



**IMPAX**  
*LABORATORIES, INC.*

A N N U A L R E P O R T

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# IMPAX

## 2002 Milestones



Launched, March 2002



Launched, July 2002



Launched, November 2002

### Quarter 1

- Final ANDA approval to market Fludrocortisone Acetate Tablets (generic of Florinef)
- Tentative ANDA approval for Fenofibrate Capsules (generic of Tricor capsules)
- FDA accepted ANDA filings for Fexofenadine and Pseudoephedrine Hydrochloride Extended Release Tablets (generic of Allegra-D) and Oxycodone Hydrochloride 80 mg Extended Release Tablets (generic of OxyContin)

### Quarter 2

- Tentative ANDA approval for our OTC Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets (generic of Claritin-D 12-hour) and Loratadine and Pseudoephedrine Sulfate 24-hour Extended Release Tablets (generic of Claritin-D 24-hour)
- Signed non-exclusive licensing, contract manufacturing and supply agreement with Schering Plough Corporation for the marketing of our OTC Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets.
- Signed semi-exclusive development, license and supply agreement with Wyeth acting through its Wyeth Consumer Healthcare Division for the marketing of our OTC Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 24-hour Extended Release Tablets
- Filed three new applications with FDA
- Completed construction on our new 50,400 square foot manufacturing facility

### Quarter 3

- Final ANDA approval to market Rimantadine Hydrochloride Tablets (generic of Flumadine).
- Tentative ANDA approval for Riluzole Tablets (generic of Rilutek)
- FDA accepted ANDA filing for Oxycodone Hydrochloride 40 mg Extended Release Tablets (Includes 10mg and 20mg)
- Filed one new application with FDA
- Added an additional 14,400 square feet of administrative office space in Hayward, CA
- Record revenues of over \$7.5 million, up more than 350% from 2001

### Quarter 4

- Final ANDA approval to market Omeprazole 10mg and 20mg Delayed Release Capsules (generic of Prilosec)
- Tentative ANDA approval for Omeprazole 40mg Delayed Release Capsules
- FDA accepted our files for Fenofibrate Tablets (generic of Tricor tablets) and Carbidopa and Levodopa Extended Release Tablets (generic of Sinemet CR)
- Filed four new applications with FDA
- Completed construction on renovations to our R&D facility
- Record revenues of over \$8.4 million, up more than 400% from 2001

### Year 2002

- Received eight ANDA approvals from FDA – five tentative, three final
- Filed a total of eight new applications with the FDA
- Record sales revenue of nearly \$25 million, up more than 370% from 2001



## My Fellow Stockholders:

It is my pleasure to report to you on the significant accomplishments of IMPAX Laboratories, Inc. during 2002. By a number of metrics, the IMPAX team accomplished a great deal last year. With each successive quarter we achieved record revenues. For the year, revenues were a record \$24.5 million, up more than 370% from 2001 as we began marketing new products and resumed the marketing of others.

Our pipeline of U.S. regulatory filings continues to grow. We began the year with 15 Abbreviated New Drug Applications (ANDAs) at the FDA, filed eight new applications during 2002 and finished the year with 19 applications on file addressing \$5.8 billion of pharmaceutical market sales. We received eight ANDA approvals during 2002. These included three final ANDA approvals:

- Fludrocortisone Acetate Tablets, a generic version of Florinef<sup>®</sup> for the treatment of Addison's disease
- Rimantadine Hydrochloride Tablets, a generic form of Flumadine<sup>®</sup> for the treatment of influenza A virus
- Omeprazole Delayed Release Capsules 10 and 20 mg strengths, which are generic versions of Prilosec<sup>®</sup> for the treatment of ulcers and gastrointestinal reflux

Additionally, FDA granted five products tentative approval, for which final approval was contingent upon the outcome of litigation, the 30-month stay process under Paragraph IV of the Hatch-Waxman Amendments or any applicable marketing exclusivity. Those products are:

- Fenofibrate Capsules (generic of Tricor<sup>®</sup>),
- Loratadine and Pseudoephedrine Sulfate 24-hour ER Tablets (generic of Claritin-D<sup>®</sup> 24-Hour)
- Omeprazole 40 mg Delayed Release Capsules (generic of Prilosec<sup>®</sup>)
- Loratadine and Pseudoephedrine Sulfate 12-hour ER Tablets (generic of Claritin-D<sup>®</sup> 12-Hour)
- Riluzole Tablets (generic of Rilutek<sup>®</sup>).

