if any. Our estimate of fair value considers publicly available information regarding the market capitalization of our Company, as well as (i) publicly available information regarding comparable publicly-traded companies in the generic pharmaceutical industry, (ii) the financial projections and future prospects of our business, including its growth opportunities and likely operational improvements, and (iii) comparable sales prices, if available.

As part of the first step to assess potential impairment, we compare our estimate of fair value for the Company to the book value of our consolidated net assets. If the book value of our net assets is greater than our estimate of fair value, we would then proceed to the second step to measure the impairment, if any.

The second step compares the implied fair value of goodwill with its carrying value. The implied fair value is determined by allocating the fair value of the reporting unit to all of the assets and liabilities of that unit as if the reporting unit had been acquired in a business combination, and the fair value of the reporting unit was the purchase price paid to acquire the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. If the carrying amount of the reporting unit goodwill is greater than its implied fair value, an impairment loss will be recognized in the amount of the excess.

On a quarterly basis, we perform a review of our business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, we would consult with one or more valuation specialists in estimating the impact on our estimate of fair value. We believe the estimation methods are reasonable and reflective of common valuation practices. We perform our annual goodwill impairment test in the fourth quarter of each year. No impairments were noted during the years ended December 31, 2003 and 2002.

At December 31, 2003 and 2002, the Company had recorded goodwill of approximately \$28 million.

## **General**

Impax Laboratories, Inc. was formed through a business combination on December 14, 1999, between Impax Pharmaceuticals, Inc., a privately held drug delivery company, and Global Pharmaceutical Corporation, a generic pharmaceutical company. Impax Pharmaceuticals, Inc. merged with and into Global, with Impax Pharmaceuticals, Inc. stockholders receiving 3.3358 shares of Global common stock for each share of Impax Pharmaceuticals, Inc. At the conclusion of the merger, Impax Pharmaceuticals, Inc. stockholders held over 70% of the combined company. For accounting purposes, the merger has been treated as a recapitalization of Impax Pharmaceuticals, Inc., with Impax Pharmaceuticals, Inc. deemed the acquirer of Global in a reverse acquisition. As a reverse acquisition, our historical operating results prior to the merger are those of Impax Pharmaceuticals, Inc. and only include the operating results of Global after the merger. In connection with the merger, Global changed its name to Impax Laboratories, Inc.

We are a technology based, specialty pharmaceutical company applying formulation and development expertise, as well as our drug delivery technology, to the development of controlled-release and niche generics, in addition to the development of branded products. As of March 5, 2004, we market thirty-one generic pharmaceuticals, which represent dosage variations of thirteen different pharmaceutical compounds, and have nineteen applications pending at the FDA, including six tentatively approved, that address \$6.8 billion in U.S. product sales for the twelve months ended December 31, 2003. Fifteen of these filings were made under Paragraph IV of the Hatch-Waxman Amendments. We have approximately twenty-four other products in various stages of development for which applications have not yet been filed. These products are generic versions of brand name pharmaceuticals that had U.S. market sales of approximately \$13.8 billion for the twelve months ended December 31, 2003.

## **Results of Operations**

We have incurred net losses in each year since our inception. We had an accumulated deficit of \$104,549,000 at December 31, 2003.

## **Year Ended December 31, 2003 Compared to Year Ended December 31, 2002**

### ***Revenues***

The net revenues for the year ended December 31, 2003 were \$58,818,000 as compared to \$24,515,000 for the year ended December 31, 2002. The year-over-year increase was primarily due to the introduction of OTC Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets, and Flavoxate Hydrochloride 100 mg Tablets during 2003; and higher sales, of Minocycline Hydrochloride 50 mg, 75 mg, and 100 mg Capsules, Fludrocortisone Acetate Tablets 0.1 mg, and the LIPRAM product family. In addition, in December 2003, the \$3,500,000 from Teva which represented the reversal of part of the refundable deposit under the strategic alliance agreement for its exercise of the exclusivity option for certain products. The following table summarizes the activity in net sales for the years ended December 31, 2003 and 2002:

(in \$000's)	<u>2003</u>	<u>2002</u>
Product sales	\$ 73,462	\$ 38,400
Revenue from reversal of refundable deposit from Teva	3,500	—
Other revenues	<u>1,753</u>	<u>757</u>
Gross Sales	\$ 78,715	39,157
Less:		
Actual returns	1,254	1,281
Increase in reserve for product returns	1,021	1,200
Rebates, chargebacks and other credits	<u>17,622</u>	<u>12,161</u>
Net Sales	<u>\$ 58,818</u>	<u>\$ 24,515</u>

Other revenues also represent revenues recognized pursuant to strategic agreements with Schering-Plough, Wyeth, and Novartis, which include up-front and milestone payments and the reversal of part of the refundable deposit from Teva, mentioned above.

The increase in rebates, chargebacks, and other credits was primarily due to increased sales volume.

### ***Cost of Sales***

The cost of sales for the year ended December 31, 2003 was \$43,769,000 as compared to \$18,492,000 for the same period in 2002. This increase in 2003 as compared to 2002 was primarily due to higher sales volume, increased expenses related to ramping up production for new product introduction, (personnel, supplies, and training), and \$2,365,000 of product batches written-off during the fourth quarter of 2003, primarily related to anticipated new product launches. Also in 2003, there were unabsorbed fixed costs due to excess capacity in Hayward, California and Philadelphia, Pennsylvania facilities.

### ***Gross Margin***

The gross margin for the year ended December 31, 2003 was \$15,049,000 as compared to a gross margin of \$6,023,000 for the year ended December 31, 2002. The increase in 2003 gross margin was due to higher net sales, and higher revenue from strategic alliances which include up-front and milestone payments of \$1,753,000 as compared to \$757,000 in 2002. In addition, the \$3,500,000 from Teva represented the reversal of part of the refundable deposit under the strategic alliance agreement for its exercise of the exclusivity option for certain products.

### ***Research and Development Expenses***

The research and development expenses for the year ended December 31, 2003 were \$17,185,000, less expense reimbursements of \$247,000 by Teva under the strategic alliance agreement signed in June 2001, as compared to \$16,254,000 less expense reimbursements of \$705,000 by Teva for the same period in 2002. The increase in 2003 research and development expenses as compared to 2002 was primarily due to higher legal expenses related to patents and alleged patent infringement lawsuits, and personnel costs.

### ***Selling Expenses***

The selling expenses for the year ended December 31, 2003 were \$2,497,000 as compared to \$2,836,000 for the same period in 2002. The decrease in selling expenses as compared to 2002 was due primarily to lower advertising, trade shows, and market research expenses.

### ***General and Administrative Expenses***

The general and administrative expenses for the year ended December 31, 2003 were \$9,176,000 as compared to \$8,396,000 for the same period in 2002. The increase in 2003 general and administrative expenses as compared to 2002 was primarily due to higher personnel costs, professional fees, and insurance premiums.

### ***Interest Income***

Interest income for the year ended December 31, 2003 was \$280,000 as compared to \$644,000 for the same period in 2002, primarily due to lower interest rates.

### ***Interest Expense***

The interest expense for the year ended December 31, 2003, was \$952,000 as compared to \$565,000 for the year ended December 31, 2002, as follows:

(in \$000's)	<u>2003</u>	<u>2002</u>
Interest expense	\$ 952	\$ 565
Forgiveness of interest on refundable deposit	—	(876)
Less: amount capitalized	<u>—</u>	<u>201</u>
Total interest expense	<u>\$ 952</u>	<u>\$ (110)</u>

The increase in the 2003 interest expense as compared to 2002 interest expense was primarily due to the revolving credit facility and term loan agreement signed with Congress Financial in October 2002. In December 2003, the Company transferred the \$25 million revolving credit facility and term loan from Congress Financial to Wachovia Bank N.A., thereby securing lower interest and less restrictive borrowing terms.

Under the strategic alliance agreement with Teva previously described in Part I, Item 1, if IMPAX received tentative or final approval for any of three products of the twelve covered by this agreement, the accrued interest on the \$22 million refundable deposit would be forgiven and no future interest would accrue. During 2002, we met this condition, resulting in the reversal of the accrued interest in the fourth quarter of 2002.

### ***Net Loss***

The net loss for the year ended December 31, 2003 was \$14,207,000, as compared to \$20,040,000 for the year ended December 31, 2002. The decrease in the net loss of \$5,833,000 was primarily due to increased sales revenues, which partially offset increases in manufacturing expenses, research and development, and operating expenses.

## **Year Ended December 31, 2002 Compared to Year Ended December 31, 2001**

### ***Overview***

The net loss for the year ended December 31, 2002 was \$20,040,000, as compared to \$25,111,000 for the year ended December 31, 2001, which included goodwill amortization of \$3,504,000. The decrease in the net loss of \$5,071,000 was primarily due to the absence of amortization of goodwill due to the adoption of SFAS 142 effective January 1, 2002 and increased sales that were partially offset by increases in research and development, and operating expenses. The 2002 results included a benefit from the reversal of the interest expense on the refundable deposit from Teva of approximately \$675,000.

### ***Revenues***

The net sales for the year ended December 31, 2002 were \$24,515,000 as compared to \$6,591,000 for the same period in 2001. The year-over-year increase resulted from increased sales of Fludrocortisone Acetate Tablets 0.1 mg, introduced at the end of the first quarter of 2002; Minocycline Hydrochloride 50 mg, 75 mg, and 100 mg Capsules, launched in the third quarter of 2002; Terbutaline Sulfate 2.5 mg and 5.0 mg Tablets, introduced since July 2001; Rimantadine Hydrochloride 100 mg Tablets, launched in the fourth quarter of 2002; higher Lipram sales; lower product returns; and revenue from strategic agreements. The following table summarizes the activity in net sales for the years ended December 31, 2002 and 2001:

(in \$000's)	<u>2002</u>	<u>2001</u>
Product sales	\$ 38,400	\$ 16,119
Other revenues	<u>757</u>	<u>-</u>
Gross Revenues	39,157	16,119
Less:		
Actual returns	1,281	2,841
Increase in reserve for product returns	1,200	1,684
Rebates, chargebacks and other credits	<u>12,161</u>	<u>5,003</u>
Net Revenues	<u>\$ 24,515</u>	<u>\$ 6,591</u>

Other revenues represent revenues recognized pursuant to strategic agreements with Schering-Plough, Wyeth, and Novartis.

The increase in rebates, chargebacks, and other credits was primarily due to increased sales volume.

### ***Cost of Sales***

The cost of sales for the year ended December 31, 2002 was \$18,492,000 as compared to \$9,669,000 for the same period in 2001. This increase in 2002 as compared to 2001 was primarily due to higher sales volume, startup costs of the new manufacturing facility in Hayward, California and unabsorbed fixed costs due to excess plant capacity in the Hayward, California and Philadelphia, Pennsylvania facilities. Because of the nature of returns (discontinued products or short-dated products), we concluded the returned inventory had no value to the Company and the products were destroyed.

### ***Gross Margin***

The gross margin for the year ended December 31, 2002 was \$6,023,000 as compared to a negative gross margin of \$3,078,000 for the year ended December 31, 2001. The increase in 2002 gross margin was due to higher net sales and better product mix from the newly introduced products.

### ***Research and Development Expenses***

The research and development expenses for the year ended December 31, 2002 were \$16,254,000, less expense reimbursements of \$705,000 by Teva under the strategic alliance agreement signed in June 2001, as compared to \$11,890,000 less expense reimbursements of \$918,000 by Teva for the same period in 2001. The increase in 2002 research and development expenses as compared to 2001 was primarily due to higher materials, product introduction, legal expenses related to patents and alleged patent infringement lawsuits, and personnel costs.

### ***Selling Expenses***

The selling expenses for the year ended December 31, 2002 were \$2,836,000 as compared to \$2,186,000 for the same period in 2001. The increase in selling expenses as compared to 2001 was due primarily to higher advertising, trade shows, and personnel costs.

### ***General and Administrative Expenses***

The general and administrative expenses for the year ended December 31, 2002 were \$8,396,000 as compared to \$9,258,000 for the same period in 2001, including goodwill amortization of approximately \$3,504,000. The decrease in 2002 general and administrative expenses as compared to 2001 was primarily due to the absence of goodwill amortization of approximately \$3,504,000, offset by higher personnel costs, professional fees, insurance premiums, and recruiting expenses.

### ***Interest Income***

Interest income for the year ended December 31, 2002 was \$644,000 as compared to \$1,148,000 for the same period in 2001, due to lower cash equivalents and short-term investments, and lower interest rates.

### ***Interest Expense***

The interest expense for the year ended December 31, 2002, was \$565,000 as compared to \$253,000 for the year ended December 31, 2001, as follows:

(in \$000's)	<u>2002</u>	<u>2001</u>
Interest expense	\$ 565	\$ 253
Interest on refundable deposit	—	876
Forgiveness of interest on refundable deposit	(876)	—
Less: amount capitalized	<u>201</u>	<u>200</u>
Total interest expense	<u>\$ (110)</u>	<u>\$ 929</u>

The increase in the 2002 interest expense as compared to the comparable period in 2001 was primarily due to the two Cathay Bank loans, which were outstanding for the full year in 2002 versus a partial year in 2001, and the revolving credit facility and term loan agreement signed with Congress Financial in October 2002.

Under the strategic alliance agreement with Teva previously described in Part I, Item 1, if IMPAX received tentative or final approval for any of three products of the twelve covered by this agreement, the accrued interest on the \$22 million refundable deposit would be forgiven and no future interest would accrue. During 2002, we met this condition, resulting in the reversal of the accrued interest in the fourth quarter of 2002 and no future interest will accrue.

### ***Net Loss***

The net loss for the year ended December 31, 2002 was \$20,040,000, as compared to \$25,111,000 for the year ended December 31, 2001, which included goodwill amortization of \$3,504,000. The decrease in the net loss of \$5,071,000 was primarily due to the absence of amortization of goodwill due to the adoption of SFAS 142 effective January 1, 2002 and increased sales that were partially offset by increases in research and development, and operating expenses. The 2002 results included a benefit from the reversal of the interest expense on the refundable deposit from Teva of approximately \$675,000.

### ***Liquidity and Capital Resources***

At December 31, 2003, we had \$15,505,000 in cash and cash equivalents as compared to \$10,219,000 at December 31, 2002.

The net cash provided by financing activities for the year ended December 31, 2003, was approximately \$28,911,000, consisting of the \$23,317,000 net proceeds from a private placement of common stock and warrants, and proceeds of \$1,995,000 from issuance of common stock upon exercise of stock options and warrants, and net borrowings of \$3,643,000 from the credit facility.

In December 2003, the Company transferred the \$25 million Loan and Security Agreement from Congress Financial Corporation to Wachovia Bank, N.A., thereby securing lower interest and less restrictive borrowing terms. The revolving loan is collateralized by eligible accounts receivable and inventory, subject to sublimits and other terms, and the term loan is collateralized by machinery and equipment, with a 60-month amortization. In addition, a \$10 million restricted cash account was established as collateral for this credit facility to be reduced based on meeting certain cumulative positive cash flow targets. The interest rates for the revolving loans are prime rate plus 0.75%, or eurodollar rate plus 2.75%, at our option, based on excess availability. The term loan has an interest rate of prime rate plus 1.5%, or eurodollar rate plus 4%, at our option. As of December 31, 2003, we borrowed approximately \$7,642,000 against the revolving credit line and \$3,290,000 against the term loan. The borrowing availability under the revolving credit line changes daily based on eligible accounts receivable and inventory. The revolving credit facility and the term loan agreement have two financial covenants: one related to Adjusted Excess Availability, and the other one related to Capital Expenditures limits. At December 31, 2003, both financial covenants were met.

Net cash of \$19,223,000 was used by operating activities during the twelve months ended December 31, 2003, which was primarily the result of inventory buildup for new products of approximately \$18,001,000 and an increase of accounts receivable of \$3,361,000, primarily due to increased sales, partially offset by increases in accounts payable of \$15,254,000, accrued expenses and other current liabilities of \$1,406,000, primarily due to the building of inventories relating to products

expected to be launched in 2004. In addition, the \$3,500,000 from Teva represented the reversal of part of the refundable deposit under the strategic alliance agreement for its exercise of the exclusivity option for certain products.

Our capital expenditures for the twelve months ended December 31, 2003 were \$4,402,000 as compared to \$15,054,000 for the same period in 2002 when we completed our new production facility in Hayward, California. We expect our 2004 capital expenditures to be higher than 2003, as we plan for future product launches in the coming years.

The \$22 million refundable deposit from Teva was reduced during 2003 by \$17 million through a combination of 888,918 shares of common stock issued to Teva in September 2003 for a total value of \$13.5 million, and Teva's exercise of its option to retain marketing exclusivity for certain products in December 2003 for a total value of \$3.5 million. In January 2004, Teva's exercise of the marketing exclusivity option for certain products reduced the refundable deposit to \$2.5 million. On January 15, 2004, we satisfied the remaining \$2.5 million refundable deposit obligation to Teva by issuing 160,951 shares of common stock to Teva. As of February 27, 2004, to our knowledge, Teva owns 2,511,952 shares of IMPAX common stock, or approximately 4.3% of the outstanding common stock.

We expect to incur significant operating expenses, particularly research and development, for the foreseeable future in order to execute our business plan. We, therefore, anticipate that such operating expenses, as well as planned capital expenditures, will constitute a material use of our cash resources.

Although our existing cash and cash equivalents are expected to decline during 2004, we believe that our existing cash and cash equivalent balances, together with our term loan and revolving line of credit with Wachovia Bank, N.A., will be sufficient to meet our requirements for the next twelve months. We may seek additional financing through strategic alliances and/or debt or equity markets to fund our planned 2004 capital expenditures, our research and development plans, and potential revenues shortfall due to delays in new product introductions. However, we may be unable to obtain such financing at all or on acceptable terms.

To date, we funded our research and development and other operating activities through equity and debt financings, and strategic alliances.

We have not paid any cash dividends on our common stock and we do not plan to pay any cash dividends in the foreseeable future. We plan to retain any earnings for the operation and expansion of our business. Our loan agreements and our strategic agreement with Teva prohibit the payment of dividends without the other party's consent.

Our total contractual commitments on loans, operating leases, and royalty agreements as of December 31, 2003, were as follows:

(\$ in millions)	<u>Total</u>	<u>Within 1 Year</u>	<u>1 - 3 Years</u>	<u>3 - 5 Years</u>	<u>After 5 Years</u>
On Balance Sheet Commitments:					
Credit Facilities And Long Term Debt	\$9.9	\$1.1	\$3.2	\$0.3	\$5.3
Other Liabilities	<u>13.8</u>	<u>11.5</u>	<u>0.6</u>	<u>1.1</u>	<u>0.6</u>
Total Balance Sheet Commitments	<u>23.7</u>	<u>12.6</u>	<u>3.8</u>	<u>1.4</u>	<u>5.9</u>
Off Balance Sheet Commitments:					
Operating Leases	2.2	0.7	1.2	0.3	—
Royalty Agreements	3.7	1.0	2.1	0.6	—
Material Purchases	<u>23.0</u>	<u>23.0</u>	<u>—</u>	<u>—</u>	<u>—</u>
Total Off Balance Sheet Commitments	<u>28.9</u>	<u>24.7</u>	<u>3.3</u>	<u>0.9</u>	<u>—</u>
Total Commitments	<u>\$52.6</u>	<u>\$37.3</u>	<u>\$7.1</u>	<u>\$2.3</u>	<u>\$5.9</u>

Excluded from this table is the Mandatorily Redeemable Preferred Stock which is a non-cash commitment. In February 2004, the Mandatorily Redeemable Preferred Stock was converted into 1,500,000 shares of common stock.

### Recent Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 143, "Accounting for Asset Retirement Obligations," which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 applies to legal obligations associated

with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal use of the asset.

The Company adopted the provisions of SFAS No. 143 on January 1, 2003. Upon initial application of the provisions of SFAS No. 143, entities are required to recognize a liability for any existing asset retirement obligations adjusted for cumulative accretion to the date of adoption of this Statement, an asset retirement cost capitalized as an increase to the carrying amount of the associated long-lived asset, and accumulated depreciation on that capitalized cost. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." This Statement, which updates, clarifies and simplifies existing accounting pronouncements, addresses the reporting of debt extinguishments and accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. The provisions of this Statement are generally effective for the Company's 2003 fiscal year or, in the case of specific provisions, for transactions occurring after May 15, 2002 or for financial statements issued on or after May 15, 2002. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue ("EITF") No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, and concludes that an entity's commitment to an exit plan does not, by itself, create a present obligation that meets the definition of a liability. This Statement also establishes that fair value is the objective of initial measurement of the liability. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company adopted SFAS No. 146 on January 1, 2003. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In November 2002, the EITF reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services, and/or rights to use assets. The provisions of EITF Issue No. 00-21 applies to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We implemented the provisions of EITF Issue No. 00-21 in revenue recognition of certain strategic agreements. The Company reviews all of the terms of its strategic alliances and follows the guidance from this Issue for all multiple element arrangements.