In June, we signed two more agreements for the OTC marketing of our Loratadine products. The agreement with Schering-Plough was for our Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets. The agreement with Wyeth was for our Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets as well as our 24-hour Extended release Tablets. These new partners, combined with our existing partnership with Novartis, give us a strong marketing resource for our Loratadine products in the OTC market.

Also in June we completed construction of, and began commercial manufacturing in, our new 50,400 square foot dosage form manufacturing facility in Hayward, CA. This facility has expanded our production capability significantly and gives us an annual production capacity of up to approximately one and one half billion tablets/capsules.

We started off 2003 by strengthening our senior management team. Michael Wokasch, who served us well on our Board of Directors, relinquished his seat to become Chief Operating Officer. In January 2003, we were pleased to announce that Michael's Board seat has been assumed by Peter Terreri, a 20-year veteran of the generic pharmaceutical industry with a strong expertise in finance.

Recently, we were granted FDA approval for our generic version of OTC Claritin-D 12-hour, with 180 days of marketing exclusivity relating to our "first to file" status and began making shipments. At this writing, you can look for our product on store shelves under the Claritin-D<sup>®</sup> 12-hour brand, and soon under Wyeth's Alavert<sup>™</sup> brand.

We continue to work aggressively on new products, and plan to file at least six new applications during 2003. With 19 ANDAs pending, and our ongoing development efforts, we are laying the groundwork for the years to come. On a final note, I want to express my gratitude to our nearly 300 dedicated and hard working employees, whose ongoing efforts are positioning our company for long-term success.

Sincerely,

Chairman and Co-Chief Executive Officer

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

**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, 2002

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)

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

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

**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

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

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 28, 2002) was approximately \$206,607,575.<sup>(1)</sup> As of June 28, 2002, there were 47,750,632 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 2003 Annual Meeting of Stockholders, which is expected to be filed no later than 120 days after the Registrant's fiscal year ended December 31, 2002.

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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 \$7.49, the last reported sale price for the Company's common stock on June 28, 2002, 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 are primarily focusing our efforts on selected controlled-release generic versions of brand name pharmaceuticals. We are also developing other generic pharmaceuticals that 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 generic products through its Global Pharmaceuticals division and intends to market its branded products through the Impax Pharmaceuticals division. Additionally, where strategically appropriate, IMPAX has developed 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, a Delaware corporation, maintains its headquarters in Hayward, California, in an approximately 35,125 square foot facility that also serves as the primary development center of the Company. A second facility of approximately 50,400 square feet, located in Hayward, California, serves as the primary manufacturing center. The third facility is approximately 14,400 square feet located in Hayward, California and is used primarily for administration. A fourth facility, located in Philadelphia, Pennsylvania, serves as the primary commercial center, with sales and marketing, packaging, warehousing, and distribution occurring in this approximate 113,000 square foot facility.

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
Allegra-D®	Aventis S.A.
Alavert™	Wyeth Consumer Products

TRADEMARK	OWNER
Betapace®	Berlex Laboratories
Brethine®	aaPharma
Claritin-D®	Schering-Plough Corp.
Claritin Reditabs®	Schering-Plough Corp.
Creon®	Solvay Pharmaceuticals
Flumadine®	Forest Laboratories, Inc.
Florinef®	King 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.
Tricor® capsules and tablets	Abbott Laboratories
Ultrase®	Scandipharm
Wellbutrin® and Wellbutrin SR®	GlaxoSmithKline
Zyban®	GlaxoSmithKline

## 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 Abbreviated New Drug Applications (“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. We also entered into agreements to grant Novartis, Wyeth, and Schering-Plough marketing rights to market over-the-counter (“OTC”) versions of our generic Claritin (loratadine) products. We will depend on our strategic alliances with Teva, Novartis, Wyeth, and Schering-Plough to achieve market penetration and generate revenues for those products covered by the alliances. We intend to 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 eight 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 the Development of 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.

## **Background**

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

According to IMS Health Incorporated (“IMS”), product sales for the oral controlled-release segment of the U.S. prescription drug market were approximately \$16.3 billion for the year ended December 31, 2002. The FDA has approved more than 80 different oral controlled-release brand name products for sale in the United States. 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 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 Drug Companies***

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:

- **ANDA Approvals** – ANDA approvals have increased significantly in the last seven years. Since 1996, the FDA has approved approximately 234 ANDAs per year. During this period, the median approval time for ANDAs has been reduced from approximately 23 months to approximately 18 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. In 2001, approximately 45% of the prescriptions in the United States were filled with generics. This fill rate 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 Office of Generic Drugs estimates that, by 2004, \$30 billion of brand name drugs will lose patent protection and, by 2010, \$48 billion will lose this protection.

## **Technology**

We have developed eight different proprietary controlled-release delivery technologies that can be utilized with a variety of oral dosage forms and drugs. 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 four U.S. patents, have filed one application, and expect to file three additional U.S. patent applications and various foreign patent applications relating to our drug delivery technologies. We also apply 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 proprietary 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 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 United States Patent and Trademark Office (“USPTO”) has granted us a patent for CMDS; patent #US 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; patent #US 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. We have filed a patent application for DMDS with the USPTO.
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.

## Drug Delivery Technology

## Description

	<p>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 expect to file a patent application for PMDS with the USPTO.</p>
Multi-Ingredient Multiple-Action Delivery System (MMDS)	<p>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.</p>
Particle Dispersion Systems (PDS)	<p>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: Patent #US 6,531,158.</p>
Pharmaceutical Stabilization System (PSS)	<p>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: patent #US 6,333,332.</p>
Rapid Dissolving Delivery System (RDDS)	<p>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.</p>

## **Products And Product Development**

We currently market twenty-seven generic pharmaceuticals that represent dosage variations of twelve 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 February 24, 2003, we had nineteen applications pending at the Food and Drug Administration (“FDA”), including three tentatively approved, that address more than \$5.8 billion in U.S. product sales for the twelve months ended December 31, 2002. Thirteen of these filings were made under Paragraph IV of the Hatch-Waxman Amendments. We have approximately seventeen 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 \$3.2 billion for the twelve months ended December 31, 2002.

All the sales data referenced herein is based on information obtained from IMS Health, US, all channels, for the year ended December 31, 2002.

The following table lists the ten recent Abbreviated New Drug Applications (“ANDAs”) which have been approved:

## SPECIALTY

## CONTROLLED RELEASE

Product	Strengths	U.S. Market Size (mil)	Product	Strengths	U.S. Market Size (mil)
Minocycline Hydrochloride Capsules	50mg, 75mg, 100mg	\$180	Omeprazole Delayed Released Capsules	10mg, 20mg	\$3,197
Sotalol Hydrochloride Tablets	80mg, 120mg, 160mg, 240mg	\$69	Loratadine and Pseudoephedrine Sulfate 12-hour Extended Release Tablets	5mg/120mg	\$296
Riluzole Tablets	50mg	\$35	Pentoxifylline Extended Release Tablets	400mg	\$35
Fludrocortisone Acetate Tablets	0.1mg	\$29	Orphenadrine Citrate Extended Release Tablets	100mg	\$19
Terbutaline Sulfate Tablets	2.5mg, 5mg	\$13			
Rimantadine Hydrochloride Tablets	100mg	\$7			
	TOTAL	\$333		TOTAL	\$3,547

The following table provides the current status of the Generic Controlled-Release (CR) Projects:

	Project	Innovator	Status	U.S. Market Size (mil)
CR1	Disclosed Projects	8 Projects	Pending at FDA	\$4,487
	Omeprazole 40mg Delayed Released Capsules	Prilosec (AstraZeneca)	Tentative Approval	\$340
	Bupropion Hydrochloride 100mg and 150mg Extended Release Tablets	Wellbutrin SR (Glaxo)	Paragraph IV	\$1,501
	Bupropion Hydrochloride 150mg Extended Release Tablets	Zyban (Glaxo)	Paragraph IV	\$78
	Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24 hour Extended Release Tablets	Claritin-D 24 hr (Schering)	Tentative Approval	\$489
	Fexofenadine and Pseudoephedrine Hydrochloride 60mg/120mg Extended Release Tablets	Allegra-D (Aventis)	Paragraph IV	\$407
	Oxycodone Hydrochloride 80mg Extended Release Tablet	OxyContin (Purdue)	Paragraph IV	\$544
	Oxycodone Hydrochloride 10mg, 20mg, and 40mg Extended Release Tablets	OxyContin (Purdue)	Paragraph IV	\$974