Also in November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34." FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 were effective for the year ended December 31, 2002. The provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of a guarantor's year-end. The Company has not issued any guarantees as of December 31, 2003 and 2002, respectively.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure, amendment of FASB Statement No. 123." This statement provides additional transition guidance for those entities that elect to voluntarily adopt the provisions of SFAS No. 123, "Accounting for Stock Based Compensation." Furthermore, SFAS No. 148 mandates new disclosures in both interim and year-end financial statements within the Company's Significant Accounting Policies footnote. The Company has elected not to adopt the recognition provisions of SFAS No. 123, as amended by SFAS No. 148. However, the Company has adopted the disclosure provisions for the current fiscal year and has included this information in Note 1 to the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. On October 8, 2003, the FASB decided to

defer FIN 46 until the first reporting period ending after December 15, 2003. The provisions of this Interpretation did not have a material impact on the Company's financial condition or results of operations.

In December 2003, the FASB issued FIN No. 46R, Consolidation of Variable Interest Entities, clarifying the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. The provisions of this Interpretation do not have a material impact on the Company's financial condition or results of operations.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." The changes in this Statement improve financial reporting by requiring that contracts with comparable characteristics be accounted for similarly. In particular, this Statement (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of Statement 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. Those changes will result in more consistent reporting of contracts as either derivatives or hybrid instruments. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." The Statement improves the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. This new Statement requires that those instruments be classified as liabilities in the balance sheet and is effective at the beginning of the first interim period beginning after June 15, 2003. The Company adopted SFAS No. 150 on July 1, 2003. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In December 2003, the FASB revised SFAS 132, "Employers' Disclosure About Pensions and Other Post Retirement Benefits." This Statement does not change the measurement or recognition of those plans required by FASB 87, "Employers' Accounting for Pensions," and No. 106, "Employers' Accounting for Post Retirement Benefits Other than Pensions." This Statement retains the disclosure requirements contained in FASB No. 132, "Employers' Disclosure about Pensions and Other Post Retirement Plans." The provisions of this Statement do not have a material impact on the Company's financial condition or results of operations.

### **Major Operational Highlights for the Twelve Months Ended December 31, 2003**

- On January 27, 2003, Abbott Laboratories filed a lawsuit against the Company in the U.S. District Court of Delaware alleging patent infringement related to IMPAX's filing of an ANDA for a generic version of the cholesterol drug Tricor Tablets. Tricor is a treatment for very high serum triglyceride levels. U.S. sales of Tricor Tablets were approximately \$591 million for the twelve months ended December 31, 2003, according to NDCHealth.
- On January 30, 2003, the FDA granted final approval to the Company's ANDA for a generic version of Rilutek (Riluzole 50 mg) tablets. Aventis markets Rilutek for the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. Approval followed the expiration of Aventis' Orphan Drug Exclusivity on December 12, 2002. According to NDCHealth, U.S. sales of Rilutek were \$31.9 million for the twelve months ended December 31, 2003.
- On January 31, 2003, the FDA granted final approval to the Company's ANDA for a generic version of Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate, 5 mg/120 mg) Extended Release Tablets. FDA approved a switch in Claritin-D 12-hour's status from a prescription drug to an over-the-counter (OTC) drug for the relief of symptoms of seasonal allergic rhinitis (hay fever) on December 9, 2002.
- Also in January 2003, following final approval from FDA and under the terms of a non-exclusive Licensing Contract Manufacturing and Supply Agreement, we commenced shipping the generic version of Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate) 5 mg/120 mg Extended Release Tablets to Schering-Plough Corporation. Schering-Plough launched its OTC Claritin-D 12-hour in March 2003. Shipments to Wyeth under our Development, License and Supply Agreement with them started in late March. Wyeth launched this product in mid-May as Alavert D-12.
- In February 2003, Merck & Co., Inc. filed a lawsuit against the Company in the federal district court in Delaware alleging patent infringement related to our filing of an ANDA for a generic version of Sinemet CR Tablets. Sinemet CR is used to treat patients with Parkinsonism. U.S. sales of Sinemet CR and the currently marketed generic equivalent were

approximately \$81 million in the twelve months ended December 31, 2003, according to NDCHealth. In April 2003, Merck & Co., Inc. withdrew its lawsuit alleging patent infringement related to our filing of the ANDA for a generic version of Sinemet CR Tablets.

- On March 28, 2003, U.S. District Court in Chicago ruled that our Fenofibrate Capsules, a generic form of Tricor Micronized Capsules, does not infringe Abbott Laboratories' patent on this product. Tricor is marketed for the treatment of hypercholesterolemia and hypertriglyceridemia. According to NDCHealth, U.S. sales of the capsule form of the lipid-regulating agent were approximately \$2.5 million for the twelve months ending December 31, 2003, as Abbott converted usage to the tablet form prior to the availability of generic capsules. On October 27, 2003, the FDA granted final approval to the Company's ANDA for the Fenofibrate Capsules.
- On April 28, 2003, the FDA granted approval to the Company's ANDA for a generic version of Mestinon (Pyridostigmine Bromide) 60 mg Tablets. ICN Pharmaceuticals, Inc. markets Mestinon for symptomatic treatment of myasthenia gravis. Myasthenia gravis is a neuromuscular disorder primarily characterized by muscle weakness and rapid muscle fatigue. According to NDCHealth, U.S. sales of Mestinon were \$17.2 million for the twelve months ended December 31, 2003.
- On May 7, 2003, the Company completed a private placement of 4,394,081 shares of common stock, and warrants to purchase 878,815 shares of common stock to a group of institutional investors for a purchase price of \$24.0 million. In addition, the investors purchased an additional 183,000 shares of common stock on May 16, 2003 for approximately \$1.0 million. The total offering price of the private placement was \$25,000,000. The net proceeds of \$23,324,000 are to be used for general corporate purposes. A Form S-3 registration statement registering the resale of the shares of common stock and the shares of common stock underlying the warrants was filed with the Securities and Exchange Commission on June 6, 2003.
- On May 28, 2003, the FDA accepted our filing of an ANDA for a generic version of Wellbutrin SR (Bupropion Hydrochloride) 200 mg Tablets. GlaxoSmithKline markets Wellbutrin SR for the treatment of depression. U.S. sales of Wellbutrin SR 200 mg Tablets were approximately \$265.3 million in the twelve months ended December 31, 2003, according to the NDCHealth.
- On July 31, 2003, the Company entered into an Exclusivity Transfer Agreement with Andrx Corporation and a subsidiary of Teva Pharmaceutical Industries Ltd. pertaining to pending ANDAs for bioequivalent versions of Wellbutrin SR and Zyban (Bupropion Hydrochloride) 100 mg and 150 mg Extended Release Tablets filed by Andrx, as well as by the Company. Pursuant to the Company's existing Strategic Alliance Agreement with Teva, Teva has U.S. marketing rights to IMPAX's versions of these products. These two strengths of Wellbutrin SR and Zyban, marketed by GlaxoSmithKline, had U.S. sales of over \$1.7 billion for the twelve-month period ended December 31, 2003 according to NDCHealth.

The parties believe that the Andrx ANDAs for the products were entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity. Under the Exclusivity Transfer Agreement, Andrx will continue to seek approval of its ANDAs. The agreement provides, among other things, that if Andrx is unable to launch its own products within a defined period of time, and IMPAX is able to market its products, Andrx will enable IMPAX to launch its own products through Teva, with the parties sharing certain payments with Andrx relating to the sale of the products for a 180-day period. Should Andrx launch its own products prior to the IMPAX product launch, it will share with IMPAX certain payments for a 180-day period.

- On August 1, 2003, the Court of Appeals for the Federal Circuit in Washington, D.C. upheld the lower court decision that ruled against certain claims by Schering-Plough Corporation of U.S. Patent No. 4,569,716 in litigation relating to the antihistamine products Claritin (Loratadine) and Claritin-D (Loratadine and Pseudoephedrine Sulfate).
- On August 5, 2003, the U.S. Patent and Trademark Office granted the company a patent for our "Multiplex Drug Delivery System Suitable for Oral Administration." The U.S. patent number is 6,602,521.
- On August 29, 2003, the Company announced that the FDA has granted approval to the Company's ANDA for a generic version of Urispas (Flavoxate Hydrochloride) 100 mg tablets. Ortho McNeil Pharmaceutical, Inc. markets Urispas for the symptomatic relief of various urinary tract conditions including dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis and urethrotrigonitis. According to NDCHealth, U.S. sales of Urispas were \$7.3 million for the twelve months ended December 31, 2003.

- On September 2, 2003, the Company announced that the FDA granted approval to the Company's ANDA for a generic version of Aralen (Chloroquine Phosphate) 500 mg tablets. Sanofi Winthrop Pharmaceuticals markets Aralen for the suppressive treatment and for acute attacks of malaria. According to NDCHealth, the U.S. market for Chloroquine products was \$2.9 million for the twelve months ended December 31, 2003.
- On September 5, 2003, the Company announced that the FDA granted tentative approval to the Company's ANDA for a generic version of OxyContin (Oxycodone Hydrochloride) Controlled Release Tablets, 80 mg. Purdue Pharma markets OxyContin for the management of moderate to severe pain. According to NDCHealth, U.S. sales of OxyContin Controlled Release Tablets, 80 mg were \$633.9 million for the twelve months ended December 31, 2003.
- On September 9, 2003, the Company announced that Alza Corporation, a Johnson & Johnson unit, had filed a lawsuit against the Company in the United States District Court, Northern District of California alleging patent infringement related to IMPAX's filing of an ANDA for a generic version of Ditropan XL (Oxybutynin Chloride) Tablets, 15 mg. Ditropan XL Tablets are used for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Additionally, IMPAX has filed for generic versions of Ditropan XL Tablets, 5 mg and 10 mg; total U.S. sales for all three strengths were \$362.0 million for the twelve months ended December 31, 2003, according to NDCHealth.
- On September 30, 2003, the Company announced that the FDA granted approval to the Company's ANDA for a generic version of Claritin Reditabs (Loratadine Orally Disintegrating Tablets) 10 mg. Schering-Plough markets Claritin Reditabs as an OTC drug for the relief of symptoms of seasonal allergic rhinitis (hay fever). According to NDCHealth, U.S. sales of Claritin Reditabs were over \$39 million for the twelve months ended December 31, 2003.
- On October 27, 2003, the Company announced that it had entered into a Settlement and License Agreement with Schering-Plough related to IMPAX's generic version of Claritin-D 24-hour (Loratadine and Pseudoephedrine Sulfate, 10 mg/240 mg) Extended Release Tablets. This agreement resolved all of the outstanding patent litigation between the parties on this product.
- On November 19, 2003, the Company announced that the FDA has accepted the Company's filing of an ANDA for a generic version of Adderall XR 30 mg Capsules. Adderall XR is a once daily extended-release, mixed salts of a single-entity amphetamine product. Shire Pharmaceuticals Group plc markets the product for the treatment of Attention Deficit and Hyperactivity Disorder. According to NDCHealth, U.S. sales of Adderall XR Capsules were approximately \$150.6 million in the twelve months ended December 31, 2003. Shire received initial FDA approval of this product in October of 2001.
- On December 24, 2003, the Company announced that the FDA has granted tentative approval to the Company's ANDA for generic versions of OxyContin (Oxycodone Hydrochloride) Controlled Release Tablets, 10, 20 and 40 mg. Purdue Pharma markets OxyContin for the management of moderate to severe pain. According to NDCHealth, U.S. sales of OxyContin Controlled Release Tablets, 10, 20 and 40 mg, were \$1,182 million for the 12 months ended December 31, 2003.
- On December 30, 2003, the Company announced that Shire Laboratories Inc., a subsidiary of Shire Pharmaceuticals Group PLC, has filed a lawsuit against the Company in the U.S. District Court for the District of Delaware alleging patent infringement related to IMPAX's filing of an ANDA for a generic version of Adderall XR 30 mg Capsules.

## **Risk Factors**

*An investment in our common stock involves a high degree of risk. You should consider carefully the following risk factors, as well as the other information included in this 10-K report, in deciding whether to invest in our common stock. This 10-K report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in this "Risk Factors" section, and elsewhere in this report.*

## **Risks Related to Our Business**

### **We have experienced, and expect to continue to experience, operating losses and negative cash flow from operations and our future profitability is uncertain.**

We do not know whether or when our business will ever be profitable or generate positive cash flow, and our ability to become profitable or obtain positive cash flow is uncertain. We have not generated significant revenues to date and have experienced operating losses and negative cash flow from operations since our inception. As of December 31, 2003, our accumulated deficit was \$104,549,000 and we had outstanding indebtedness in an aggregate principal amount of \$22,564,000 (including \$5,000,000 due Teva Pharmaceuticals Curacao, N.V., a subsidiary of Teva Pharmaceutical Industries, Ltd.). To remain operational, we must, among other things:

- continue to obtain sufficient capital to fund our operations;
- obtain from the FDA approval for our products;
- prevail in patent infringement litigation in which we are involved;
- successfully launch our new products; and
- comply with the many complex governmental regulations that deal with virtually every aspect of our business activities.

We may never become profitable or generate positive cash flow from operations.

### **We currently have a limited number of commercialized products, and these products generate limited revenues and are expected to have declining revenues over their product lives.**

We currently market thirty-one generic pharmaceuticals which represent dosage variations of thirteen different pharmaceutical compounds. Our revenues from these products for the 12 months ended December 31, 2003 were approximately \$53.6 million. We do not anticipate further revenue growth from these products; rather, we anticipate that revenues from these products will decline over time. As a result, our future prospects are dependent on our ability to successfully introduce new products. As of March 5, 2004, we had nineteen applications pending at the FDA for generic versions of brand name pharmaceuticals. The FDA and the regulatory authorities may not approve our products submitted to them or our other products under development. Additionally, we may not successfully complete our development efforts. Even if the FDA approves our products, we may not be able to market our products if we do not prevail in the patent infringement litigation in which we are involved. Our future results of operations will depend significantly upon our ability to develop, receive FDA approval for, and market new pharmaceutical products.

### **Our efforts may not result in required FDA approval of our new drug products.**

We are required to obtain FDA approval before marketing our drug products. The FDA approval requirements are costly and time consuming. We apply our drug-delivery technologies and formulation skills to develop bioequivalent versions of selected controlled-release brand name pharmaceuticals. Bioequivalent pharmaceuticals, commonly referred to as generics, are the pharmaceutical and therapeutic equivalents of brand name drug products and are usually marketed under their established nonproprietary drug names rather than by a brand name. Controlled-release drug-delivery technologies are designed to release drug dosages at specific times and in specific locations in the body and generally provide more consistent and appropriate drug levels in the bloodstream than immediate-release dosage forms. Controlled-release drugs may improve drug efficacy, reduce side effects and be more “patient friendly” by reducing the number of times a drug must be taken.

To obtain FDA approval for a new drug product, a prospective manufacturer must submit a new drug application, or NDA, containing the results of clinical studies supporting the drug product’s safety and efficacy. For bioequivalent drugs, drugs that contain the same active ingredient and are of the same route of administration, dosage form, strength and indication(s) as drugs already approved for use in the U.S. (the reference listed drugs), a prospective manufacturer must submit an abbreviated new drug application, an ANDA. An ANDA is similar to an NDA except that an ANDA is only required to contain bioavailability data demonstrating that the generic formulation is bioequivalent to the previously approved reference listed drug, indicating that the rate of absorption and the levels of concentration of a generic drug in the body do not show a significant difference from those of the previously approved reference listed drug product. As a result, ANDA filings, compared to NDAs, save development costs. Additionally, there are no user or filing fees required by the FDA for ANDAs.

Our bioequivalence studies and other data may not result in FDA approval to market our new drug products. While we believe that the FDA’s ANDA procedures will apply to our bioequivalent versions of controlled-release drugs, these drugs may not be suitable for, or approved as part of, these abbreviated applications. In addition, even if our drug products are

suitable for FDA approval by filing an ANDA, the abbreviated applications are costly and time consuming to complete. If our efforts to obtain FDA approval for our current and future drug products are not successful, our business and future prospects will be substantially harmed.

**Approvals for our new drug products may become more difficult to obtain if the FDA institutes changes to its approval requirements.**

Some abbreviated application procedures for controlled-release drugs and other products, including those related to our ANDA filings, are presently the subject of petitions filed by brand name drug manufacturers, which seek changes from the FDA in the approval requirements for particular drugs. We cannot predict at this time whether the FDA will make any changes to its abbreviated application requirements as a result of these petitions, or the effect that any changes may have on us. Any changes in FDA regulations may make it more difficult for us to file ANDAs or obtain approval of our ANDAs and thus may materially harm our business and financial results.

**We are subject to substantial patent litigation that could delay or prevent our commercialization of products.**

Patent certification requirements for controlled-release drugs and for some new drugs could also result in significant delays in obtaining FDA approval if the holder or holders of the brand name patents initiate infringement litigation. We apply our processes and formulations to develop a product that will produce the brand product's physiological characteristics but not infringe upon the patents of the NDA owner or other innovator. In connection with this process, we conduct studies to establish that our product is bioequivalent to the brand product, and obtain legal advice that our products do not infringe the NDA owner's or the innovator's patents and/or that such patents are invalid or unenforceable. As required by the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments, we then assemble and submit an ANDA to the FDA for review. If we believe that our product does not infringe a patent associated with the brand product which has been listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation Book, commonly referred to as the "Orange Book", or that such patent is invalid or unenforceable, we are required to make a certification to this effect. This certification is called a Paragraph IV Certification.

Once the FDA accepts our ANDA for filing, we must also send notice that we have filed an ANDA with a Paragraph IV Certification to the NDA owner and patent holder, explaining the basis for our position that the patent(s) is not infringed and/or is invalid or unenforceable. The NDA owner or patent holder may then initiate a legal challenge for patent infringement. If they do so within 45 days of their receipt of notice of our Paragraph IV certification, that ensuing lawsuit will automatically prevent the FDA from approving our ANDA until the earlier of 30 months, expiration of the patent, or when the infringement case is decided in our favor. In addition, delays in obtaining FDA approval of abbreviated applications and some new drug applications can also result from a marketing exclusivity period and/or an extension of patent terms. Thus, as the developer of bioequivalent products, we may invest a significant amount of time and expense in the development of these products only to be subject to significant delay and the uncertain result of patent litigation before our products may be commercialized. Additionally, patent litigation is, in itself, both costly and time consuming, and the outcome of patent litigation is difficult to predict.

As of March 5, 2004, we had nineteen applications pending at the FDA for generic versions of brand name pharmaceuticals. Patent litigation has been filed and is still outstanding in connection with seven ANDAs that we have filed with Paragraph IV Certifications. We anticipate that additional legal actions may be filed against us as we file additional applications. Patent litigation may also be brought against us in connection with NDA products that we may pursue. Our business and financial results could be materially harmed by the delays in marketing our products as a result of litigation, an unfavorable outcome in any litigation, or the expense of litigation, whether or not it is successful.

**If our strategic alliance with Teva fails to benefit us as expected, our business will be harmed.**

In June 2001, we entered into a Strategic Alliance Agreement with Teva for 12 controlled-release generic pharmaceutical products. The agreement granted Teva exclusive U.S. marketing rights for six of our products pending approval at the FDA and six products under development at the time of the agreement. Of the six products not yet filed, we have filed ANDAs for four with the FDA. Under the agreement, we will be responsible for manufacturing and supplying Teva with all of its requirements for these products and will share with Teva in the gross margins from its sale of the products. Teva's exclusive marketing right for each product will run for a period of 10 years in each country from the date of Teva's first sale of that product. Unless either party provides appropriate notice, this 10-year period will automatically be extended for two additional years.

Teva elected to commercialize a competing product to one of the four products filed since June 2001, which it developed internally. Pursuant to the agreement, we have elected to participate in the development and commercialization of Teva's

competing product and share in the gross margins of that product. Teva also has an option to acquire exclusive marketing rights in the rest of North America, South America, the European Union, and Israel for these products.

We will depend on our strategic alliance with Teva to achieve market penetration and revenue generation for the products covered by the agreement. We entered into the agreement with Teva on the basis of certain expectations of the level of sales of the products which Teva will achieve. If we fail to maintain our strategic alliance with Teva, or if our strategic alliance with Teva fails to benefit us as expected, our revenues will not meet our expectations and our business will be harmed.