	Project	Innovator	Status	U.S. Market Size (mil)
	Carbidopa and Levodopa 25 mg/100mg and 50mg/200mg Extended Release Tablets	Sinemet CR (BMS)	Paragraph IV	\$154
CR1	Undisclosed Projects	2 Projects	Pending at FDA	\$533
	Total Group CR1 Projects	10 Projects	Pending at FDA	\$5,020
	Total Group CR2 Projects	9 Projects	Under Development	\$3,386
		19 Total Controlled Release Projects		\$8,406

The following table provides the current status of the Generic Specialty (SP) Projects:

	Project	Innovator	Status	U.S. Market Size (mil)
SP1	Disclosed Projects	3 Projects	Pending at FDA	\$743
	Fenofibrate 67mg, 134mg, and 200mg Capsules	Tricor Capsules (Abbott)	Tentative Approval	\$2
	Loratadine 10mg Orally Disintegrating Tablets	Claritin Reditabs (Schering)	Paragraph IV	\$330
	Fenofibrate 160mg Tablets	Tricor Tablets (Abbott)	Paragraph IV	\$411
SP1	Undisclosed Projects	6 Projects	Pending at FDA	\$119
	Total Group SP1 Projects	9 Projects	Pending at FDA	\$862
	Total Group SP2 Projects	8 Projects	Under Development	\$272
		17 Total Generic Specialty Projects		\$1,134

### ***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 proprietary processes 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. We currently have four ANDAs approved and ten ANDAs under review by the FDA for controlled-release generic pharmaceuticals. Nine of our pending ANDA filings for controlled-release generic pharmaceuticals contain certifications under Paragraph IV of the Hatch-Waxman Amendments. Under Paragraph IV, we are required to certify to the FDA that we believe our product will not infringe the innovator's patents, or that such patents are invalid or unenforceable. This certification is known as a "Paragraph IV Certification."

If the FDA accepts our ANDA, we must send a Paragraph IV Certification to the patent and NDA holder. The patent holder may then initiate a legal challenge to our Paragraph IV Certification 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. 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.

*Prilosec* In March 2000, the FDA accepted our ANDA submission for a bioequivalent version of Prilosec, which is used for the treatment of ulcers and gastroesophageal reflux disease, and is currently being marketed by AstraZeneca PLC. AstraZeneca has commenced patent litigation against us with respect to this product. Our ANDA was granted final approval for the 10mg and 20mg strengths, and tentative approval for the 40mg strength, by the FDA on November 10, 2002. Total U.S. sales for Prilosec were approximately \$3.5 billion in 2002.

*Wellbutrin SR* In June 2000, the FDA accepted our ANDA submission for a bioequivalent version of Wellbutrin SR, which is used to treat depression, and is currently being marketed by GlaxoSmithKline plc (“Glaxo”). Glaxo commenced patent infringement litigation against us with respect to this product in October 2000. In August 2002, the United States District Court, Northern District of California, issued an order granting IMPAX’s Motion for Summary Judgment of Non-Infringement. This ruling is currently under appeal by Glaxo. Total U.S. sales for Wellbutrin SR were approximately \$1.5 billion in 2002.

*Zyban* In June 2000, the FDA accepted our ANDA submission for a bioequivalent version of Zyban, which is prescribed for the cessation of smoking, and is currently being marketed by Glaxo. Glaxo commenced patent infringement litigation against us with respect to this product in October 2000. In August 2002 the United States District Court, Northern District of California, issued an order granting IMPAX’s Motion for Summary Judgment of Non-Infringement. This ruling is currently under appeal by Glaxo. Total U.S. sales for Zyban were approximately \$78 million in 2002.

*Claritin-D 24* In September 2000, the FDA accepted our ANDA submission for a bioequivalent version of Claritin-D 24-hour, which is a once-a-day antihistamine for the treatment of allergies and is currently being marketed by Schering-Plough. Schering-Plough commenced patent infringement litigation against us with respect to this product in January 2001. Schering-Plough said in a March 8, 2002 press release that it had filed with the U.S. Food and Drug Administration to switch all Claritin formulations from prescription to OTC marketing status. The FDA granted tentative approval to our ANDA in May 2002. In August 2002, a United States District Court in Newark, New Jersey ruled some of the claims on a patent filed by Schering-Plough covering desloratadine, the metabolized form of Claritin’s active ingredient loratadine, were anticipated by prior patent and were not valid. In doing so, the judge granted a Motion for Summary Judgment filed by 15 generic drug manufacturers, including IMPAX. This ruling is currently being appealed by Schering-Plough. In December 2002, FDA approved Schering-Plough’s request to switch this product to OTC marketing status. Total U.S. sales of Claritin-D 24-hour were approximately \$489 million in 2002. Another Schering-Plough patent covering loratadine formulations is still being litigated.

*Claritin-D 12* In December 2000, the FDA accepted our ANDA submission for the bioequivalent version of Claritin-D 12-hour, which is an antihistamine for the treatment of allergies and is currently being marketed by Schering-Plough. Schering-Plough commenced litigation against us with respect to this product in January 2001. Schering-Plough said in a March 8, 2002 press release that it had filed with the U.S. Food and Drug Administration to switch all Claritin formulations from prescription to OTC marketing status. The FDA granted tentative approval to our ANDA in May 2002. In August 2002, a United States District Court in Newark, New Jersey ruled some of the claims on a patent filed by Schering-Plough covering desloratadine, the metabolized form of Claritin’s active ingredient loratadine, were anticipated by prior patent and were not valid. In doing so, the judge granted a Motion for Summary Judgment filed by 15 generic drug manufacturers, including IMPAX. This ruling is currently being appealed by Schering-Plough. In December 2002, the FDA approved Schering-Plough’s request to switch this product to OTC marketing status. Our ANDA was granted final approval by the FDA in January 2003 and we began shipping the product at the end of January 2003. Total U.S. sales of Claritin-D 12-hour were approximately \$296 million in 2002.

*Allegra-D* In December 2001, the FDA accepted 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. Total U.S. sales for Allegra-D were approximately \$407 million in 2002.

- OxyContin 80mg* In December 2001, the FDA accepted our ANDA submission for a bioequivalent version of the 80mg 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. Total U.S. sales for OxyContin 80mg were approximately \$544 million in 2002.
- OxyContin 10mg, 20mg and 40 mg* In June 2002, the FDA accepted our ANDA submission for a bioequivalent version of the 40mg strength of OxyContin, which is used for the management of moderate to severe pain, and is currently marketed by Purdue Pharmaceuticals L.P. This application was subsequently amended to add the 10mg and 20mg strengths. Purdue commenced patent litigation against us with respect to this product in September 2002. Total U.S. sales for OxyContin 10mg, 20mg and 40mg were approximately \$974 million in 2002.
- Sinemet CR* In December 2002, the FDA accepted our ANDA submission for a bioequivalent version of Sinemet CR that is used in the treatment of Parkinsonism and is currently distributed by Bristol Myers Squibb. Merck & Co., the patent holder, commenced patent infringement litigation against us with respect to this product in February 2003. Total U.S. market sales for Sinemet CR and its generic equivalent were \$154 million in 2002.

We have also submitted ANDAs related to two additional products, the details of which have not been publicly disclosed, with U.S. sales of approximately \$533 million for the twelve months ended December 31, 2002.

We believe that 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 would run from commencement of the first commercial marketing of the product. We do not believe we were the first to file with respect to our other pending applications with Paragraph IV Certifications.

In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10mg/240mg 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 milestone payments and a royalty on Wyeth sales.

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

In addition to the products for which we have submitted applications, we have nine other controlled-release ANDA eligible products in various stages of development. Total U.S. sales for the brand name versions of these products were approximately \$3.4 billion in 2002. 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 February 24, 2003 we had nine applications pending at the FDA for other generic pharmaceuticals. These applications are for products that are generic versions of brand name pharmaceuticals whose total U.S. sales were approximately \$862 million for the twelve months ended December 31, 2002. We have an additional eight other products under development relating to brand name products that had approximately \$272 million in total U.S. sales for the twelve months ended December 31, 2002.