**If our Exclusivity Transfer Agreement with Andrx fails to benefit us as expected, our business will be harmed.**

In July 2003, we entered into an Exclusivity Transfer Agreement with Andrx and Teva in order to gain market access for generic versions of GlaxoSmithKline's Wellbutrin SR for depression and Zyban for smoking cessation. Bupropion is the active ingredient in Wellbutrin SR and Zyban. The FDA has granted final approval to our ANDA for the 100 mg dosage form of this product. The ANDA related to our 150 mg dosage form, and the ANDA filed by Andrx are awaiting final FDA marketing approval.

We believe that the Andrx ANDA for the 150 mg dosage form is entitled to the marketing exclusivity period provided by law. As a result, we cannot receive marketing approval of our products until 180-days after Andrx commences the marketing of its own product(s) or Andrx waives its exclusivity rights. The Exclusivity Transfer Agreement provides a mechanism whereby Andrx will determine whether it will continue pursuing the approval of its own ANDAs for sale as the first generic versions of Wellbutrin SR and Zyban or will instead allow the FDA to approve the ANDAs for our products which will be marketed by Teva. If Andrx allows our products to be marketed before its own, Andrx is entitled to receive certain payments from us for a 180-day period. If Andrx continues to attempt to gain the earlier approval and sale of its own products, Andrx will share with us certain payments for a similar 180-day period.

We will depend on our agreement with Andrx to gain market access and revenue generation for the products covered by the agreement during the 180-day exclusivity period. If Andrx determines to proceed with its own products, we will not be able to market our product during this exclusivity period and will only receive the royalty provided for in the agreement. We entered into the agreement with Andrx and Teva on the basis of certain expectations of the level of sales of the products that will be achieved. If we fail to maintain our collaboration with Andrx and Teva, or if our collaboration with Andrx and Teva fails to benefit us as expected, our revenues will not meet our expectations and our business will be harmed.

**Our stockholders may be adversely affected by strategic alliances or licensing arrangements we make with other companies.**

We have entered into strategic alliances or license agreements with respect to certain products with Andrx, Teva, Wyeth, Novartis, and Schering-Plough. In the future, we may enter into strategic alliances or licensing arrangements with respect to other products with these or other companies. These arrangements may require us to relinquish rights to certain of our technologies or product candidates, or to grant licenses on terms that ultimately may prove to be unfavorable to us, either of which could reduce the market value of our common stock.

**We face intense competition in the pharmaceutical industry from both brand name and generic manufacturers, and wholesalers that could severely limit our growth and results of operations.**

The pharmaceutical industry is highly competitive and many of our competitors have longer operating histories and substantially greater financial, research and development, marketing, and other resources than us. We are subject to competition from numerous other entities that currently operate in the pharmaceutical industry, including companies that are engaged in the development of controlled-release drug-delivery technologies and products, and other manufacturers that may decide to undertake in-house development of these products. Our generic products may be subject to competition from, among other products, competing generic products marketed by the patent holder. The following table, based upon publicly available information, reflects the companies which to our knowledge market brand name or generic products that compete with our five largest product families currently on the market which accounted for approximately 92% of our revenues for the year ended December 31, 2003:

<b>Product</b>	<b>Brand Competition</b>	<b>Generic Competition</b>
LIPRAM Capsules (Pancreatic enzymes)	McNeil Laboratories (Pancrease), Solvay Pharmaceuticals (Creon), Scandipharm (Ultrase)	Ethex Corporation, Mutual Pharmaceuticals, Contract Pharmacal
Terbutaline Sulfate 2.5 mg and 5.0 mg Tablets	aai Pharma (Brethine)	None
Loratadine and Pseudoephedrine Sulfate Extended Release Tablets	Schering-Plough (Claritin-D 24-hour, Clarinex D)	Andrx
Fludrocortisone Acetate 0.1 mg Tablets	King Pharmaceuticals (Florinef)	Barr Laboratories
Minocycline Hydrochloride 50mg, 75mg, and 100mg Capsules	Wyeth (Minocin) Medicis (Dynacin)	Barr, Aligen, Breckenridge, ESI Lederle, Geneva, Ivax, H. C. Moore, Qualitest, Par, Ranbaxy, Teva, Watson, URL, Warner-Chilcott

Some of our competitors have greater experience than we do in obtaining FDA and other regulatory approvals. Our competitors may succeed in developing products that are more effective or cheaper to use than products we may develop. These developments may render our products uncompetitive. We may be unable to continue to compete successfully with these companies.

The following table, based upon publicly available information, reflects the companies which to our knowledge, market or will market brand name or generic products that are likely to compete with the major products we currently have under development:

<b>Development Product</b>	<b>Brand Competition</b>	<b>Potential Generic Competition</b>
Omeprazole Delayed Release Capsules	AstraZeneca (Prilosec, Nexium), Proctor and Gamble (Prilosec 1)	Andrx, Genpharm International, Dr. Reddy Laboratories Ltd., KUDCO/Schwarz Pharma, Eon Labs, Lek International Pharmaceutical Group, Mylan Laboratories, Apotex USA and IVAX Pharmaceuticals
Bupropion Hydrochloride Extended Release Tablets	GlaxoSmithKline, Biovail (Wellbutrin SR, Zyban, Wellbutrin XL)	Andrx, Watson Laboratories, Eon Labs, Excel Pharmaceuticals
Loratadine Orally Disintegrating Tablets	Schering-Plough (Claritin Reditabs, Clarinex Reditabs), Wyeth (Alavert)	Cima Labs, Andrx
Fenofibrate Capsules and Tablets	Abbott Labs (Tricor Tablets)	Teva, Pharmaceutical Resources, Cypher Pharmaceuticals
Fexofenadine and Pseudoephedrine Hydrochloride Extended Release Tablets	Aventis (Allegra-D)	Barr Laboratories, Mylan Laboratories
Carbidopa and Levodopa Extended Release Tablets	Bristol Myers Squibb (Sinemet CR)	Mylan Laboratories
Oxycodone Hydrochloride Extended Release Tablets	Purdue Pharma (OxyContin)	Boehringer Ingelheim/Roxane Pharmaceuticals, Endo Pharmaceuticals, Teva

In order to obtain market share for our generic products, our products will need to be successfully marketed to pharmaceutical wholesalers, chain drug stores which warehouse products, mass merchandisers, mail-order pharmacies and others. These entities often purchase generic products from a limited number of suppliers, which they then sell to end-users. Among the factors considered by these entities in purchasing a generic product are price, on-time delivery, a good record

with the FDA and relationship. In order to obtain market share for our brand name products, we will be dependent on physicians prescribing our products to their patients. Among the factors considered by physicians in prescribing a brand name product is the quality and effectiveness of the product. We have only limited experience in marketing our generic products and have no experience in marketing brand name products. We, or our strategic partners, may not be able to successfully market our products.

**We face risks relating to our goodwill and intangibles.**

At December 31, 2003, our goodwill and intangibles were approximately \$28.0 million, or approximately 21% of our total assets. We may never realize the value of our goodwill and intangibles. We will continue to evaluate, on a regular basis, whether events or circumstances have occurred that indicate all, or a portion, of the carrying amount of goodwill may no longer be recoverable, in which case an impairment charge to earnings would become necessary. Although as of December 31, 2003, the carrying value of goodwill was not impaired based on our assessment performed in accordance with accounting principles generally accepted in the U.S., any such future determination requiring the write-off of a significant portion of carrying value of goodwill could have a material adverse effect on our financial condition or results of operations.

**Our limited capital may make it difficult for us to repay indebtedness, or require us to modify our business operations and plans by spending less money on research and development programs, developing fewer products, and filing fewer drug applications with the FDA.**

Our cash used in operations has exceeded cash generated from operations in each period since our inception. We anticipate continuing to incur expenses substantially in excess of our product revenues for the foreseeable future. As of December 31, 2003, we had outstanding indebtedness of approximately \$22,564,000, of which \$17,564,000 bears interest at rates ranging from 2.0% to 8.17% annually and the balance does not bear interest. For the quarter and year ended December 31, 2003, we paid interest on our indebtedness of approximately \$214,000 and \$952,000 respectively. Additionally, as of December 31, 2003, we had an accumulated stockholders' deficit of approximately \$104,549,000. We may not be able to maintain adequate capital at any given time or from time to time in the future, which could result in less money being spent on research and development programs, fewer products being developed or at a slower pace, and fewer drug applications being filed with the FDA.

**If we are unable to continue to obtain financing, we may not be able to sustain our business operations.**

As of December 31, 2003, we had approximately \$15.5 million of cash and cash equivalents and \$10.0 million in restricted cash that serves as collateral for the \$25.0 million revolving credit facility and loan agreement with Wachovia Bank, N.A. Although we estimate that these funds will be sufficient for at least the next 12 months of operations at our planned expenditure levels, these funds may not be sufficient and additional financing may be required. We may seek additional financing through strategic alliances and/or equity or debt markets to fund the planned capital expenditures, if required, and to fund our research and development plans, and potential revenue shortfalls due to delays in new product introductions. The exact amount and timing of future capital requirements will depend upon many factors, including continued progress with our research and development programs, expansion of these programs, the approval and launch of new products, as well as the amount of revenues generated by our existing products. We may not be successful in obtaining additional capital in amounts sufficient to fund our operations. Additional financing also may not be available to us on terms favorable to us or our stockholders, or at all. In the event that adequate funds are not available, our business operations and plans may be adversely affected.

**Generic drug makers are often most profitable when they are the first producer of a generic drug, and we do not know if we will be the first producer of any generic drug product.**

The first generic drug manufacturers receiving FDA approval for generic equivalents of related brand name products have often captured greater market share from the brand name product than later arriving generic manufacturers. The development of a new generic drug product, including its formulation, testing and FDA approval, generally takes approximately three or more years. Consequently, we may select drugs for development several years in advance of their anticipated entry to market and cannot know what the market or level of competition will be for that particular product if and when we begin selling the product. In addition, by introducing generic versions of their own brand name products prior to the expiration of the patents for those drugs, brand name drug companies have attempted to prevent generic drug manufacturers from producing or capturing market share for certain products. Brand name companies have also attempted to prevent competing generic drug products from being treated as equivalent to their brand name products. We expect efforts of this type to continue.

The Congress amended provisions of the Hatch-Waxman Amendments clarifying certain issues pertaining to 180-day exclusivity in Title X of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) in November

2003. The first company to file a substantially complete ANDA for a reference listed brand name drug certifying that any listed patent(s) for that drug is not infringed and/or is invalid or unenforceable obtains, in most cases, upon the FDA approval, 180 days of market exclusivity. There may continue to be uncertainty about which generic applicant is entitled to 180-day exclusivity, particularly as to applications filed before August 2003, the date specified in the MMA. Issues relating to 180-day exclusivity have been subject to extensive litigation and constantly changing guidance by the FDA.

In March 2004, the FDA announced that it would publish the date on which the first ANDA was filed which will be entitled to 180-day exclusivity. We believe we were the first to file with the FDA on only one ANDA. In addition, the laws and regulations could result in us not being able to utilize all or any portion of the 180-day market exclusivity period on ANDA products we were the first to file on, depending on the timing and outcome of court decisions in patent litigation. Issues relating to 180-day exclusivity may adversely affect our business by reducing the exclusivity period we may have for one of our products or delaying the approval of our products where another generic applicant has 180-day exclusivity.

**Our inexperience in conducting clinical trials and submitting New Drug Applications and uncertainties inherent in clinical trials could result in delays in product development and commercialization.**

Prior to seeking FDA approval for the commercial sale of brand name controlled-release formulations under development or any drug we develop which does not qualify for the FDA's abbreviated application procedures, we must demonstrate through clinical trials that these products are safe and effective for use. We have no experience in conducting and supervising clinical trials. The process of completing clinical trials and preparing an NDA may take several years and requires substantial resources. We have never submitted an NDA. Our studies and filings may not result in FDA approval to market our new drug products and, if the FDA grants approval, we cannot predict the timing of any approval.

Additionally, a number of difficulties and uncertainties are associated with clinical trials. The results of clinical trials may not be indicative of results that would be obtained from large-scale testing. Clinical trials are often conducted with patients having advanced stages of disease and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the pharmaceutical agents being tested, but which nevertheless affect the clinical trial results. Moreover, our clinical trials may not demonstrate sufficient safety and efficacy to obtain FDA approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials even after promising results in pre-clinical studies. These failures have often resulted in decreases in the stock prices of these companies. If any of our products under development are not shown to be safe and effective in clinical trials, our business and financial results could be materially harmed.

**Our assumptions may not bear out as we expect.**

Our expectations regarding the success of our products and our business are based on assumptions which may not bear out as we expect. In our press releases and other public documents, we have forecasted the accomplishment of objectives material to our success, such as anticipated filings with the FDA and anticipated receipt of FDA approvals. For example, we have assumed that we will file with the FDA at least six ANDAs per year. The actual timing and results of these events can vary dramatically due to factors such as the uncertainties inherent in the drug development and regulatory approval process, and delays in achieving manufacturing capacity and marketing infrastructure sufficient to commercialize our products. We may not make regulatory submissions or receive regulatory approvals as forecasted, or we may not be able to adhere to our current schedule for product launches.

**The time necessary to develop generic drugs may adversely affect if and when, and the rate at which, we receive a return on our capital.**

We begin our development activities for a new generic drug product several years in advance of the patent expiration date of the brand name drug equivalent. The development process, including drug formulation, testing, and FDA review and approval, often takes three or more years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a product, the actual market for a product at the time it is available for sale may be significantly less than the originally projected market for the product. If this were to occur, our potential return on our investment in developing the product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the product. It is also possible for the manufacturer of the brand name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand name drug from the prescription market to the over-the-counter market. If this were to occur, we would be prohibited from marketing our product other than as an over-the-counter drug, in which case product revenues could be significantly less than we anticipated.

**Our revenues and operating results have fluctuated, and could fluctuate significantly in the future, which may have a material adverse effect on our results of operations and stock price.**

Our revenues and operating results may vary significantly from quarter to quarter as well as in comparison to the corresponding quarter of the preceding year. Variations may result from, among other factors:

- the timing of FDA approvals we receive;
- the timing of process validation for particular generic drug products;
- the timing of product launches;
- the introduction of new products by others that render our products obsolete or noncompetitive;
- the outcome of our patent infringement litigation; and
- the addition or loss of customers.

Our results of operations will also depend on our ability to maintain selling prices and gross profit margins. As competition from other manufacturers intensifies, selling prices and gross profit margins often decline, which has been our experience with our existing products. Our future operating results may also be affected by a variety of additional factors, including the results of future patent challenges and the market acceptance of our new products.

**Extensive regulations govern the manufacturing, labeling, distribution, and promotion of our products.**

The manufacturing, distribution, processing, formulation, packaging, labeling and advertising of our products are subject to extensive regulation by federal agencies, including the FDA, the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Consumer Product Safety Commission and the Environmental Protection Agency (EPA), among others. We are also subject to state and local laws, regulations and agencies in California, Pennsylvania and elsewhere.

In addition to approval prior to marketing any of our products, the FDA also requires that certain records be kept and reports be made, mandates registration of the facilities of drug manufacturers and listing of their products, and has the authority to inspect manufacturing facilities for compliance with its current Good Manufacturing Practices regulation. Moreover, after the FDA approves one of our products, we may have to withdraw it from the market if our manufacturing is not in accordance with FDA standards, the approval for the product or our own internal specifications or standards. The FDA has the authority to withdraw approvals of previously approved drugs for cause, to request recalls of products, to bar companies and individuals from future drug application submissions and, through action in court, to seize products, institute criminal prosecution, or close manufacturing plants in response to violations. Our business and financial results could be materially harmed by any failure to comply with the FDA's manufacturing and other regulatory requirements.

In addition, numerous federal and state requirements exist for a variety of controlled substances which may be part of our product formulations. For example, the DEA regulates narcotics and the California Bureau of Narcotic Enforcement (BNE) regulates certain precursor substances, including ephedrine and similar substances. These and other regulatory agencies have far-reaching authority. For example, the DEA has similar authority to the FDA and may also pursue monetary penalties, and the California BNE has authority to issue, suspend and revoke precursor permits. Compliance with the complex and extensive regulatory requirements is difficult and expensive. If we fail to comply with the numerous federal, state and local rules and regulations, our current or future operations could be curtailed and our business and financial results could be materially harmed.

**We will need an effective sales organization to market and sell our future brand name products and our failure to build or maintain an effective sales organization may harm our business.**

We do not currently market products under our own brand and we cannot assure you that we ever will do so. Currently, we do not have an active sales division to market and sell any brand name products that we may develop or acquire. We may not be able to recruit qualified sales personnel to market our brand name products prior to the time those products are available for commercial launch. Our inability to enter into satisfactory sales and marketing arrangements in the future may materially harm our business and financial results. We may have to rely on collaborative partners to market our branded products. These partners may not have our same interests in marketing the products and may fail to effectively market the products, and we may lose control over the sales of these products.

**Decreases in health care reimbursements could limit our ability to sell our products or decrease our revenues.**

Our ability to maintain revenues for our products will depend in part on the extent to which reimbursement for the cost of pharmaceuticals will be available from government health administration agencies, private health insurers, and other

organizations. In addition, third-party payors are attempting to control costs by limiting the level of reimbursement for medical products, including pharmaceuticals, which may adversely affect the pricing of our products. Moreover, health care reform has been, and is expected to continue to be, an area of national and state focus, which could result in the adoption of measures that could adversely affect the pricing of pharmaceuticals or the amount of reimbursement available from third-party payors. We cannot assure you that health care providers, patients, or third-party payors will accept and pay for our pharmaceuticals. In addition, there is no guarantee that health care reimbursement laws or policies will not materially harm our ability to sell our products profitably or prevent us from realizing an appropriate return on our investment in product development.

**We depend on our patents and trade secrets, and our future success is dependent on our ability to protect these secrets and not infringe on the rights of others.**

We believe that patent and trade secret protection is important to our business and that our future success will depend, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the rights of others. We have been issued six U.S. patents and various foreign patent applications relating to our drug-delivery technologies. Our U.S. patents are for our Concentric Multiple-Particulate Delivery System, our Timed Multiple-Action Delivery System, our Particle Dispersion System, our Dividable Multiple-Action Drug Delivery System, our Multiplex Drug Delivery System, and our Pharmaceutical Stabilization System. We expect to apply for additional U.S. and foreign patents in the future. The issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. In addition, the issuance of a patent to us does not mean that our products do not infringe on the patents of others. We cannot assure you that:

- our patents, or any future patents, will prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents;
- any of our future processes or products will be patentable;
- any pending or additional patents will be issued in any or all appropriate jurisdictions;
- our processes or products will not infringe upon the patents of third parties; or
- we will have the resources to defend against charges of patent infringement by third parties or to protect our own patent rights against infringement by third parties.

We also rely on trade secrets and proprietary knowledge which we generally seek to protect by confidentiality and non-disclosure agreements with employees, consultants, licensees and pharmaceutical companies. If these agreements are breached, we may not have adequate remedies for any breach, and our trade secrets may otherwise become known by our competitors.

**Our business and financial results could be materially harmed if we fail to avoid infringement of the patent or proprietary rights of others or to protect our patent rights.**

We have exposure to patent infringement litigation as a result of our product development efforts, which could adversely affect our product introduction efforts and be costly. The patent position of pharmaceutical firms involves many complex legal and technical issues and has recently been the subject of much litigation. There is no clear policy establishing the breadth of claims allowed or the degree of protection afforded under these patents. During the past several years, there has been an increasing tendency for the innovator of the original patented product to bring patent litigation against a generic drug company. This litigation is often initiated as an attempt to delay the entry of the generic drug product and reduce its market penetration.

We obtained \$7.0 million of patent infringement liability insurance from AISLIC covering us against the costs associated with patent infringement claims made against us relating to seven ANDAs we filed under Paragraph IV of the Hatch-Waxman Amendments. Correspondence received from AISLIC indicated that as of February 4, 2004, one of the policies had approximately \$19,770 remaining on its limit of liability, and the second of the policies had reached the limit of its liability. We do not believe that this type of litigation insurance will be available to us on acceptable terms for our other current or future ANDAs. While Teva has agreed to pay 45% to 50% of the attorneys' fees and costs in excess of \$7.0 million related to the twelve products covered by our strategic alliance agreement with it, we will be responsible for the remaining expenses and costs for these products and all of the costs associated with patent litigation for our other products and our future products.

Our liability insurance coverage may not be sufficient to cover any liability resulting from alleged or proven patent infringement. If a court determines that we infringed on patent or proprietary rights, the liability could materially harm our business and financial results.

**We may be subject to product liability litigation and any claims brought against us could have a material adverse effect on us.**

The design, development and manufacture of our products involve an inherent risk of product liability claims and associated adverse publicity. We currently have product liability insurance which covers us for liability of up to \$20 million. This insurance may not be adequate to cover any product liability claims to which we may become subject. Product liability insurance coverage is expensive, difficult to obtain, and may not be available in the future on acceptable terms, or at all. Any claims brought against us, whether fully covered by insurance or not, could have a material adverse effect on us.

**Since we derive a substantial percentage of our revenue from contracts with a few customers, the loss of one or all of these customers would have a negative impact on our results of operations and financial condition.**

We derive a substantial portion of our revenue from a few customers. Our four major customers, Amerisource-Bergen, Cardinal Health, McKesson, and Schering-Plough accounted for approximately 64% of total revenue for the year ended December 31, 2003. At December 31, 2003, accounts receivable from these four customers represented approximately 75% of total trade receivables. The loss of one or all of these customers would have a substantial negative impact on our results of operations and financial condition.

**We are dependent on a small number of suppliers for our raw materials, and any delay or unavailability of raw materials can materially adversely affect our ability to produce products.**

The FDA requires identification of raw material suppliers in applications for approval of drug products. If raw materials were unavailable from a specified supplier, FDA approval of a new supplier could delay the manufacture of the drug involved. In addition, some materials used in our products are currently available from only one supplier or a limited number of suppliers. Approximately 17% of our 2003 net sales were attributable to one product family, which is supplied by a sole - source supplier, Eurand America, Inc., under an exclusive licensing agreement that expires in 2007. Generally, we would need up to one year to find and qualify a new sole-source supplier. If we receive less than one year's notice from a sole - source supplier that it intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Further, a significant portion of our raw materials may be available only from foreign sources. Foreign sources can be subject to the special risks of doing business abroad, including:

- greater possibility for disruption due to transportation or communication problems;
- the relative instability of some foreign governments and economies;
- interim price volatility based on labor unrest, materials or equipment shortages, export duties, restrictions on the transfer of funds, or fluctuations in currency exchange rates; and
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

In addition, recent changes in patent laws in certain foreign jurisdictions (primarily in Europe) may make it increasingly difficult to obtain raw materials for research and development prior to expiration of applicable United States or foreign patents. Any inability to obtain raw materials on a timely basis, or any significant price increases that cannot be passed on to customers, could have a material adverse effect on us.

The delay or unavailability of raw materials can materially adversely affect our ability to produce products. This can materially adversely affect our business and operations.

**We depend on key officers and qualified scientific and technical employees, and our limited resources may make it more difficult to attract and retain these personnel.**

As a small company with approximately 453 full-time employees as of February 27, 2004, the success of our present and future operations will depend to a great extent on the collective experience, abilities, and continued service of Charles Hsiao, our Chairman, Barry R. Edwards, our Chief Executive Officer, Larry Hsu, our President, and certain of our other executive officers. We do not have any employment agreements with any of our executive officers, other than Dr. Hsiao, Mr. Edwards and Dr. Hsu. We do not maintain key man life insurance on the lives of any of our executives. If we lose the services of any of these executive officers, it could have a material adverse effect on us. Because of the specialized scientific nature of our business, we are also highly dependent upon our ability to continue to attract and retain qualified scientific and technical personnel. Loss of the services of, or failure to recruit, key scientific and technical personnel would be significantly detrimental to our product development programs. Our small size and limited financial and other resources may make it more difficult for us to attract and retain qualified officers and qualified scientific and technical personnel.

**We have limited manufacturing capacity requiring us to build additional capacity for products in our pipeline. Our manufacturing facilities must comply with stringent FDA and other regulatory requirements.**

We currently have seven facilities, five of which are in California: (i) Building 1, a 35,125 square foot facility which serves as our corporate headquarters and our primary research and development center; (ii) Building 2, a 50,400 square foot facility, which serves as our primary manufacturing center; (iii) Building 3, a 14,400 square foot facility used as an administrative office and warehouse facility; (iv) Building 5, a 61,800 square foot facility used for warehousing production materials; and (v) Building 6, a 3,280 square foot facility used for research and development. The other two facilities are located in Pennsylvania: (i) Building 4, a 113,000 square foot facility which serves as our main center for packaging, warehousing and distribution; and (ii) Building 7, a 44,000 square foot facility will be used as our center for sales and marketing and additional warehousing. See “Item 2 – Properties.”

In June 2002, we completed construction of our Hayward, California manufacturing center (Building 2). This new manufacturing facility must continue to be in compliance with current Good Manufacturing Practices. Our facilities are subject to periodic inspections by the FDA and we cannot assure you that the facilities will continue to be in compliance with current Good Manufacturing Practices or other regulatory requirements. Failure to comply with such requirements could result in significant delays in the development, approval, and distribution of our planned products, and may require us to incur significant additional expense to comply with current Good Manufacturing Practices or other regulatory requirements.

The DEA also periodically inspects facilities for compliance with security, recordkeeping, and other requirements that govern controlled substances. We cannot assure you that we will be in compliance with DEA requirements in the future.

**Our compliance with environmental, safety, and health laws may necessitate substantial expenditures in the future, the capital for which may not be available to us.**

We cannot accurately predict the outcome or timing of future expenditures that we may be required to make in order to comply with the federal, state, and local environmental, safety, and health laws and regulations that are applicable to our operations and facilities. We must comply with environmental laws that govern, among other things, airborne emissions, waste water discharges, workplace safety, and solid and hazardous waste disposal. We are also subject to potential liability for the remediation of contamination associated with both present and past hazardous waste generation, handling, and disposal activities. We are subject periodically to environmental compliance reviews by environmental, safety, and health regulatory agencies. Environmental laws have changed in recent years and we may become subject to stricter environmental standards in the future and face larger capital expenditures in order to comply with environmental laws. Our limited capital makes it uncertain whether we will be able to pay for larger than expected capital expenditures. Also, future costs of compliance with new environmental, safety, and health requirements could have a material adverse effect on our financial condition or results of operations and cash flows.

**If we are unable to manage our growth, our business will suffer.**

We have experienced rapid growth of our operations. We have increased our full-time employee count from 273 as of February 28, 2003 to 453 as of February 27, 2004. The number of ANDAs pending approval at the FDA has increased from 11 at June 30, 2001 to 20 at December 31, 2003. This growth has required us to expand, upgrade, and improve our administrative, operational, and management systems, controls and resources. We anticipate additional growth in connection with the expansion of our manufacturing operations, development of our brand name products, and our marketing and sales efforts for the products we develop. Although we cannot assure you that we will, in fact, grow as we expect, if we fail to manage growth effectively or to develop a successful marketing approach, our business and financial results will be materially harmed.

**Terrorist attacks, such as the attacks that occurred in New York and Washington, DC on September 11, 2001, and other acts of violence or war may materially adversely affect us.**

Terrorist attacks may negatively affect our operations. These attacks or armed conflicts may directly impact our physical facilities or those of our suppliers or customers. Furthermore, these attacks may make travel and the transportation of our products more difficult and more expensive, and ultimately affect our sales.

Also as a result of terrorism, the United States may be involved in armed conflicts that could have a further impact on our sales, our supply chain, and our ability to deliver products to our customers. Political and economic instability in some regions of the world may also result, and could negatively impact our business. The consequences of armed conflicts are unpredictable, and we may not be able to foresee events that could have an adverse effect on our business or your investment.

More generally, any of these events could cause consumer confidence and spending to decrease or result in increased volatility in the United States and worldwide financial markets and economy. They also could result in, or exacerbate, economic recession in the United States or abroad. Any of these occurrences could have a significant impact on our operating results, revenues, and costs and may result in the volatility of the market price for our securities and on the future prices of our securities.

**Our corporate headquarters, manufacturing, and research and development activities are located in an earthquake zone and these operations could be interrupted in the event of an earthquake.**

Our corporate headquarters, manufacturing operations in California, and research and development activities related to process technologies are located near major earthquake fault lines. In the event of a major earthquake, we could experience business interruptions, destruction of facilities, and/or loss of life, all of which could materially adversely affect our business.

**Our stockholders may sustain future dilution in ownership as a result of the terms of some of our outstanding securities or future issuances of securities.**

We may need to raise additional capital in the future to fund our operations and planned expansion. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for equity securities, ownership dilution to our stockholders will result. For instance, on January 30, 2004, 75,000 outstanding shares of our Series 2 preferred stock, were converted into an aggregate of 1,500,000 shares of our common stock. On January 15, 2004, we paid the outstanding amount of \$2.5 million of the refundable deposit to Teva by the issuance of 160,751 shares of our common stock. In addition, as of December 31, 2003, we also had outstanding warrants to purchase 1,571,232 shares of common stock and outstanding stock options to purchase 5,886,815 shares of common stock. To the extent that holders exercise their warrants and options to purchase common stock, stockholders' ownership interest in our common stock will be diluted.

**A substantial number of our shares are eligible for future sale and the sale of our shares into the market may depress our stock price.**

Our stock price may be depressed by future sales of our shares or perception that future sales may occur. We had 55,307,136 shares outstanding as of December 31, 2003, of which approximately 15,582,778 shares were owned by our officers and directors or their affiliates and are considered restricted shares. Substantially all of these shares have been registered for sale under the Securities Act of 1933, as amended (which we refer to as the Securities Act) and, subject to certain limitations, may be sold at any time without restriction. The remaining shares of our outstanding common stock are freely tradable. In addition, on January 30, 2004, 75,000 outstanding shares of our Series 2 Preferred Stock were converted into an aggregate of 1,500,000 shares of common stock, and on January 15, 2004, we paid the outstanding amount of \$2.5 million of the refundable deposit to Teva by the issuance of 160,751 shares of our common stock. The common stock into which the Series 2 Preferred Stock was converted has been, and the common stock issued to Teva, will be registered for sale under the Securities Act and, subject to certain limitations and, upon registration, may be sold at any time without restriction. Warrants for 1,571,232 shares (and the shares underlying these warrants) have been registered for sale under the Securities Act and, subject to certain limitations, may be sold at any time. As of December 31, 2003, we also had outstanding warrants to purchase 1,571,232 shares of common stock, and outstanding stock options to purchase 5,886,815 shares of common stock. The shares underlying the stock options have been registered under the Securities Act and, subject to certain limitations, may be sold upon exercise of the stock options without restriction. As of December 31, 2003, we had 3,172,605 shares of common stock available for issuance under employee benefit plans in addition to the 5,886,815 shares issuable upon exercise of the options referred to above. We are unable to estimate the amount, timing, or nature of future sales of common stock. Sales of substantial amounts of the common stock in the public market, or the perception that these sales may occur, may lower the common stock's market price.

**Control of our company is concentrated among our directors and executive officers, its affiliates and related entities who own approximately 28% of our outstanding common stock and who can exercise significant influence over all matters requiring stockholder approval.**

As of December 31, 2003, our present directors, executive officers and their respective affiliates and related entities owned approximately 28% of our outstanding common stock. Certain of these stockholders have the right to obtain additional shares of our equity securities under certain circumstances. They are entitled to preemptive rights, meaning that they are entitled to purchase additional shares of our equity securities when we sell shares of our equity in order to maintain their percentage ownership in our company, and are also entitled to anti-dilution protection, meaning that they will receive additional shares of our common stock in the event that we issue shares of our common or preferred stock at a lower purchase price than the purchase price paid for shares issued to these stockholders. These stockholders can exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant

corporate transactions. This concentration of ownership may also potentially delay or prevent a change in control of our company.

**Our stock price is likely to remain volatile.**

The stock market has, from time to time, experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In addition, the market price of our common stock, like the stock price of many publicly traded specialty pharmaceutical companies, has been and will likely continue to be volatile. For example, the sale price of our stock during 2003 ranged from a high of \$16.49 during the quarter ended September 30, 2003 to a low of \$3.01 during the quarter ended March 31, 2003.

Prices of our common stock may be influenced by many factors, including:

- investor perception of us;
- analyst recommendations;
- market conditions relating to specialty pharmaceutical companies;
- announcements of new products by us or our competitors;
- publicity regarding actual or potential development relating to products under development by us or our competitors;
- developments or disputes concerning patent or proprietary rights;
- delays in the development or approval of our product candidates;
- regulatory developments;
- period to period fluctuations in our financial results and those of our competitors;
- future sales of substantial amounts of common stock by stockholders; and
- economic and other external factors.

**We have and may in the future issue additional preferred stock which could adversely affect the rights of holders of our common stock.**

Our Board of Directors has the authority to issue up to 2,000,000 shares of our preferred stock and to determine the price, rights, preferences, and privileges of those shares without any further vote or action by the stockholders. Preferred stockholders could adversely affect the rights and interests of holders of common stock by:

- exercising voting, redemption, and conversion rights to the detriment of the holders of common stock;
- receiving preferences over the holders of common stock regarding assets or surplus funds in the event of our dissolution or liquidation;
- delaying, deferring, or preventing a change in control of our company;
- discouraging bids for our common stock at a premium over the market price of the common stock; and
- otherwise adversely affecting the market price of the common stock.

**We are not likely to pay dividends.**

We have not paid any cash dividends on our common stock and we do not plan to pay any cash dividends in the foreseeable future. We plan to retain any earnings for the operation and expansion of our business. Our loan agreements and our strategic agreement with Teva prohibit the payment of dividends without the other party's consent.

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

The Company's investment portfolio consisted of cash and cash equivalents and marketable securities stated at cost which approximates market value. The primary objective of the Company's investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, the Company maintains its portfolio in a variety of high credit quality securities, including U.S. Government securities, treasury bills, short-term commercial paper, and highly rated money market funds. One hundred percent of the Company's portfolio matures in less than one year. The carrying value of the investment portfolio approximates the market value at December 31, 2003. The Company's debt instruments at December 31, 2003, are subject to fixed and variable interest rates and principal payments. We believe that the fair value of our fixed and variable rate long-term debt and refundable deposit approximates its carrying value of approximately \$23 million at December 31, 2003. While changes in market interest rates may affect the fair value of our fixed and variable rate long-term debt, we believe the effect, if any, of reasonably possible near-term changes in the fair value of such debt on the Company's financial statements will not be material.

We do not use derivative financial instruments and have no material foreign exchange or commodity price risks.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this Item is included in the financial statements set forth in Item 15(a) under the heading “Financial Statements” as a part of this report.

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

On September 18, 2003, the Company dismissed PricewaterhouseCoopers LLP as its independent accountants. The Company's Audit Committee made and approved the decision to change independent accountants. The reports of PricewaterhouseCoopers LLP on the Company's financial statements for the past two fiscal years contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle. In connection with its audits for the two most recent fiscal years and through September 18, 2003, there were no disagreements with PricewaterhouseCoopers LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of PricewaterhouseCoopers LLP, would have caused them to make reference thereto in their report on the financial statements for such years. During the two most recent fiscal years and through September 18, 2003, there were no reportable events (as defined in Regulation S-K, Item 304 (a)(1)(v)).

As of October 2, 2003, the Company engaged Deloitte & Touche LLP as its new independent accountants. The decision to engage Deloitte & Touche LLP was made and approved by the Audit Committee of the Board of Directors. During the two most recent fiscal years and through October 2, 2003, the Company had not consulted with Deloitte & Touche LLP regarding (i) either the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements; or (ii) any matter that was either the subject of a disagreement, (as that term is described in Item 304 (a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event (as that term is described in Item 304(a)(1)(v) of Regulation S-K).

## **ITEM 9A. CONTROLS AND PROCEDURES**

The Company, under the supervision and with the participation of its management, including its principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of its disclosure controls and procedures as of the end of the period covered by this report. Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective in reaching a reasonable level of assurance that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission's rules and forms.

The principal executive officer and principal financial officer also conducted an evaluation of internal control over financial reporting (“Internal Control”) to determine whether any changes in Internal Control occurred during the Company's fourth fiscal quarter that have materially affected or which are reasonably likely to materially affect Internal Control. Based on that evaluation, there has been no such change during the quarter covered by this report.

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, within the Company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. The Company conducts periodic evaluations to enhance, where necessary, its procedures and controls.

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

#### Directors

The information concerning directors of Impax Laboratories, Inc. required under this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A, relating to the Registrant's 2004 Annual Meeting of Stockholders, to be held on May 17, 2004 (the "2004 Proxy Statement").

#### Executive Officers

The information concerning executive officers of Impax Laboratories, Inc. required under this Item is provided under Item 1 of this report.

### ITEM 11. EXECUTIVE COMPENSATION

The information required under this Item is incorporated herein by reference to our 2004 Proxy Statement.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table details information regarding the company's existing equity compensation plans as of December 31, 2003:

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 plans approved by security holders .....	5,886,815	\$5.11	2,704,553
Equity Compensation Plans not approved by security holders <sup>(1)</sup> ..	<u>31,948</u>	<u>—</u>	<u>468,052</u>
Total.....	<u>5,918,763</u>		<u>3,172,605</u>

<sup>(1)</sup> See page F-24, Note 15 for information on IMPAX Employee Stock Purchase Plan.

The remaining information required under this Item is incorporated herein by reference to our 2004 Proxy Statement.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under this Item is incorporated herein by reference to our 2004 Proxy Statement.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated herein by reference to our 2004 Proxy Statement.

## PART IV

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

#### (a) 1. FINANCIAL STATEMENTS

The following are included herein under Item 8:	<u>Page Number</u>
Independent Auditors' Report .....	F-2
Report of Independent Accountants.....	F-3
Balance Sheets as of December 31, 2003 and 2002.....	F-4
Statements of Operations for each of the three years in the period ended December 31, 2003 .....	F-5
Statements of Changes in Stockholders' Equity for each of the three years in the period ended December 31, 2003 .....	F-6
Statements of Cash Flows for each of the three years in the period ended December 31, 2003 .....	F-7
Notes to Financial Statements.....	F-8 to F-27

#### 2. FINANCIAL STATEMENT SCHEDULES

Schedules have been omitted since they are either not required, not applicable, or the information has otherwise been included.