We have submitted ANDAs for generic versions of the following brand name products, the first three of which were made under Paragraph IV of the Hatch-Waxman Amendments:

*Claritin Reditabs* In October 2000, the FDA accepted our ANDA submission for a bioequivalent version of Claritin Reditabs, which is used for the relief of seasonal allergic rhinitis, and is currently marketed by Schering-Plough. Schering-Plough commenced litigation against us with respect to this product in January 2001. Schering-Plough said in a March 8, 2002 press release that it had filed with the U.S. Food and Drug Administration to switch all Claritin formulations from prescription to OTC marketing status. The FDA granted tentative approval to our ANDA in May 2002. In August 2002, the United States District Court in Newark, New Jersey ruled some of the claims on a patent filed by Schering-Plough covering desloratadine, the metabolized form of Claritin's active ingredient loratadine, were anticipated by prior patent and were not valid. In doing so, the judge granted a Motion for Summary Judgment filed by 15 generic drug manufacturers, including IMPAX. This ruling is currently being appealed by Schering-Plough. In December 2002, the FDA approved Schering-Plough's request to switch this product to OTC marketing status. Our ANDA was granted final approval by the FDA in January 2003 and we began shipping the product at the end of January 2003. Total U.S. sales for Claritin Reditabs were approximately \$330.2 million for the twelve months ended December 31, 2002.

*Tricor Capsules* In May 2000, the FDA accepted our ANDA submission for a bioequivalent version of Tricor Capsules, which is used for the treatment of very high serum triglyceride levels, and was formerly marketed by Abbott Laboratories ("Abbott"). Abbott has commenced patent infringement litigation against us with respect to this product. We received tentative FDA approval of this ANDA in February 2002. Total U.S. sales for Tricor Capsules were approximately \$2.3 million for the twelve months ended December 31, 2002. On March 26, 2003, the United States District Court in Chicago, Illinois, ruled that our ANDA does not infringe Abbott's patent.

*Tricor Tablets* In December 2002, the FDA accepted our ANDA submission for a bioequivalent version of Tricor 160mg 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. Total U.S. sales for Tricor Tablets were approximately \$410.5 million for the twelve months ended December 31, 2002.

*Rilutek Tablets* In May 2001, the FDA accepted 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 (ODE) 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 patent #US 5,527,814 that was only recently listed by Aventis in the FDA "Orange Book." On December 12, 2002, the District Court of Wilmington, Delaware, granted the Preliminary Injunction Notice brought by Aventis in October 2002 to forestall our entry into this market. Trial is currently scheduled for October 2003. Total U.S. sales for Rilutek were approximately \$34.8 million for the twelve months ended December 31, 2002.

We have also submitted applications relating to six additional products, the details of which have not been publicly disclosed, with U.S. sales of approximately \$119 million for the twelve months ended December 31, 2002.

In December 2001, we entered into a License and Supply Agreement granting to Novartis exclusive rights to market an OTC generic Claritin (loratadine) product. 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.

In addition, we currently market twenty-seven generic pharmaceuticals that represent twelve different pharmaceutical compounds. Our revenues from these products were approximately \$23.8 million in the year ended December 31, 2002.

### ***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, in addition, 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 Co-Chief Executive Officer, Larry Hsu, Ph.D., our President, Michael G. Wokasch, our Chief Operating Officer, and Nigel Fleming, Ph.D., a Director, all have extensive experience in developing and/or marketing products for the treatment of CNS disorders.

According to IMS Health Incorporated data, CNS is the largest therapeutic category in the U.S. with 2002 retail sales of \$32 billion, or 15.7% of the \$203 billion U.S. retail drug market. CNS drug sales grew 10.4% in 2002 versus a sales growth of 9.1% 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. In the United States, approximately 4,500 neurologists write approximately 75% of all prescriptions for CNS related disorders.

We have three CNS projects under development. We are currently evaluating three additional brand name projects.

These potential products may require us to file 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. We believe that developing NDAs for this type of brand name product 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 because the FDA has previously approved the core chemical entities of these products. We believe we may also be eligible for FDA marketing exclusivity rights for certain products which we develop in our brand name drug development programs that will be ultimately approved by the FDA.