#### 3. EXHIBITS

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Restated Certificate of Incorporation of the Company of Global Pharmaceutical Corporation dated November 2, 1995. <sup>(1)</sup>
3.12	Certificate of Amendment of Restated Certificate of Incorporation of Global Pharmaceutical Corporation, dated May 14, 1999. <sup>(5)</sup>
3.13	Certificate of Amendment of Restated Certificate of Incorporation of Global Pharmaceutical Corporation, dated December 14, 1999. <sup>(5)</sup>
3.14	Certificate of Merger of Impax Pharmaceuticals, Inc. and Global Pharmaceutical Corporation <sup>(5)</sup>
3.15	Certificate of Designations of Series 1-A Convertible Preferred Stock and Series 1-B Convertible Preferred Stock. <sup>(5)</sup>
3.16	Certificate of Designations of Series 2 Convertible Preferred Stock dated as of March 23, 2000. <sup>(5)</sup>
3.17	Certificate of Amendment of Restated Certificate of Incorporation of Impax Laboratories dated as of October 3, 2000 <sup>(13)</sup>
3.6	By-laws of the Company. <sup>(13)</sup>
10.1	Exclusivity Transfer Agreement with Andrx and Teva <sup>(14)</sup>

- 10.6 The Company's 1995 Stock Incentive Plan. <sup>(1)</sup>
- 10.19 Security Agreement by and between the Company and PIDC Local Development Corporation, dated October 15, 1993, with related Note and Commitment, and Waiver and Consent dated November 13, 1995. <sup>(1)</sup>
- 10.21 Loan Agreement by and between PIDC Financing Corporation and the Pennsylvania Industrial Development Authority ("PIDA") for a loan in a principal amount not to exceed \$1,026,000, dated April 18, 1994, with Waiver and Consent dated November 13, 1995. <sup>(1)</sup>
- 10.22 Open-End Mortgage between PIDC Financing Corporation and PIDA dated April 18, 1994. <sup>(1)</sup>
- 10.25 Assignment of Installment Sale Agreement by and among PIDC Financing Corporation, PIDA and GPC Florida, dated April 18, 1994. <sup>(1)</sup>
- 10.26 Installment Sale Agreement by and between PIDC Financing Corporation and GPC Florida dated April 18, 1994. <sup>(1)</sup>
- 10.27 PIDC Financing Corporation Note to the PIDA, dated April 18, 1994. <sup>(1)</sup>
- 10.29 Consent, Subordination and Assumption Agreement by and among GPC Florida, PIDC Financing Corporation and PIDA, dated April 18, 1994. <sup>(1)</sup>
- 10.40 Technical Collaboration Agreement by and between the Company and Genpharm Inc. dated January 8, 1997. <sup>(2)</sup>
- 10.43 Development, License and Supply Agreement with Eurand America, Inc. dated August 20, 1997. <sup>(3)</sup>
- 10.44 License and Supply Agreement with Eurand America, Inc. dated August 20, 1997. <sup>(3)</sup>
- 10.48 Employment Agreement of Charles Hsiao, Ph.D., dated as of December 14, 1999. <sup>(4)(6)</sup>
- 10.49 Employment Agreement of Barry R. Edwards, dated as of December 14, 1999. <sup>(4)(6)</sup>
- 10.50 Employment Agreement of Larry Hsu, Ph.D., dated as of December 14, 1999. <sup>(4)(6)</sup>
- 10.51 1999 Equity Incentive Plan of Impax Laboratories, Inc. <sup>(4)(6)(7)</sup>
- 10.55 Strategic Alliance Agreement between TEVA PHARMACEUTICALS CURACAO N.V. and IMPAX LABORATORIES, INC. dated June 27, 2001 <sup>(8)</sup>
- 10.56 Business and Loan Agreement between IMPAX LABORATORIES, INC. and CATHAY BANK dated June 22, 2001. <sup>(8)</sup>
- 10.57 Business Loan Agreement between IMPAX LABORATORIES, INC. and CATHAY BANK dated November 12, 2001. <sup>(9)</sup>
- 10.58 License Agreement between Novartis Consumer Health, Inc. and Impax Laboratories, Inc. dated December 17, 2001. <sup>(9)</sup>
- 10.59 Supply Agreement between Novartis Consumer Health, Inc. and Impax Laboratories, Inc. dated December 17, 2001. <sup>(9)</sup>
- 10.60 Supply Agreement between Wyeth Consumer Healthcare Division. and Impax Laboratories, Inc. dated June 20, 2002 for Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets) and Claritin-D 24 (Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24-hour Extended Release Tablets). <sup>(10)</sup>

- 10.61 Supply Agreement between Schering-Plough (Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-Hour Extended Release Tablets) dated June 24, 2002. <sup>(10)</sup>
- 10.62 Loan and Security Agreement with Congress Financial dated October 23, 2002. <sup>(11)</sup>
- 10.63 2002 Equity Incentive Plan <sup>(12)</sup>
- 10.64 First Amendment to Loan and Security Agreement between Wachovia Bank, successor by specific assignment to Congress Financial Corporation, and Impax Laboratories, Inc. dated December 2, 2003. <sup>(15)</sup>
- 10.65 Amendment No. 1 to Exclusivity Transfer Agreement dated December 30, 2003. <sup>(15)</sup>
- 14.1 Code of Ethics <sup>(15)</sup>
- 23.1 Consent of PricewaterhouseCoopers LLP <sup>(15)</sup>
- 23.2 Consent of Deloitte & Touche LLP <sup>(15)</sup>
- 31.1 Rule 13a-14(a)/15d-14(a) Certifications of Chief Executive Officer <sup>(15)</sup>
- 31.2 Rule 13a-14(a)/15d-14(a) Certifications of Chief Financial Officer <sup>(15)</sup>
- 32.1 Section 1350, Certification of Chief Executive Officer <sup>(15)</sup>
- 32.2 Section 1350, Certification of Chief Financial Officer <sup>(15)</sup>

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<sup>(1)</sup> Previously filed with the Commission as Exhibits to, and incorporated herein by reference from , the Registrant's Registration Statement on Form SB-2 (File No. 33-99310-NY)

<sup>(2)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from , the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.

<sup>(3)</sup> Previously filed with the Commission as Exhibits to, and incorporated herein by reference from , the Registrant's Quarterly Report on Form 10-QSB for the quarterly period ended September 30, 1997.

<sup>(4)</sup> Indicates management contract or compensatory plan or arrangement.

<sup>(5)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1999.

<sup>(6)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Registration Statement on Form S-4 (File No. 333-90599).

<sup>(7)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Registration Statement on Form S-8 (File No. 333-37968).

<sup>(8)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Quarterly Report on Form 10-QSB for the quarterly period ended June 30, 2001.

<sup>(9)</sup> Previously filed with the Commission as Exhibit 10, and incorporated herein by reference from, the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.

<sup>(10)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002.

<sup>(11)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2002.

<sup>(12)</sup> Previously filed with the Commission, and incorporated herein by reference from, the Registrant's Registration Statement on Form S-8 filed on May 24, 2002 (File No. 333-89098).

<sup>(13)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.

<sup>(14)</sup> Previously filed with the Commission as Exhibit to, and incorporated herein by reference from, the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2003.

<sup>(15)</sup> Filed herewith.

(b) Reports on Form 8-K.

- On October 2, 2003, the Company filed a report on Form 8-K (Item 4) announcing that it had elected Deloitte & Touche LLP as its new independent accountants.
- On October 28, 2003, the Company furnished a report on Form 8-K (Item 9) regarding a press release announcing that the Company had entered into a settlement and license agreement with Schering-Plough related to IMPAX's Claritin-D 24-hour Extended Release Tablets.
- On November 5, 2003, the Company furnished a report on Form 8-K (Item 9) announcing earnings for the third quarter ended September 30, 2003.
- On December 24, 2003, the Company furnished a report on Form 8-K (Item 9) regarding a press release announcing that the FDA had granted tentative approval to the Company's ANDA for generic versions of OxyContin Controlled Release Tablets 10 mg, 20 mg, and 40 mg.
- On December 30, 2003, the Company furnished a report on Form 8-K (Item 9) regarding a press release announcing that Shire Laboratories Inc. had filed a lawsuit against the Company related to IMPAX's filing of an ANDA for a generic version of 30 mg Adderall XR.

## 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.

IMPAX LABORATORIES, INC.  
(Registrant)

By /s/ BARRY R. EDWARDS  
Chief Executive Officer  
Date: March 12, 2004

By /s/ CORNEL C. SPIEGLER  
Chief Financial Officer  
Date: March 12, 2004

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

<u>/s/ CHARLES HSIAO, Ph.D.</u> (Charles Hsiao, Ph.D.)	<u>Chairman and Director</u>	March 12, 2004
<u>/s/ BARRY R. EDWARDS</u> (Barry R. Edwards)	<u>Chief Executive Officer and Director</u> (Principal Executive Officer)	March 12, 2004
<u>/s/ LARRY HSU, Ph.D.</u> (Larry Hsu, Ph.D.)	<u>President and Director</u>	March 12, 2004
<u>/s/ CORNEL C. SPIEGLER</u> (Cornel C. Spiegler)	<u>Chief Financial Officer and Corporate Secretary</u> (Principal Financial and Accounting Officer)	March 12, 2004
<u>/s/ LESLIE Z. BENET, Ph.D.</u> (Leslie Z. Benet, Ph.D.)	<u>Director</u>	March 12, 2004
<u>/s/ ROBERT L. BURR</u> (Robert L. Burr)	<u>Director</u>	March 12, 2004
<u>/s/ DAVID J. EDWARDS</u> (David J. Edwards)	<u>Director</u>	March 12, 2004
<u>/s/ NIGEL FLEMING, Ph.D.</u> (Nigel Fleming, Ph.D.)	<u>Director</u>	March 12, 2004
<u>/s/ MICHAEL MARKBREITER</u> (Michael Markbreiter)	<u>Director</u>	March 12, 2004
<u>/s/ OH KIM SUN</u> (Oh Kim Sun)	<u>Director</u>	March 12, 2004
<u>/s/ PETER R. TERRERI</u> (Peter R. Terreri)	<u>Director</u>	March 12, 2004

**IMPAX LABORATORIES, INC.**  
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## INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of  
Impax Laboratories, Inc.  
Hayward, California

We have audited the accompanying balance sheet of Impax Laboratories, Inc. as of December 31, 2003, and the related statements of operations, changes in stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements of the Company for the year ended December 31, 2002 and 2001, were audited by other auditors whose report, dated March 24, 2003, expressed an unqualified opinion on those statements and included an explanatory paragraph that described the adoption of Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets" discussed in Note 2 to the financial statements.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. 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 audit provides a reasonable basis for our opinion.

In our opinion, the 2003 financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2003, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

DELOITTE & TOUCHE LLP

Philadelphia, Pennsylvania

March 10, 2004

## REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors  
and Stockholders of Impax Laboratories, Inc.

In our opinion, the financial statements listed in the index appearing under Item 15(a)(1) on page 59 present fairly, in all material respects, the financial position of Impax Laboratories, Inc. at December 31, 2002, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the financial statements, on January 1, 2002, Impax Laboratories, Inc. adopted Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets."

PRICEWATERHOUSECOOPERS LLP

March 24, 2003  
Philadelphia, Pennsylvania

**IMPAX LABORATORIES, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share data)

	<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,505	\$ 10,219
Accounts receivable, net	9,885	6,524
Inventory	28,479	10,478
Prepaid expenses and other assets	1,427	973
Total current assets	55,296	28,194
Restricted Cash	10,000	10,000
Property, plant and equipment, net	38,132	37,065
Investments and other assets	1,325	807
Goodwill, net	27,574	27,574
Intangibles, net	379	763
Total assets	\$ 132,706	\$ 104,403
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 1,068	\$ 861
Accounts payable	22,783	7,529
Revolving Line of Credit	7,642	3,999
Accrued expenses and deferred revenues	10,872	10,859
Total current liabilities	42,365	23,248
Long term debt	8,854	9,105
Refundable deposit from Teva	5,000	22,000
Deferred revenues and other liabilities	2,879	1,486
	59,098	55,839
Commitments and contingencies		
Mandatorily redeemable convertible Preferred Stock:		
Series 2 mandatorily redeemable convertible Preferred Stock, \$0.01 par value		
75,000 shares outstanding at December 31, 2003, and 2002,		
redeemable at \$100 per share	7,500	7,500
	7,500	7,500
Stockholders' equity:		
Common stock, \$0.01 par value, 75,000,000 shares authorized		
and 55,307,136 and 47,874,614 shares issued and outstanding		
at December 31, 2003, and 2002, respectively	553	479
Additional paid-in capital	170,104	131,085
Unearned compensation	-	(158)
Accumulated deficit	(104,549)	(90,342)
Total stockholders' equity	66,108	41,064
Total liabilities and stockholders' equity	\$ 132,706	\$ 104,403

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

**IMPAX LABORATORIES, INC.**  
**STATEMENTS OF OPERATIONS**  
(dollars in thousands, except share and per share data)

	<u>Year Ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net sales	\$ 53,565	\$ 23,758	\$ 6,591
Revenue from reversal of refundable deposit from Teva	3,500	—	—
Other Revenue	<u>1,753</u>	<u>757</u>	<u>—</u>
Total Revenues	\$ 58,818	\$ 24,515	\$ 6,591
Cost of sales	<u>43,769</u>	<u>18,492</u>	<u>9,669</u>
Gross margin (loss)	15,049	6,023	(3,078)
Research and development	17,185	16,254	11,890
Less: Reimbursements from Teva	<u>(247)</u>	<u>(705)</u>	<u>(918)</u>
Research and development, net	16,938	15,549	10,972
Selling Expenses	2,497	2,836	2,186
General and administrative	9,176	8,396	9,258
Other operating income (expense), net	<u>27</u>	<u>(36)</u>	<u>164</u>
Net loss from operations	(13,535)	(20,794)	(25,330)
Interest income	280	644	1,148
Interest (expense)	<u>(952)</u>	<u>110</u>	<u>(929)</u>
Net loss before provision for income taxes	\$ (14,207)	\$ (20,040)	\$ (25,111)
Provision for income taxes	—	—	—
Net loss	<u>\$ (14,207)</u>	<u>\$ (20,040)</u>	<u>\$ (25,111)</u>
Net loss per share (basic and diluted)	<u>\$ (0.28)</u>	<u>\$ (0.42)</u>	<u>\$ (0.60)</u>
Weighted average common shares outstanding	<u>51,346,587</u>	<u>47,444,364</u>	<u>41,555,818</u>

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

**IMPAX LABORATORIES, INC.**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**FOR EACH OF THE THREE YEARS IN THE PERIOD ENDED DECEMBER 31, 2003**  
**(dollars and shares in thousands)**

	Common Stock		Additional	Unearned	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	<u>Paid In</u>	<u>Capital</u>	<u>Compensation</u>	<u>Deficit</u>
Balance at January 1, 2001 .....	32,295	\$323	\$76,740	(\$1,118)	(\$45,191)	\$30,754
Sale of Common Stock .....	2,773	28	25,036	-	-	25,064
Conversion of Series 1 Mandatory Redeemable Convertible Preferred Stock .....	10,041	100	16,203	-	-	16,303
Conversion of Series 2 Mandatory Redeemable Convertible Preferred Stock .....	900	9	4,491	-	-	4,500
Exercise of warrants and options .....	672	6	667	-	-	673
Expenses related to sale of stock .....	-	-	(233)	-	-	(233)
Fair value of stock options issued to consultant....	-	-	53	(27)	-	26
Amortization of unearned compensation .....	-	-	-	472	-	472
Net loss .....	-	-	-	-	(25,111)	(25,111)
Balance at December 31, 2001 .....	<u>46,681</u>	<u>\$466</u>	<u>\$122,957</u>	<u>(\$673)</u>	<u>(\$70,302)</u>	<u>\$52,448</u>
Sale of Common Stock .....	883	10	7,490	-	-	7,500
Exercise of warrants and options and sale of stock under ESPP .....	311	3	406	-	-	409
Reversal of previous year expenses related to sale of stock, (net) .....	-	-	146	-	-	146
Fair value of stock options issued to consultant....	-	-	86	(63)	-	23
Amortization of unearned compensation .....	-	-	-	578	-	578
Net loss .....	-	-	-	-	(20,040)	(20,040)
Balance at December 31, 2002 .....	<u>47,875</u>	<u>\$479</u>	<u>\$131,085</u>	<u>(\$158)</u>	<u>(\$90,342)</u>	<u>\$41,064</u>
Sale of Common Stock .....	5,466	55	36,761	-	-	36,816
Exercise of warrants and options and sale of stock under ESPP .....	1,966	19	1,977	-	-	1,996
Fair value of stock options issued to consultant....	-	-	281	-	-	281
Amortization of unearned compensation .....	-	-	-	158	-	158
Net loss .....	-	-	-	-	(14,207)	(14,207)
Balance at December 31, 2003 .....	<u>55,307</u>	<u>\$553</u>	<u>\$170,104</u>	<u>\$ 0</u>	<u>(\$104,549)</u>	<u>\$66,108</u>

The accompanying notes are an integral part of these financial statements

**IMPAX LABORATORIES, INC.**  
**STATEMENTS OF CASH FLOWS**  
(dollars in thousands)

	<u>Year ended December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (14,207)	\$ (20,040)	\$ (25,111)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	3,719	2,707	5,828
Reversal of refundable deposit from Teva	(3,500)	-	-
Non-cash compensation charge (warrants and options)	439	515	498
Change in assets and liabilities:			
Accounts receivable	(3,361)	(3,001)	(1,942)
Inventory	(18,001)	(6,990)	(539)
Prepaid expenses and other assets	(972)	300	(1,018)
Accounts payable	15,254	3,533	1,720
Other liabilities	<u>1,406</u>	<u>7,777</u>	<u>2,687</u>
Net cash used in operating activities	<u>(19,223)</u>	<u>(15,199)</u>	<u>(17,877)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(4,402)	(15,054)	(16,575)
Purchases of short-term investments	-	-	(32,232)
Sale and maturities of short term investments	<u>          </u>	<u>20,422</u>	<u>19,590</u>
Net cash provided by (used in) investing activities	<u>(4,402)</u>	<u>5,368</u>	<u>(29,217)</u>
<b>Cash flows from financing activities:</b>			
Revolving line of credit borrowings (repayments)	3,643	3,999	(2,425)
Additions to long-term debt	949	3,150	5,770
Repayment of long-term debt	(993)	(284)	(159)
Proceeds from sale of common stock (net of expense)	23,317	7,500	24,831
Proceeds from issuance of common stock (upon exercise of stock options and warrants) and sale of common stock under ESPP	1,995	409	673
Reversal of previous year expenses related to sales of stock (net)	-	232	-
Refundable deposit from Teva	-	-	22,000
Restricted Cash Account with Wachovia Securities	<u>          </u>	<u>( 10,000)</u>	<u>          </u>
Net cash provided by financing activities	<u>28,911</u>	<u>5,006</u>	<u>50,690</u>
Net increase in cash and cash equivalents	5,286	(4,825)	3,596
Cash and cash equivalents, beginning of the year	<u>10,219</u>	<u>15,044</u>	<u>11,448</u>
Cash and cash equivalents, end of year	<u>15,505</u>	<u>10,219</u>	<u>15,044</u>
Cash paid for interest	<u>\$ 959,000</u>	<u>\$ 561,000</u>	<u>\$ 224,000</u>
Cash paid for income taxes	<u>          0</u>	<u>          0</u>	<u>          0</u>

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

Supplemental disclosure of non-cash investing and financing activities: In September 2003, the Company issued 888,918 shares of common stock to Teva, paying \$13.5 million of the original \$22 million refundable deposit.

**NOTES TO FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2003, 2002, AND 2001**

**NOTE 1. – THE COMPANY**

*Nature of Operations*

The financial statements included herein have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission.

Impax Laboratories, Inc.'s ("IMPAX," "we," "us," or "the Company") main business is the development, manufacturing, and marketing of specialty prescription pharmaceutical products utilizing its own formulation expertise and drug delivery technologies. As of March 5, 2004, the Company is marketing thirty-one generic pharmaceuticals, which represent dosage variations of thirteen different pharmaceutical compounds, and has nineteen Abbreviated New Drug Applications (ANDAs) under review with the U.S. Food and Drug Administration (FDA). Fourteen of these ANDAs were filed under Paragraph IV of the Hatch-Waxman Amendments. The Company has approximately twenty-four other products in various stages of development for which applications have not yet been filed.

We have experienced, and expect to continue to experience, operating losses and negative cash flow from operations, and our future profitability is uncertain. We do not know whether or when our business will ever be profitable or generate positive cash flow, and our ability to become profitable or obtain positive cash flow is uncertain. We have not generated significant revenues to date and have experienced operating losses and negative cash flow from operations since our inception. As of December 31, 2003, our accumulated deficit was \$104,549,000 and we had outstanding indebtedness in an aggregate amount of \$22,564,000, including the \$5,000,000 refundable deposit from Teva. To remain operational, we must, among other things:

- continue to obtain sufficient capital to fund our operations;
- obtain from the FDA approval for our products;
- prevail in patent infringement litigations in which we are involved;
- successfully launch our new products; and
- comply with the many complex governmental regulations that deal with virtually every aspect of our business activities.

We expect to incur significant operating expenses, particularly research and development, for the foreseeable future in order to execute our business plan. We, therefore, anticipate that such operating expenses, as well as planned capital expenditures, will constitute a material use of our cash resources.

Although our existing cash and cash equivalents are expected to decline during the remainder of 2004, we believe that our existing cash and cash equivalent balances, together with our term loan and revolving line of credit, will be sufficient to meet our requirements for the next twelve months. We may, however, seek additional financing through strategic alliances and/or equity or debt markets to fund the planned capital expenditures, and to fund our research and development plans, and potential revenues shortfall due to delays in new product introductions. However, we may be unable to obtain such financing at all, or on terms acceptable to us.

To date, the Company has funded its research and development and other operating activities through equity, debt financings and strategic alliances.

**NOTE 2. – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### ***Cash and Cash Equivalents***

The Company considers all short-term investments with maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents are stated at amortized cost, which approximates market value.

### ***Short-Term Investments***

Short-term investments represent investments in fixed rate financial instruments with maturities of greater than three months but less than twelve months at the time of purchase. They are stated at cost, which approximates market value.

### ***Fair Value of Financial Instruments***

The fair values of the Company's cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their carrying values due to their relative short maturities. The Company believes that the fair value of its fixed and variable rate long-term debt and refundable deposit approximates its carrying value.

### ***Allowance for Doubtful Accounts***

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments; these allowances are for specific accounts.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk are cash, cash equivalents, short-term investments, and accounts receivable. The Company limits its credit risk associated with cash, cash equivalents and investments by placing its investments with highly rated money market funds, U.S. Government securities, treasury bills and short-term commercial paper. The Company limits its credit risk with respect to accounts receivable by performing ongoing credit evaluations and, when deemed necessary, requiring letters of credit, guarantees, or collateral.

The Company has four major customers, Amerisource-Bergen, Cardinal Health, McKesson, and Schering-Plough, that account for approximately 64% of total revenue for the year ended December 31, 2003. At December 31, 2003, accounts receivable from these four customers, represent approximately 75% of total trade receivables. The Company had three major customers in 2002 and 2001 that accounted for 57% and 55% of total revenue for the years ended December 31, 2002 and 2001. At December 31, 2002 and 2001, accounts receivable due from the three customers were 64% and 69%, respectively. The Company's net revenue attributable to one product family, which is supplied by Eurand America, Inc., for the years ended December 31, 2003, 2002, and 2001 was 17%, 35% and 64%, respectively.

### ***Inventory***

Inventory is stated at the lower of cost or market. Cost is determined using a standard cost method, which assumes a first-in, first-out (FIFO) flow of goods. Standard costs are revised annually, and significant variances between actual costs and standard costs are apportioned to inventory and cost of goods sold based upon inventory turnover. Costs include materials, labor, quality control, and production overhead. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During 2003, the Company evaluated the risk of building commercial quantities as inventories of certain products that had not received FDA approval. The Company decided to build and capitalize inventories in commercial quantities prior to receiving FDA approval.

We are dependent on a small number of suppliers for our raw materials, and any delay or unavailability of raw materials can materially adversely affect our ability to produce products. The Company believes it has, and will continue to have, adequate and dependable sources for the supply of raw materials and components for its manufacturing requirements.

### ***Property, Plant and Equipment***

Property, plant and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Costs incurred in connection with the construction or major renovation of facilities, including interest directly related to such projects, are capitalized as construction in progress. Depreciation is recognized using the straight-line method based on the estimated useful lives of the related assets. The Company complies with SFAS No. 34, "Capitalization of Interest Cost" and, accordingly, is capitalizing interest based on capital expenditures during the year and the

weighted average of borrowing interest rates. For the years ended December 31, 2003 and 2002, capitalized interest was \$0 and \$201,000, respectively.

### **Investments**

The Company's investments in other than cash equivalents are carried at fair value based upon the nature of the investments, their ultimate maturity date, the restrictions imposed by the PIDA and PIDC loan agreements dated July 29, 1997 (See Note 10) and management's intention with respect to holding these securities.

### **Goodwill**

Prior to the adoption of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets," we amortized goodwill on a straight-line basis over its estimated useful life. The Company adopted the provisions of SFAS No. 142, effective January 1, 2002; no impairment was noted. In adopting SFAS 142, we no longer amortize goodwill. The table below illustrates the effects of removing goodwill amortization, by period, on our reported net loss for the twelve months ended December 31, 2003, 2002, and 2001:

<b>Net Loss</b>	<b>For the Years Ended December 31,</b>		
	<b><u>2003</u></b>	<b><u>2002</u></b>	<b><u>2001</u></b>
Reported net loss	\$14,207,000	\$20,040,000	\$25,111,000
Add back: Goodwill amortization	—	—	<u>(3,502,000)</u>
Adjusted net loss	<u>\$14,207,000</u>	<u>\$20,040,000</u>	<u>\$21,609,000</u>

	<b>For the Years Ended December 31,</b>		
	<b><u>2003</u></b>	<b><u>2002</u></b>	<b><u>2001</u></b>
Basic and diluted loss per common share			
Reported net loss	<u>\$(0.28)</u>	<u>\$(0.42)</u>	<u>\$(0.60)</u>
Add back: goodwill	—	—	<u>0.08</u>
Adjusted net loss per share (basic and diluted)	<u>\$(0.28)</u>	<u>\$(0.42)</u>	<u>\$(0.52)</u>

Under the provisions of SFAS No. 142, the Company performs the annual review for impairment at the reporting unit level, which the Company has determined to be consistent with its business segment, that is, the entire Company.

Effective January 1, 2002, we evaluated the recoverability and measured the possible impairment of our goodwill under SFAS 142. The impairment test is a two-step process that begins with the estimation of the fair value of the reporting unit. The first step screens for potential impairment and the second step measures the amount of the impairment, if any. Our estimate of fair value considers publicly available information regarding the market capitalization of our Company, as well as (i) publicly available information regarding comparable publicly-traded companies in the generic pharmaceutical industry, (ii) the financial projections and future prospects of our business, including its growth opportunities and likely operational improvements, and (iii) comparable sales prices, if available.

As part of the first step to assess potential impairment, we compare our estimate of fair value for the Company to the book value of our consolidated net assets. If the book value of our net assets is greater than our estimate of fair value, we would then proceed to the second step to measure the impairment, if any.

The second step compares the implied fair value of goodwill with its carrying value. The implied fair value is determined by allocating the fair value of the reporting unit to all of the assets and liabilities of that unit as if the reporting unit had been acquired in a business combination, and the fair value of the reporting unit was the purchase price paid to acquire the reporting unit. The excess of the fair value of the reporting unit over the amounts assigned to its assets and liabilities is the implied fair value of goodwill. If the carrying amount of the reporting unit goodwill is greater than its implied fair value, an impairment loss will be recognized in the amount of the excess.

On a quarterly basis, we perform a review of our business to determine if events or changes in circumstances have occurred which could have a material adverse effect on the fair value of the Company and its goodwill. If such events or changes in circumstances were deemed to have occurred, we would consult with one or more valuation specialists in estimating the impact on our estimate of fair value. We believe the estimation methods are reasonable and reflective of common valuation practices. We perform our annual

goodwill impairment test in the fourth quarter of each year. No impairments were noted during the years ended December 31, 2003 and 2002.

### ***Intangibles***

Intangible assets, comprised of product rights and licenses, are amortized on a straight-line basis over the estimated useful life of 3 to 8 years.

### ***Impaired Assets***

The Company evaluates the carrying value of long-lived assets to be held and used, including definite lived intangible assets, when events or changes in circumstances indicate that the carrying value may not be recoverable. The carrying value of a long-lived asset is considered impaired when the total projected undiscounted cash flows from such asset are separately identifiable and are less than its carrying value. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the projected cash flows discounted at a rate commensurate with the risk involved. Losses on long-lived assets to be disposed of are determined in a similar manner, except that fair values are reduced for disposal costs. As the Company's assumptions related to assets to be held and used are subject to change, additional write-downs may be required in the future.

### ***Revenue Recognition***

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin ("SAB") 101 issued by the Securities and Exchange Commission ("SEC") in December 1999. We recognize revenue from the sale of products when the shipment of products is received and accepted by the customer. Provisions for estimated discounts, rebates, chargebacks, returns and other adjustments are provided for in the period the related sales are recorded. In December 2003, the Staff Accounting Bulletin (SAB) 104 was issued by the SEC. This bulletin revises and clarifies portions of Topic 13 of the Staff Accounting Bulletin to be consistent with current accounting and auditing guidance and SEC rules and regulations.

Emerging Issues Task Force ("EITF") Issue No. 00-21 supplemented SAB 101 for accounting for multiple element arrangements.

The Company has entered into several strategic alliances that involve the delivery of multiple products and services over an extended period of time. In multiple element arrangements, the Company must determine whether any or all of the elements of the arrangement can be separated from one another. If separation is possible, revenue is recognized for each deliverable when the revenue recognition criteria for the specific deliverable is achieved. If separation is not possible, revenue recognition is required to be spread over an extended period.

Under EITF Issue No. 00-21, an arrangement with multiple elements, the delivered item should be considered a separate unit of accounting if all of the following criteria are met:

- 1) the delivered item has value to the customer on a standalone basis;
- 2) there is objective and reliable evidence of the fair value of the undelivered item; and
- 3) if the arrangement included a general right of return, or whether delivery or performance of the undelivered item is considered probable.

The Company reviews all of the terms of its strategic alliances and follows the guidance from EITF Issue No. 00-21 for multiple element arrangements.

### ***Returns***

The sales return reserve is calculated using an historical lag period (that is, the time between when the product is sold and when it is ultimately returned as determined from the Company's system generated lag period report) and return rates, adjusted by estimates of the future return rates based on various assumptions which may include changes to internal policies and procedures, changes in business practices and commercial terms with customers, competitive position of each product, amount of inventory in the pipeline, the introduction of new products, and changes in market sales information.

Our returned goods policy requires prior authorization for the return, with corresponding credits being issued at the original invoice prices, less amounts previously granted to the customer for rebates and chargebacks. Products eligible for return must be expired and returned within one year following the expiration date of the product. Prior to 2002, we required returns of products within six months

of expiration date. Because of the lengths of the lag period and volatility that may occur from quarter to quarter, we are currently using a rolling 21-month calculation to estimate our product return rate.

In addition to the rolling 21-month calculation, we review the level of pipeline inventory at major wholesalers to assess the reasonableness of our estimate of future returns. Although the pipeline inventory information may not always be accurate or timely, it represents another data point in estimating the sales returns reserve. If we believe that a wholesaler may have too much inventory on hand, a discussion with the wholesaler takes place and an action plan is developed to reduce inventory levels related to a particular product including, but not limited to, suspending new orders and redirecting the inventory to other distribution centers.

Further, in 2003, we have developed an order flagging mechanism based on historical purchases by individual customers. This new process allows the Company to evaluate any customer orders for quantities higher than historical purchases.

The Company believes that its estimated returns reserves were adequate at each balance sheet date since they were formed based on the information that was known and available, which were supported by the Company's historical experience when similar events occurred in the past, and management's overall knowledge of and experience in the generic pharmaceutical industry. In estimating its returns reserve, the Company looks to returns after the balance sheet date but prior to filing its financial statements to ensure that any unusual trends are considered.

### ***Rebates and Chargebacks***

The sales rebates are calculated at the point of sale, based on pre-existing written customer agreements by product, and accrued on a monthly basis. Typically, these rebates are for a fixed percentage, as agreed to by the Company and the customer in writing, multiplied by the dollar volume purchased.

The vast majority of chargebacks are also calculated at the point of sale as the difference between the list price and contract price by product (with the wholesalers) and accrued on a monthly basis. Therefore, for these chargebacks, the amount is fixed and determinable at the point of sale. Additionally, a relatively small percentage of chargebacks are estimated at the point of sale to the wholesaler as the difference between the wholesalers' contract price and the Company's contract price with retail pharmacies or buying groups.

### ***Shelf-Stock Reserve***

A reserve is estimated at the point of sale for certain products for which it is probable that shelf-stock credits to customers for inventory remaining on their shelves following a decrease in the market price of these products will be granted. When estimating this reserve, we consider the competitive products, the estimated decline in market prices, and the amount of inventory in the pipeline. At December 31, 2003 and 2002, the shelf-stock reserve, included in accrued expenses, was \$232,000 and \$660,000 respectively.

### ***Shipping and Handling Fees and Costs***

Shipping and handling fees related to sales transactions are recorded as sales expense. Shipping and handling costs which are recorded in selling expense were \$232,000, \$195,000, and \$132,000, in 2003, 2002, and 2001, respectively.

### ***Research and Development***

Research and development activities are expensed as incurred and consist of self-funded research and development costs and costs associated with work performed under collaborative research and development agreements.

### ***Derivatives***

On January 1, 2001 the Company adopted SFAS No. 133, as amended by SFAS No. 138, "Accounting for Certain Derivative Instruments and Certain Hedging Activities." The adoption of SFAS No. 133, was amended by SFAS No. 138. In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement No. 133 on Derivative Instruments and Hedging Activity" which amended SFAS No. 138 and clarified financial accounting and reporting for derivative instruments. The adoption of this Statement did not have a material impact on the Company's financial condition or results of operations.

### ***Income Taxes***

The Company utilizes the asset and liability method of accounting for income taxes as set forth in SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences

attributable to temporary differences between the carrying amounts and the tax basis of assets and liabilities. Valuation allowances are provided on deferred tax assets for which it is more likely than not that some portion or all will not be realized.

### ***Stock-Based Compensation***

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees". Compensation cost for stock options, if any, is measured as the excess of the quoted market price of the stock at the date of grant over the amount an employee must pay to acquire the stock. The Company has adopted the disclosure only provisions of SFAS No. 123 and SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure – An Amendment to FASB Statement No. 123".

Had compensation cost for the Company's Plans been determined based on the fair value at the grant dates for the awards under a method prescribed by SFAS No. 148, "Accounting for Stock Based Compensation," the Company's loss would have been increased to the pro forma amounts indicated below (in thousands):

	Twelve Months Ended		
	<u>December 31,</u>		
	<u>2003</u>	<u>2002</u>	<u>2001</u>
Net loss, as reported	\$ (14,207)	\$ (20,040)	\$ (25,111)
Add: Stock-based employee compensation included in reported net income, net of related tax effects	158	578	472
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(3,498)</u>	<u>(2,718)</u>	<u>(1,450)</u>
Pro forma net loss	<u>\$ (17,547)</u>	<u>\$ (22,180)</u>	<u>\$ (26,089)</u>
Earnings per share:			
Basic - as reported	<u>\$ (0.28)</u>	<u>\$ (0.42)</u>	<u>\$ (0.60)</u>
Basic - pro forma	<u>\$ (0.34)</u>	<u>\$ (0.47)</u>	<u>\$ (0.63)</u>
Diluted - as reported	<u>\$ (0.28)</u>	<u>\$ (0.42)</u>	<u>\$ (0.60)</u>
Diluted - pro forma	<u>\$ (0.34)</u>	<u>\$ (0.47)</u>	<u>\$ (0.63)</u>

The pro forma results may not be representative of the effect on reported operations for future years. The Company calculated the fair value of each option grant on the date of grant using the Black-Scholes pricing method with the following assumptions: dividend yield at 0%; weighted average expected option term of five years; risk free interest rate of 3.03%, 4.39%, and 4.30% for the years ended December 31, 2003, 2002, and 2001, respectively. The expected stock price volatility for the years ended December 31, 2003, 2002 and 2001 were 81.7%, 50.0% and 50.0%, respectively. The weighted average fair value of options granted during 2003, 2002, and 2001 was \$4.23, \$3.18, and \$4.43, respectively.

### ***Comprehensive Income***

The Company has adopted the provisions of SFAS No. 130, "Reporting Comprehensive Income." This Statement establishes standards for the reporting and display of comprehensive income and its components. Comprehensive income is defined to include all changes in equity during a period except those resulting from investments by owners and distributions to owners. Since inception, the Company has not had transactions that are required to be reported in other comprehensive income. Comprehensive income (loss) for each period presented is equal to the net income (loss) for each period as presented in the Statements of Operations.

### ***Business Segments***

The Company operates in one business segment and has one group of products, generic pharmaceuticals. The Company's revenues are derived from, and its assets are located in, the United States of America.

### ***Computation of Basic and Diluted Net Loss Per Share***

The Company reports both basic earnings per share, which is based on the weighted-average number of common shares outstanding, and diluted earnings per share, which is based on the weighted average number of common shares outstanding and all dilutive potential common shares outstanding. Because the Company had net losses in each of the years presented, only the weighted average of common shares outstanding has been used to calculate both basic earnings per share and diluted earnings per share, as inclusion of the potential common shares would be anti-dilutive.

Mandatorily redeemable convertible stock of 1,500,000 common shares (on an as-converted basis), warrants to purchase 1,571,232, 2,548,266 and 2,798,266 common shares, and stock options to purchase 5,886,815, 4,625,525 and 3,285,069 common shares were outstanding at December 31, 2003, 2002, and 2001, but were not included in the calculation of diluted earnings per share, as their effect would be anti-dilutive.

### ***Recent Accounting Pronouncements***

In August 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 143, "Accounting for Asset Retirement Obligations," which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and/or normal use of the asset.

The Company adopted the provisions of SFAS No. 143 on January 1, 2003. Upon initial application of the provisions of SFAS No. 143, entities are required to recognize a liability for any existing asset retirement obligations adjusted for cumulative accretion to the date of adoption of this Statement, an asset retirement cost capitalized as an increase to the carrying amount of the associated long-lived asset, and accumulated depreciation on that capitalized cost. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections." This Statement, which updates, clarifies and simplifies existing accounting pronouncements, addresses the reporting of debt extinguishments and accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. The provisions of this Statement are generally effective for the Company's 2003 fiscal year or, in the case of specific provisions, for transactions occurring after May 15, 2002 or for financial statements issued on or after May 15, 2002. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue ("EITF") No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred, and concludes that an entity's commitment to an exit plan does not, by itself, create a present obligation that meets the definition of a liability. This Statement also establishes that fair value is the objective of initial measurement of the liability. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. The Company adopted SFAS No. 146 on January 1, 2003. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In November 2002, the EITF reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services, and/or rights to use assets. The provisions of EITF Issue No. 00-21 applies to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We implemented the provisions of EITF Issue No. 00-21 in revenue recognition of certain strategic agreements. The Company reviews all of the terms of its strategic alliances and follows the guidance from this Issue for all multiple element arrangements.

Also in November 2002, the FASB issued FASB Interpretation No. 45 ("FIN 45"), "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34." FIN 45 clarifies the requirements of SFAS No. 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 were effective for the year ended December 31, 2002. The provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002, irrespective of a guarantor's year-end. The Company has not issued any guarantees as of December 31, 2003 and 2002, respectively.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure, amendment of FASB Statement No. 123." This statement provides additional transition guidance for those entities that elect to

voluntarily adopt the provisions of SFAS No. 123, "Accounting for Stock Based Compensation." Furthermore, SFAS No. 148 mandates new disclosures in both interim and year-end financial statements within the Company's Significant Accounting Policies footnote. The Company has elected not to adopt the recognition provisions of SFAS No. 123, as amended by SFAS No. 148. However, the Company has adopted the disclosure provisions for the current fiscal year and has included this information in Note 1 to the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. On October 8, 2003, the FASB decided to defer FIN 46 until the first reporting period ending after December 15, 2003. The provisions of this Interpretation did not have a material impact on the Company's financial condition or results of operations.

In December 2003, the FASB issued FIN No. 46R, Consolidation of Variable Interest Entities, clarifying the application of Accounting Research Bulletin No. 51, Consolidated Financial Statements, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. The provisions of this Interpretation do not have a material impact on the Company's financial condition or results of operations.

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." The changes in this Statement improve financial reporting by requiring that contracts with comparable characteristics be accounted for similarly. In particular, this Statement (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in paragraph 6(b) of Statement 133, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and (4) amends certain other existing pronouncements. Those changes will result in more consistent reporting of contracts as either derivatives or hybrid instruments. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity." The Statement improves the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity. This new Statement requires that those instruments be classified as liabilities in the balance sheet and is effective at the beginning of the first interim period beginning after June 15, 2003. The Company adopted SFAS No. 150 on July 1, 2003. The provisions of this Statement did not have a material impact on the Company's financial condition or results of operations.

In December 2003, the FASB revised SFAS 132, "Employers' Disclosure About Pensions and Other Post Retirement Benefits." This Statement does not change the measurement or recognition of those plans required by FASB 87, "Employers' Accounting for Pensions," and No. 106, "Employers' Accounting for Post Retirement Benefits Other than Pensions." This Statement retains the disclosure requirements contained in FASB No. 132, "Employers' Disclosure about Pensions and Other Post Retirement Plans." The provisions of this Statement do not have a material impact on the Company's financial condition or results of operations.

### NOTE 3 – ACCOUNTS RECEIVABLE

Gross receivables and related deductions at December 31, 2003, 2002 and 2001 are set forth below:

(in \$000's)	<u>Year 2003</u>	<u>Year 2002</u>	<u>Year 2001</u>
Gross accounts receivable	\$ 17,091	\$ 9,827	\$ 5,112
Less: Accrued rebates	(2,700)	(1,525)	(886)
Less: Accrued chargebacks	(4,101)	(1,373)	(580)
Less: Other deductions	<u>( 405)</u>	<u>(405)</u>	<u>(123)</u>
Net accounts receivable	<u>\$ 9,885</u>	<u>\$ 6,524</u>	<u>\$ 3,523</u>

Other deductions include allowance for disputed items, doubtful accounts, and cash discounts.

Chargebacks and Rebates Accruals activity for the years ended December 31, 2003, 2002 and 2001, is set forth below.

**CHARGEBACKS ACCRUAL**

(in \$000's)	<u>Year 2003</u>	<u>Year 2002</u>	<u>Year 2001</u>
Beginning Balance	\$ 1,373	\$ 580	\$ 144
Add: Provision related to sales made in current period	10,571	4,632	1,938
Less: Credits issued during the current period	<u>(7,843)</u>	<u>(3,839)</u>	<u>(1,502)</u>
Ending Balance	<u>\$ 4,101</u>	<u>\$ 1,373</u>	<u>\$ 580</u>

**REBATES ACCRUAL**

(in \$000's)	<u>Year 2003</u>	<u>Year 2002</u>	<u>Year 2001</u>
Beginning Balance	\$ 1,525	\$ 886	\$ 181
Add: Provision related to sales made in current period	6,680	4,095	2,052
Less: Credits issued during the current period	<u>(5,505)</u>	<u>(3,456)</u>	<u>(1,347)</u>
Ending Balance	<u>\$ 2,700</u>	<u>\$ 1,525</u>	<u>\$ 886</u>

**NOTE 4 – INVENTORY**

Our inventory consists of the following:

(in \$000s)	<u>December 31, 2003</u>	<u>December 31, 2002</u>
Raw materials .....	\$ 9,671	\$ 7,122
Work in process .....	5,303	365
Finished goods .....	<u>13,505</u>	<u>2,991</u>
	<u>\$ 28,479</u>	<u>\$ 10,478</u>

Historically, IMPAX considered product costs as inventory once the Company received FDA approval to market its ANDA related products. During the twelve months ended December 31, 2003, the Company evaluated the risk of building commercial quantities as inventories of certain products that have not received FDA approval. For the first time, the Company decided to build and capitalize inventories in commercial quantities prior to receiving FDA approval. The Company, as do most companies in the generic pharmaceutical industry, may build inventories of certain products that have not yet received FDA approval and/or satisfactory resolution of patent infringement litigation, when it believes that such action is appropriate to increase its commercial opportunity.

As of December 31, 2003, the Company's total inventory of \$28,479,000 included approximately \$16,956,000 in inventories relating to products pending launch while IMPAX awaits receipt of FDA marketing approval and/or satisfactory resolution of patent infringement litigation, as follows:

(in \$000s)	
Raw materials	\$ 2,561
Work in process	3,744
Finished goods	<u>10,651</u>
Total	<u>\$ 16,956</u>

Of the \$16,956,000 inventories related to products pending launch, approximately \$9,342,000 are considered risk protected because of our strategic alliance agreements.

Subsequent to December 31, 2003, we received final FDA approval for two products, tentative approval for one product, and commenced shipping of another product for which we received final FDA approval in 2003.

#### NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consists of the following:

	Estimated useful life (years)	December 31, 2003	December 31, 2002
		(in thousands)	
Land .....	–	\$ 1,984	\$ 1,970
Building and building improvements .....	15	23,585	22,190
Equipment .....	7 - 10	17,810	13,757
Office furniture and equipment .....	5	1,292	1,161
Construction in progress .....	–	<u>2,658</u>	<u>3,869</u>
		47,329	42,947
Less: Accumulated depreciation		<u>(9,197)</u>	<u>(5,882)</u>
		<u>\$ 38,132</u>	<u>\$ 37,065</u>

Depreciation expense was \$3,335,000, \$2,323,000, and \$1,940,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

#### NOTE 6 – INTANGIBLES

Intangibles consist of the following:

	Estimated useful life (years)	December 31, 2003	December 31, 2002
		(in thousands)	
Product rights and licenses.....	3 - 8	\$ 2,691	\$ 2,691
Less: Accumulated amortization		<u>(2,312)</u>	<u>(1,928)</u>
		<u>\$ 379</u>	<u>\$ 763</u>

Amortization expense was \$384,000, \$384,000, and \$388,000 for the years ended December 31, 2003, 2002, and 2001 respectively. Expected amortization for 2004 is \$379,000. The existing intangible assets will be fully amortized by December 31, 2004.

#### NOTE 7 – ACCRUED EXPENSES AND DEFERRED REVENUES

	December 31, 2003	December 31, 2002
	(in thousands)	
Sales returns.....	\$ 4,121	\$ 3,100
Deferred revenues .....	1,751	3,633
Accrued salaries and payroll related expenses.....	1,649	984
Patent infringement and other legal expenses .....	1,327	516
Accrued Medicaid rebates.....	613	275
Accrued royalty and gross profit sharing expense .....	559	446
Other accruals .....	469	914
Accrued shelf stock price protection .....	232	660
Accrued professional fees .....	<u>151</u>	<u>331</u>
	<u>\$ 10,872</u>	<u>\$ 10,859</u>

#### RETURNS ACCRUAL

(in \$000's)	Year 2003	Year 2002	Year 2001
Beginning Balance	\$ 3,100	\$ 1,900	\$ 216

Add: Provision related to sales made in current period	2,276	2,462	4,525
Less: Credits issued during the current period	<u>(1,255)</u>	<u>(1,262)</u>	<u>(2,841)</u>
Ending Balance	\$ <u>4,121</u>	\$ <u>3,100</u>	\$ <u>1,900</u>

During the years ended 2003, 2002, and 2001, the Company has received product returns, for primarily expired product of \$1,255,000, \$1,262,000, and \$2,841,000, respectively. Based on its product returns reserve calculation, taking into account the historical lag time and various management assumptions and reviews, the Company has increased its reserve for future returns from \$3,100,000 at December 31, 2002 to \$4,121,000 at December 31, 2003. Therefore, the total reduction in sales recognized for the years ended December 31, 2003, 2002, and 2001 was \$2,276,000, \$2,462,000, and \$4,525,000, respectively.

#### NOTE 8 – INCOME TAXES

Due to the Company's losses since inception, no provision for income taxes is recorded for any period. The difference between the federal statutory tax rate and the Company's effective income tax rate is attributable to losses and future tax deductions for which valuation allowances have been established.

The net deferred tax assets balance is comprised of the tax effects of cumulative temporary differences, as follows:

	<u>2003</u>	December 31, (in thousands)	<u>2002</u>
Net operating losses .....	\$ 37,827		\$ 34,100
Research and development credit .....	3,095		2,764
Other .....	<u>7,629</u>		<u>4,974</u>
Total gross deferred tax assets .....	48,551		41,838
Deferred tax liability			
Tax depreciation and amortization in excess of book depreciation .....	(563)		(260)
Valuation allowance .....	<u>(47,988)</u>		<u>(41,578)</u>
Net deferred tax asset/(liability) .....	<u>\$ —</u>		<u>\$ —</u>

Deferred start-up and organization expenditures are amortized for tax purposes over a 60-month period ending 2003. Cash paid for income taxes was \$0, \$0, and \$0 for the years ended December 31, 2003, 2002, and 2001, respectively. Due to historical losses incurred by the Company, a full valuation allowance for net deferred tax assets has been provided. If the Company achieves profitability, certain of these net deferred tax assets would be available to offset future income taxes. Under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss-carryforwards may be impaired or limited in certain circumstances. Events which cause limitations in the amount of net operating losses that the Company may utilize in any one year include, but are not limited to, a cumulative ownership change of more than 50%, as defined, over a three year period.

At December 31, 2003, the Company had a net operating loss-carryforward totaling approximately \$94,600,000, which expires from 2009 through 2023. The Company also had research and development expenditure tax credits totaling approximately \$3,095,000 at December 31, 2003, which begin to expire in 2011. As indicated above, these losses and credits will have limitations. Of the \$94,600,000, approximately \$90,000,000 will be currently available as of December 31, 2003, to offset any potential future taxable profits, with the remainder being fully available by December 31, 2004.

#### NOTE 9 – REVOLVING LINE OF CREDIT

On October 23, 2002, we signed a three year, \$25 million Loan and Security Agreement with Congress Financial Corporation, comprised of a revolving loan of up to \$20,500,000, and a term loan of up to \$4,500,000. In December 2003, we transferred this loan agreement from Congress Financial to Wachovia Bank N.A., thereby securing lower interest and less restrictive borrowing terms. The revolving loan is collateralized by eligible accounts receivable and inventory, subject to sublimits and other terms, and the term loan is collateralized by machinery and equipment, with a 60-month amortization. In addition, a \$10 million restricted cash account was established as collateral for this credit facility to be reduced based on meeting certain cumulative positive cash flow targets. The interest rates for the revolving loans are prime rate plus 0.75%, or eurodollar rate plus 2.75%, at our option, based on excess availability. The term loan has an interest rate of prime rate plus 1.5%, or eurodollar rate plus 4%, at our option. As of December 31, 2003, we borrowed approximately \$7,642,000 against the revolving credit line and \$3,290,000 against the term loan. The borrowing availability under the revolving credit line changes daily based on eligible accounts receivable and inventory. The revolving credit facility and the term loan agreement have two financial covenants: one related to Adjusted Excess Availability, and the other one related to Capital Expenditures limits. At December 31, 2003, both financial covenants were met.

**NOTE 10 – LONG TERM DEBT**

	<u>2003</u>	December 31, (in thousands)	<u>2002</u>
2% loan payable to PIDA (No.1) in 180 monthly installments of \$6,602 commencing June 1, 1994, through May 1, 2009.....	\$ 406		\$ 477
3.75% loan payable to PIDA (No. 2) in 180 monthly installments of \$5,513 commencing September 1, 1997, through August 1, 2012.....	489		536
5% loan payable to DRPA in 120 monthly installments of \$3,712 commencing September 1, 1997, through August 1, 2007.....	149		185
8.17% loan payable to Cathay Bank in 83 monthly installments of \$19,540 commencing June 28, 2001, through May 27, 2008, with a balance of \$2,208,843 due on June 28, 2008 .....	2,388		2,422
7.50% loan payable to Cathay Bank in 83 monthly installments of \$24,629 commencing November 14, 2001, through October 13, 2008, with a balance of \$2,917,598 due on November 14, 2008 .....	3,200		3,248
Loan payable to Wachovia N.A. in 60 monthly installments of \$52,500 commencing December 1, 2002, through November 30, 2007, at prime interest rate plus 1.5% .....	<u>3,290</u>		<u>3,098</u>
	\$ 9,922		\$ 9,966
Less: Current portion of long-term debt .....	<u>(1,068)</u>		<u>(861)</u>
	<u>\$ 8,854</u>		<u>\$ 9,105</u>

The PIDA (No. 1) loan is collateralized by land, building and building improvements in the Philadelphia facility. The PIDA (No. 2) and the DRPA loans are collateralized by land, building, and building improvements in the Philadelphia facility, and additional collateral of \$472,000 invested in interest bearing certificates of deposit owned by the Company.

The PIDA loans contain financial and non-financial covenants, including certain covenants regarding levels of employment, which were not effective until commencement of operations. The Company is in compliance with all loan covenants.

The 8.17% Cathay Bank loan is collateralized by land, building and building improvements in the Huntwood Avenue, Hayward facility. The 7.50% Cathay Bank loan is collateralized by land, building and building improvements in the San Antonio Street, Hayward facility.

The Wachovia Bank term loan is collateralized by machinery and equipment in all the facilities owned by the Company. As previously mentioned in Note 9, the Company is in compliance with all loan covenants.

Scheduled maturities of long-term debt as of December 31, 2003, are as follows, in thousands:

2004 .....	\$ 1,068
2005 .....	1,073
2006 .....	1,086
2007 .....	1,099
2008 .....	250
Thereafter.....	<u>5,346</u>
Total .....	<u>\$ 9,922</u>

We believe that the fair value of our fixed and variable rate long-term debt and refundable deposit approximates its carrying value of approximately \$23 million at December 31, 2003.

The interest paid during the years ended December 31, 2003, 2002, and 2001 was approximately \$959,000, \$561,000, and \$224,000, respectively.

## NOTE 11 – STRATEGIC ALLIANCE AGREEMENTS

### *Strategic Alliance with Teva*

In June 2001, we entered into a Strategic Alliance Agreement with a subsidiary of Teva for twelve controlled-release generic pharmaceutical products. According to Teva, which is headquartered in Israel, Teva is among the top 30 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Close to 90% of Teva's sales are in North America and Europe. Teva develops, manufactures, and markets generic and brand name pharmaceuticals and active pharmaceutical ingredients.

The agreement granted Teva exclusive U.S. prescription marketing rights for six of our products pending approval at the FDA and six products under development at the time the agreement was signed. The six products for which ANDAs were already filed at the time of the agreement were Omeprazole 10 mg, 20 mg, and 40 mg Delayed Released Capsules (generic of Prilosec), Bupropion Hydrochloride 100 mg and 150 mg Extended Release Tablets (generic of Wellbutrin SR), Bupropion Hydrochloride 150 mg Extended Release Tablets (generic of Zyban), Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets (generic of Claritin-D 12-Hour) and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24 hour Extended Release Tablets (generic of Claritin-D 24-hour) and Loratadine Orally Disintegrating Tablets (generic of Claritin Reditabs). Of the six products under development, four have since been filed with the FDA. Teva elected to commercialize a competing product to one of the four products filed since June 2001, which it developed internally. Pursuant to the agreement, we have elected to participate in the development and commercialization of Teva's competing product and share in the gross margins of such product. Teva also had an option to acquire exclusive marketing rights in the rest of North America, South America, the European Union, and Israel for these products. We will be responsible for supplying Teva with all of its requirements for these products and will share with Teva in the gross margins from its sale of the products. We will depend on our strategic alliance with Teva to achieve market penetration for these products and to generate product revenues for us. Teva's exclusive marketing right for each product will run for a period of ten years in each country from the date of Teva's first sale of that product. Unless either party provides appropriate notice, this ten-year period will automatically be extended for two additional years.

As part of the strategic alliance agreement, Teva will share some of our costs relating to the twelve products. For the six products which were pending approval at the FDA in June 2001, Teva will pay 50% of the attorneys' fees and costs of obtaining FDA approval, including the fees and costs for the patent infringement litigation instituted by brand name pharmaceutical manufacturers in excess of the \$7.0 million to be paid by our patent litigation insurer. For three other products, for which we have since filed ANDAs with the FDA, Teva will pay 45% of all fees, costs, expenses, damages or awards, including attorneys' fees, related to patent infringement claims with respect to these products. For the remaining three products, Teva will pay 50% of these fees, costs, expenses, damages or awards.

We also agreed to sell to Teva an aggregate \$15.0 million worth of our common stock in four equal installments, with the last sale occurring on June 15, 2002. Teva purchased a total of 1,462,083 shares of our common stock. The price of the common stock was equal to the average closing sale price of our common stock measured over a ten-trading-day period ending two days prior to the date when Teva acquired the common stock. However, on the date Teva completes its first sale of any one of six of products specified in our alliance agreement, we may repurchase from Teva 16.66% (243,583) of these shares for an aggregate of \$1.00.

In addition, in consideration for the potential transfer of the marketing rights, we received \$22.0 million from Teva which assisted in the construction and improvement of our Hayward, California facilities and the development of the twelve products specified in our Strategic Alliance Agreement. The \$22 million was reflected on the balance sheet as a refundable deposit. The refundable deposit was provided in the form of a loan. Pursuant to the agreement, accrued and future interest on the refundable deposit was forgiven during 2002 as a result of our receipt of tentative or final approvals for at least three of our products. In addition, Teva forgave portions of this loan as we achieved certain milestones relating to the development and launch dates of the products described in our strategic alliance agreement. In addition, by requiring us to repay only 50% of the portion of the loan related to certain missed milestones, Teva chose to continue to have exclusive marketing rights for those products. At our option, we could repay Teva any amounts we owed them as part of the loan in cash or in shares of our common stock. The price of the common stock for purposes of repaying any amounts owed under the loan will be the average closing sale price of our common stock measured over a ten-trading-day period ending two days prior to repayment.

In September 2003, we issued 888,918 shares of our common stock to Teva, paying \$13.5 million of the original \$22.0 million refundable deposit. In December 2003, Teva exercised its option to retain marketing exclusivity for certain products and, accordingly, reduced the refundable deposit by \$3.5 million to \$5.0 million.

In January 2004, Teva's exercise of the marketing exclusivity option for certain products reduced the refundable deposit to \$2.5 million. On January 15, 2004, we satisfied the remaining \$2.5 million refundable deposit obligation to Teva by issuing 160,951 shares of our common stock to Teva. As of February 27, 2004, to our knowledge, Teva owns 2,511,952 shares of our common stock, or approximately 4.3% of the outstanding common stock.

### ***Strategic Alliance with Andrx and Teva***

In July 2003, we entered into an Exclusivity Transfer Agreement with Andrx and a subsidiary of Teva pertaining to pending ANDAs for bioequivalent versions of Wellbutrin SR and Zyban (Bupropion Hydrochloride) 100 mg and 150 mg Extended Release Tablets filed by Andrx, as well as by us. Pursuant to our existing strategic alliance agreement with Teva, Teva has U.S. marketing rights to our versions of these products. These two strengths of Wellbutrin SR and Zyban, marketed by GlaxoSmithKline, had U.S. sales of over \$1.74 billion for the twelve-month period ended December 31, 2003 according to NDCHealth.

The parties to the agreement believe that the Andrx ANDAs for the products are entitled, under the Hatch-Waxman Act, to a 180-day period of marketing exclusivity. Under the Exclusivity Transfer Agreement, Andrx will continue to seek approval of its ANDAs. The agreement provides, among other things, that if Andrx is unable to launch its own products within a defined period of time, and we are able to market our products, Andrx will enable us to launch our own products through Teva by waiving its exclusivity, with the parties sharing certain payments with Andrx relating to the sale of the products for a 180-day period. Should Andrx launch its own products prior to the Impax product launch, it will share with IMPAX certain payments for a 180-day period.

### ***OTC Alliances***

In December 2001, we entered into a License and Supply Agreement granting to Novartis exclusive rights to market our OTC Loratadine Orally Disintegrating Tablets (generic Claritin Reditabs) for the pediatric market. Under the terms of the agreement, IMPAX is responsible for developing and manufacturing the product, while Novartis is responsible for its marketing and sale. The structure of the agreement includes payment upon achievement of milestones and royalties paid to IMPAX on Novartis' sales on a quarterly basis. Novartis launched this product in February 2004 as Triaminic AllerChews.

In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10 mg/240 mg 24-hour Extended Release Tablets for the OTC market under the Alavert brand. IMPAX is responsible for developing and manufacturing the products, while Wyeth is responsible for their marketing and sale. The structure of the agreement includes payment upon achievement of milestones and royalties to IMPAX on Wyeth's sales on a quarterly basis. Wyeth launched this product in May 2003 as Alavert D-12.

In June 2002, we signed a non-exclusive Licensing, Contract Manufacturing and Supply Agreement with Schering-Plough relating to our Loratadine and Pseudoephedrine Sulfate 5 mg/120 mg 12-hour Extended Release Tablets for the OTC market under the Claritin-D 12-hour brand. The structure of the agreement included milestone payments by Schering-Plough and agreed sales prices. Shipments to Schering-Plough commenced at the end of January 2003. Schering-Plough launched our product as its OTC Claritin-D 12-hour in March 2003.

## **NOTE 12 – COMMITMENTS AND CONTINGENCIES**

### ***Leases***

The Company leases office, warehouse and laboratory facilities under non-cancelable operating leases through April 2009. Rent expense for the years ended December 31, 2003, 2002 and 2001 was \$215,000, \$56,000, and \$463,000, respectively. The Company recognizes rent expense on a straight-line basis over the lease period.

The Company also leases certain equipment under various non-cancelable operating leases with various expiration dates through 2008. Future minimum lease payments under the non-cancelable operating leases are as follows (in thousands):

Year Ended December 31	
2004	725
2005	658
2006	287
2007	273
2008	<u>247</u>
Total minimum lease payments	<u>\$ 2,190</u>

In November 2002, the FASB issued FIN No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." Guarantees and claims arise during the ordinary course of business from relationships with suppliers, customers, and strategic partners when the Company undertakes an obligation to guarantee the performance of others

through the delivery of cash or other assets if specified triggering events occur. Non-performance under a contract by the guaranteed party triggers the obligation of the Company. We reviewed all material agreements and concluded that all indemnifications are excluded from the FIN No. 45 scope of interpretation since they relate primarily to our own future performance and do not require any contingent payments.

We currently have no relationships with variable interest entities as defined in FASB Interpretation No. 46, "Consolidation of Variable Interest Entities" as of December 31, 2003.

### ***Patent Litigation***

There has been substantial litigation in the pharmaceutical, biological, and biotechnology industries with respect to the manufacture, use, and sale of new products that are the subject of conflicting patent rights. One or more patents cover most of the brand name controlled-release products for which we are developing generic versions. Under the Hatch-Waxman Amendments, when a drug developer files an ANDA for a generic drug, and the developer believes that an unexpired patent which has been listed with the FDA as covering that brand name product will not be infringed by the developer's product or is invalid or unenforceable, the developer must so certify to the FDA. That certification must also be provided to the patent holder, who may challenge the developer's certification of non-infringement, invalidity or unenforceability by filing a suit for patent infringement within 45 days of the patent holder's receipt of such certification. If the patent holder files suit, the FDA can review and approve the ANDA, but is prevented from granting final marketing approval of the product until a final judgment in the action has been rendered, or 30 months from the date the certification was received, whichever is sooner. Should a patent holder commence a lawsuit with respect to an alleged patent infringement by us, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. The delay in obtaining FDA approval to market our product candidates as a result of litigation, as well as the expense of such litigation, whether or not we are successful, could have a material adverse effect on our results of operations and financial position. In addition, there can be no assurance that any patent litigation will be resolved prior to the 30-month period. As a result, even if the FDA were to approve a product upon expiration of the 30-month period, we may not commence marketing that product if patent litigation is still pending.

Lawsuits have been filed against us in connection with fourteen of our Paragraph IV filings. The outcome of such litigation is difficult to predict because of the uncertainties inherent in patent litigation.

As part of our patent litigation strategy, we obtained two policies covering up to \$7.0 million of patent infringement liability insurance from American International Specialty Line Company ("AISLIC"), an affiliate of AIG International. This litigation insurance covers us against the costs associated with patent infringement claims made against us relating to seven of the ANDAs we filed under Paragraph IV of the Hatch-Waxman Amendments. Correspondence received from AISLIC indicated that, as of February 4, 2004, one of the policies had approximately \$19,770.12 remaining on the limit of liability and the second of the policies had reached its limit of liability. In addition, pursuant to the agreement with Teva, for the six products with ANDAs already filed with the FDA at the time of the agreement, Teva will pay 50% of the attorneys' fees and costs in excess of \$7.0 million. For three of the products with ANDAs filed since the agreement was signed, Teva will pay 45% of the attorneys' fees and costs, and for the remaining three products, Teva will pay 50% of the attorneys' fees and costs.

While Teva has agreed to pay 45% to 50% of the attorneys' fees and costs in excess of \$7 million related to the twelve products covered by our strategic alliance agreement with them, we will be responsible for the remaining expenses and costs for these products, and all of the costs associated with patent litigation for our other products and our future products.

We do not believe that this type of litigation insurance will be available to us on acceptable terms for our other current or future ANDAs. In those cases, our policy is to record such expenses as incurred.

Although the outcome and costs of the asserted and unasserted claims is difficult to predict because of the uncertainties inherent in patent litigation, management does not expect the Company's ultimate liability for such matters to have a material adverse effect on its financial condition, results of operations, or cash flows.

### **NOTE 13 – MANDATORILY REDEEMABLE CONVERTIBLE PREFERRED STOCK**

The Company has authorized 2,000,000 shares of preferred stock, \$0.01 par value per share (the "Preferred Stock"). The Company issued in March 2000, 150,000 shares of Series 2 Preferred Stock from which 75,000 were outstanding at December 31, 2003 and December 31, 2002, respectively, and are classified as Mandatorily Redeemable Convertible Preferred Stock. The remaining authorized but unissued shares could be issued with or without mandatory redemption or conversion features.

The holders of the Company's Series 2 Preferred Stock:

- vote, in general, as a single class with the holders of the common stock on all matters voted on by the stockholders of the Company, with each holder of Series 2 Preferred entitled to a number of votes equal to the number of shares of common stock into which that holders' shares would then be convertible;
- are entitled to receive dividends on an as-converted basis, with the outstanding shares of common stock payable when and as declared by the Company's Board of Directors;
- have conversion rights with the conversion price adjusted for certain events; currently, the conversion price for the Series 2 is \$5.00 per share;
- have the benefit of (a) mandatory redemption by the Company at a price per share of preferred stock of \$100 plus all declared but unpaid dividends on March 31, 2005, for the Series 2; (b) optional redemption at the option of the holders upon the occurrence of certain events, including the sale of the combined company or its assets, the elimination of a public trading market for shares of its common stock, or the insolvency of or bankruptcy filing by the combined company. In either case the redemption price can be paid, at the Company's option, in cash or shares of common stock, discounted (in the case of shares) by 10% from the then current market price of the common stock;
- have pre-emptive rights entitling them to purchase a pro rata share of any capital stock, including securities, convertible into capital stock of the Company, issued by the Company in order for the holders to retain their percentage interest in the Company; except the Company can issue shares of its capital stock without triggering the preemptive rights when issued: as pro rata dividends to all holders of common stock; as stock options to employees, officers and directors; in connection with a merger, acquisition or business combination for consideration of less than \$500,000 in any single permitted transaction and for less than \$1,000,000 in the aggregate for all permitted transactions; and during the first five years in connection with a business relationship (there is a cap on the amount of shares the Company may issue without triggering the pre-emptive rights); and
- after two years from the date of issuance, are subject to having their shares called for redemption at a price per share of preferred stock of \$100 plus all declared but unpaid dividends, at the Company's option, when the common stock has traded on its principal market for a period of thirty consecutive days with an average daily volume in excess of 50,000 shares for the 30-day period and the market price of a share of the Company's common stock is, for the Series 2, at least equal to or greater than 300% of the applicable conversion price.

On January 30, 2004, the holders of the Series 2 Preferred Stock converted their entire 75,000 preferred shares into 1,500,000 shares of common stock.

In addition, pursuant to its certificate of incorporation, the Company is authorized to issue "blank check" preferred stock. This enables the Board of Directors of the Company, from time to time, to create one or more new series of preferred stock in addition to the Series 2 Preferred. The new series of preferred stock can have the rights, preferences, privileges and restrictions designated by the Company's Board of Directors. The issuance of any new series of preferred stock could affect, among other things, the dividend, voting and liquidation rights of the Company's common stock.

#### **NOTE 14 – STOCKHOLDERS' EQUITY**

##### ***Common Stock***

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 75,000,000 shares of common stock with \$0.01 par value.

The Company has outstanding warrants as follows:

<b><u>Number of Shares Under Warrants</u></b>	<b><u>Range of Exercise Price</u></b>
765,650	\$2.000 to \$4.125 per share
<u>805,582</u>	\$4.125 to \$7.421 per share
<u><u>1,571,232</u></u>	

All the outstanding warrants are convertible into common stock. The warrants expire five years from the date of issuance.

The Company issued warrants to purchase 625,000 shares of common stock for \$4.00 per share to J. P. Morgan Chase (formerly Robert Fleming) in conjunction with Series 2 Preferred Stock. These warrants were fully exercised on February 19, 2004. The Company issued warrants to purchase 878,815 shares of common stock for \$7.421 per share to a group of institutional investors in

conjunction with a Private Placement of 4,394,081 shares of common stock in May 2003. In October 2003, warrants for 73,233 shares of common stock were exercised.

On May 7, 2003, the Company completed a private placement of 4,394,081 shares of common stock and warrants to purchase 878,815 shares of common stock to a group of institutional investors for a purchase price of \$24.0 million. In addition, the investors purchased an additional 183,000 shares of common stock on May 16, 2003 for approximately \$1.0 million. Gross proceeds from the private placement were \$25.0 million. The net proceeds of \$23.3 million were used for general corporate purposes. The sales were exempt from registration pursuant to Section 4(2) of the Securities Act and Regulation D promulgated thereunder.

If the Company issues shares of common stock or securities convertible into or exercisable for shares of common stock at a price less than \$5.462 per share prior to May 6, 2004, the Company is required to issue additional shares of common stock to the private placement purchasers equal to the additional number of shares such purchasers would have received at such lower price based on the consideration paid for the shares of common stock that such purchasers still hold from the private placement and any exercise of warrants purchased in the private placement.

Principal purchasers in the private placement (i.e., purchasers that purchased more than 1.0 million shares) are entitled to rights of first refusal with respect to certain offers and sales of the Company's securities prior to June 16, 2005.

The warrants are exercisable for a period of five years at an exercise price of \$7.421 per share. The warrants may also be exercised in a "cashless exercise." Both the warrant exercise price and the number of shares issuable upon exercise of the warrants are subject to adjustment for issuances of securities at prices below the exercise price of the warrant. If such lower priced securities are issued prior to May 8, 2004, the exercise price will be adjusted to equal the price at which such securities were sold. If such lower priced securities are issued on or after May 8, 2004, the adjustment will be based on a weighted average formula. In addition, the exercise price and the number of securities issuable upon exercise are subject to adjustment for stock splits, stock dividends and certain other corporate events.

The securities sold in the private placement are entitled to registration rights. A Form S-3 registration statement registering the resale of the shares of common stock, the warrants and the shares of common stock underlying the warrants was filed with the Securities and Exchange Commission on June 6, 2003.

### ***Unearned Compensation***

In April 1999, the Company granted 836,285 options to employees to purchase common stock for \$0.75 per share. As a result of the grant, the Company recorded \$1,805,000 of unearned compensation in accordance with APB Opinion No. 25; \$158,000, \$578,000, and \$472,000 of the unearned compensation was amortized to expense during the years ended December 31, 2003, 2002, and 2001, respectively. During 2003, the Company granted options to one consultant to purchase common stock at market price. As a result of the grant, the Company expensed approximately \$59,000 during the year ended December 31, 2003. The Company amortizes unearned compensation over the vesting period of the underlying option.

## **NOTE 15 – EMPLOYEE BENEFIT PLANS**

### ***401-(K) Defined Contribution Plan***

The Company sponsors a 401-(K) defined contribution plan covering all employees. Contributions made by the Company are determined annually by the Board of Directors. There were approximately \$313,000, \$195,000, and \$40,000 in matching contributions under this plan for the year ended December 31, 2003, 2002, and 2001, respectively.

### ***Employee Stock Purchase Plan***

In February 2001, the Board of Directors of the Company approved the 2001 Non-Qualified Employee Stock Purchase Plan ("ESPP"). Under this Plan, the Company registered 500,000 shares of common stock under a Form S-8 Registration Statement. The purpose of this Plan is to enhance employee interest in the success and progress of the Company by encouraging employee ownership of common stock of the Company. The Plan provides the opportunity to purchase the Company's common stock at a 15% discount to the market price through payroll deductions or lump-sum cash investments. During 2003, 9,757 shares of common stock were sold by the Company to its employees under this Plan for net proceeds of \$58,345.

### ***Deferred Compensation Plan***

In February 2002, the Board of Directors of the Company approved the Executive Non-Qualified Deferred Compensation Plan (the “Plan”) effective August 15, 2002 covering any executive-level employee of the Company as designated by the Board of Directors. There were approximately \$150,856 in matching contributions under this plan for the year ended December 31, 2003. The Plan has cash surrender value of \$655,242 and a deferred compensation liability of \$726,000 as of December 31, 2003.

**NOTE 16 – STOCK OPTION PLANS**

***1996 Stock Option Plan***

In September 1996, the Company adopted the 1996 Stock Option Plan (the “1996 Plan”). The 1996 Plan provides for the granting of stock options to employees and consultants of the Company. Options granted under the 1996 Plan may be either incentive stock options or non-qualified stock options. Incentive stock options (“ISO”) may be granted only to Company employees (including officers and directors who are also employees). Non-qualified stock options (“NQSO”) may be granted to Company employees and consultants. The Company has reserved 500,000 shares (pre-recapitalization) of Common Stock for issuance under the 1996 Plan.

Effective June 1, 1998, the Company’s Board of Directors approved the re-pricing of all outstanding options to \$0.75 per share, the fair market value of common stock on that date. As a result, all outstanding options at June 1, 1998, were effectively rescinded and re-issued at an exercise price of \$0.75 per share.

As a result of the merger, each outstanding and unexercised option to purchase shares of common stock was converted into new options by multiplying these options by 3.3358. Therefore, at December 31, 1999, 266,800 outstanding and unexercised options under the 1996 Plan were converted into 889,991 new options. 338,694 and 425,738 options were outstanding at December 31, 2003 and 2002, respectively.

***1999 Equity Incentive Plan (Pre-Merger)***

In April 1999, the Company adopted the 1999 Equity Incentive Plan (the “1999 Pre-Merger Plan”). The 1999 Pre-Merger Plan reserves for issuance of 1,000,000 shares (pre-recapitalization) of common stock for issuance pursuant to stock option grants, stock grants and restricted stock purchase agreements. As a result of the merger, each outstanding and unexercised option to purchase shares of common stock was converted into new options by multiplying these options by 3.3358. Therefore, at December 31, 1999, 249,300 outstanding and unexercised options under the 1999 Pre-Merger Plan were converted into 831,615 new options. 760,985 and 765,658 options were outstanding at December 31, 2003 and 2002, respectively.

***Global’s 1995 Stock Incentive Plan***

In 1995, Global’s Board of Directors adopted the 1995 Stock Incentive Plan. As a result of the merger, each outstanding and unexercised option to purchase shares of common stock was converted into one Impax Laboratories, Inc. option. 304,725 and 311,800 options were outstanding at December 31, 2003 and 2002, respectively.

***Impax Laboratories, Inc. 1999 Equity Incentive Plan***

The Company’s 1999 Equity Incentive Plan was adopted by IMPAX’s Board of Directors in December 1999, for the purpose of offering equity-based compensation incentives to eligible personnel with a view toward promoting the long-term financial success of the Company and enhancing stockholder value. In October 2000, the Company’s stockholders approved the increase in the aggregate number of shares of common stock that may be issued pursuant to the Company’s 1999 Equity Incentive Plan from 2,400,000 to 5,000,000. 3,092,702 and 3,069,829 options were outstanding at December 31, 2003 and 2002, respectively.

***Impax Laboratories, Inc. 2002 Equity Incentive Plan***

The 2002 Equity Incentive Plan was adopted by the Company’s Stockholders at the May 6, 2002 Annual Meeting for the purpose of attracting, retaining and motivating key personnel with a view toward promoting the long-term financial success of the Company and enhancing stockholder value. The aggregate number of shares of common stock that may be issued pursuant to the 2002 Equity Incentive Plan is 4,000,000 shares. 1,389,709 and 3,947,000 options were outstanding at December 31, 2003 and 2002, respectively.

To date, options granted under each of the above plans vest from three to five years and have a term of ten years. Stock option transactions in each of the past three years under the aforementioned plans in total were:

<u>2003</u>	<u>2002</u>	<u>2001</u>
Weighted	Weighted	Weighted

	Shares	Average Exercise Price	Shares	Average Exercise Price	Shares	Average Exercise Price
Options Outstanding at January 1	4,625,525	4.85	3,285,069	\$3.88	3,187,330	\$2.56
Granted	1,733,292	6.00	1,679,934	\$6.56	593,000	\$9.81
Exercised	(172,646)	3.68	(192,293)	\$1.08	(364,728)	\$1.56
Cancelled	(299,356)	7.19	(147,185)	\$9.00	(130,533)	\$5.35
Options outstanding at December 31	<u>5,886,815</u>	<u>\$5.11</u>	<u>4,625,525</u>	<u>\$4.85</u>	<u>3,285,069</u>	<u>\$3.88</u>
Options exercisable at December 31	<u>2,670,032</u>	<u>\$3.39</u>	<u>1,754,538</u>	<u>\$2.46</u>	<u>1,195,366</u>	<u>\$1.81</u>
Options available for grant at December 31	<u>2,704,553</u>		<u>4,138,789</u>		<u>1,674,538</u>	

The following table summarizes information concerning outstanding and exercisable options at December 31, 2003:

Options Outstanding				Options Exercisable	
Range of Exercise Prices	Number of Options	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.30 - \$ 0.75	766,099	4.19	\$0.73	760,095	\$0.75
\$0.82 - \$ 2.06	353,580	5.03	\$1.16	353,580	\$0.89
\$2.19 - \$ 5.63	2,589,524	7.37	\$3.94	1,092,353	\$4.27
\$5.87 - \$14.51	2,177,612	8.83	\$8.71	464,003	\$7.58
\$0.30 - \$14.51	<u>5,886,815</u>	<u>7.36</u>	<u>\$5.11</u>	<u>2,670,031</u>	<u>\$3.39</u>

#### NOTE 17 – SUBSEQUENT EVENTS

- In January 2004, Teva's exercise of the marketing exclusivity option for certain products reduced the refundable deposit to \$2.5 million. On January 15, 2004, we satisfied the remaining \$2.5 million refundable deposit obligation to Teva in full by issuing 160,951 shares of our common stock to Teva. As of February 27, 2004, to our knowledge, Teva owns 2,511,952 shares of our common stock, or approximately 4.3% of the outstanding common stock.
- On January 30, 2004, the holders of Series 2 Preferred Stock converted their entire 75,000 preferred shares into 1,500,000 shares of common stock. The warrants related to the Series 2 Preferred Stock were fully exercised on February 19, 2004.

#### NOTE 18 – SUPPLEMENTARY QUARTERLY DATA (UNAUDITED)

The following is the summary of the unaudited quarterly results of operations for the fiscal years 2003 and 2002:

(dollars in thousands except share and per share data)	Year 2003 For The Quarter Ended			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Gross Sales:				
Active Products	\$ 14,153	\$ 17,932	\$ 21,628	\$ 19,749
New NDC Lipram				
Other Revenues	<u>359</u>	<u>607</u>	<u>589</u>	<u>3,698</u>
Total	14,512	18,539	22,217	23,347
Less:				
Rebates	(1,062)	(1,741)	(2,054)	(1,114)
Chargebacks	(1,314)	(2,040)	(2,646)	(3,656)
Returns <sup>1</sup>	(132)	(188)	(389)	(1,567)
Other credits	<u>(579)</u>	<u>(503)</u>	<u>(631)</u>	<u>(281)</u>
Net Sales	11,425	14,067	16,497	16,829
Gross margin (loss)	<u>3,278</u>	<u>4,746</u>	<u>3,521</u>	<u>3,504</u>

Net loss	\$ (3,213)	\$ (2,284)	\$ (3,608)	\$ (5,102)
Net loss per share (basic and diluted)	\$ (0.07)	\$ (0.05)	\$ (0.07)	\$ (0.09)
Weighted Average Common Shares Outstanding	47,876,830	50,608,445	52,610,356	54,208,856

<sup>1</sup> Includes additional reserve amounts.

(dollars in thousands except  
share and per share data)

Year 2002  
For The Quarter Ended

	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Gross Sales:				
Active Products	5,901	7,693	9,123	11,676
New NDC Lipram	753	1,065	1,524	665
Other Revenues	<u>—</u>	<u>—</u>	<u>255</u>	<u>502</u>
Total	6,654	8,758	10,902	12,843
Less:				
Rebates	( 905)	( 1,113)	( 982)	( 1,295)
Chargebacks	( 870)	( 866)	( 1,327)	( 1,769)
Returns <sup>1</sup>	( 593)	( 902)	( 442)	( 544)
Other credits	<u>( 854)</u>	<u>( 732)</u>	<u>( 613)</u>	<u>( 835)</u>
Net Sales	3,432	5,145	7,538	8,400
Gross margin (loss)	<u>293</u>	<u>1,163</u>	<u>2,385</u>	<u>2,182</u>
Net loss	\$ (5,421)	\$ (5,938)	\$ (5,210)	\$ (3,471)
Net loss per share (basic and diluted)	\$ (0.12)	\$ (0.13)	\$ (0.11)	\$ (0.07)
Weighted Average Common Shares Outstanding	46,812,977	47,306,741	47,778,512	47,867,379

<sup>1</sup> Includes additional reserve amounts.

## BOARD OF DIRECTORS

**Leslie Z. Benet, Ph.D.** <sup>(2)(3)</sup>  
*Professor, Biopharmaceutical Sciences*  
University of California, San Francisco

**Robert L. Burr** <sup>(1) (2) (3)</sup>  
*Partner*  
Windcrest Discovery Investments LLC

**Barry R. Edwards**  
*Chief Executive Officer*  
Impax Laboratories, Inc.

**David J. Edwards** <sup>(2) (3)</sup>  
*Partner*  
Windcrest Discovery Investments LLC

**Nigel Fleming, Ph.D.** <sup>(2) (3)</sup>  
*Private Investor*

**Charles Hsiao, Ph.D.**  
*Chairman*  
Impax Laboratories, Inc.

**Larry Hsu, Ph.D.**  
*President*  
Impax Laboratories, Inc.

**Michael Markbreiter** <sup>(1)</sup>  
*Private Investor*

**Oh Kim Sun** <sup>(1)</sup>  
*Chairman*  
Ideal Force Sdn Bhd

**Peter R. Terreri** <sup>(1)</sup>  
*President and CEO*  
C G M, Inc.

<sup>(1)</sup> Member, Audit Committee

<sup>(2)</sup> Member, Compensation Committee

<sup>(3)</sup> Member, Nominating Committee

## OFFICERS

**Barry R. Edwards**  
*Chief Executive Officer*

**Larry Hsu, Ph.D.**  
*President*

**May J. Chu**  
*Senior Vice President*  
*Quality Affairs*

**David S. Doll**  
*Senior Vice President*  
*Sales and Marketing*

**Cornel C. Spiegler**  
*Chief Financial Officer and*  
*Corporate Secretary*

## CORPORATE HEADQUARTERS

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Hayward, CA 94544  
Website: [www.impaxlabs.com](http://www.impaxlabs.com)

## CORPORATE INFORMATION

*Independent Auditors*  
Deloitte & Touche LLP  
1700 Market Street  
Philadelphia, PA 19103-3984

*Corporate Counsel*  
Blank Rome LLP  
One Logan Square  
Philadelphia, PA 19103-6998

*Transfer Agent and Registrar*  
StockTrans Inc.  
44 West Lancaster Avenue  
Ardmore, PA 19003

*Annual Meeting of Stockholders*  
Monday, May 17, 2004, at 10:00 a.m. (PST)  
at Crowne Plaza Hotel, 1221 Chess Drive, Foster City, CA 94404



[www.impaxlabs.com](http://www.impaxlabs.com)