## **Sales And Marketing**

### ***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 a focus on CNS disorders.

### ***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. We had three major customers, Amerisource-Bergen, Cardinal Health and McKesson, that account for approximately 57% of total sales for the year ended December 31, 2002.

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

In June 2001, we entered into a strategic alliance agreement with a subsidiary of Teva Pharmaceutical Industries, Ltd. for twelve controlled-release generic products. The agreement grants Teva exclusive U.S. prescription marketing rights for six of our products. The six products for which ANDAs were already filed at the time of the agreement were Omeprazole 10mg,

20mg, and 40mg Delayed Released Capsules (generic of Prilosec), Bupropion Hydrochloride 100mg and 150mg Extended Release Tablets (generic of Wellbutrin), Bupropion Hydrochloride 150mg Extended Release Tablets (generic of Zyban), Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets (generic of Claritin-D 12-Hour) and Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24 hour Extended Release Tablets (generic of Claritin-D 24-hour) and Loratadine Orally Disintegrating Tablets (generic of Claritin Reditabs). The agreement allows IMPAX to enter into agreements with other companies relating to the development, supply and marketing of these products for the OTC market. Of the six products to be developed at the time the agreement was signed, three ANDAs have since been filed with the FDA. Teva elected to commercialize a competing product to one of the three products filed since June 2001, which it has 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.

In December 2001, we entered into an agreement granting Novartis exclusive rights to market an OTC loratadine product, which we will supply to Novartis.

In February 2002, we received tentative approval from the FDA for a generic version of Tricor (Fenofibrate 67mg, 134mg, and 200mg) Micronized Capsules. On March 26, 2003, the United States District Court in Chicago, Illinois, ruled that our ANDA does not infringe Abbott's patent.

In March 2002, we received FDA approval for a generic version of Florinef (Fludrocortisone Acetate 0.1mg) Tablets. This was the first approval for a generic form of Florinef.

In May 2002, we received tentative approval from the FDA for generic versions of Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate 5mg/120mg) and Claritin-D 24-hour (Loratadine and Pseudoephedrine Sulfate 10mg/240mg) Extended Release Tablets.

In June 2002, we signed a semi-exclusive agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10mg/240mg 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 milestone payments and a royalty on Wyeth sales.

Also in June 2002, we signed a non-exclusive agreement with Schering-Plough relating to our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets for the OTC market under the Claritin-D 12-hour brand. The structure of the agreement includes milestone payments and agreed sales prices. We commenced shipment to Schering-Plough at the end of January 2003.

In July 2002, we received tentative approval from the FDA for a generic version of Rilutek (Riluzole) 50mg tablets.

In September 2002, we received FDA approval for a generic version of Flumadine (Rimantadine Hydrochloride 100mg) Tablets and subsequently launched the product in the fourth quarter of 2002.

In November 2002, we received FDA approval for generic versions of Prilosec (Omeprazole Delayed Released Capsules) 10mg and 20mg, and tentative approval for a generic version of Prilosec (Omeprazole Delayed Release Capsules) 40mg. A lawsuit with AstraZeneca is still pending in the courts.

In January 2003, we received final approval from the FDA for a generic version of Rilutek (Riluzole 50mg) tablets. A lawsuit with Aventis is still pending in the courts.

Also in January 2003, we received final approval from the FDA for a generic version of Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets). Following this approval, we commenced shipping this product to Schering-Plough.

Our current products are marketed through our Global Pharmaceuticals division. 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 intends on seeking 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. According to IMS Health data, approximately 4,500 prescribing neurologists write approximately 75% of the prescriptions written by neurologists in the CNS market. We believe this concentration will allow us to maintain a relatively small sales and marketing group for CNS products.

### **Strategic Alliances**

#### ***Strategic Alliance With Teva***

In June 2001, we entered into a strategic alliance agreement with a subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva") for twelve controlled-release generic pharmaceutical products. Teva (Nasdaq: TEVA), headquartered in Israel, is among the top 40 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Over 80% 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. marketing rights for six of our products pending approval at the FDA and six products under development at the time the agreement was signed. Of the six products under development, three have been filed with the FDA. Teva elected to commercialize a competing product to one of the three 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 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 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 our 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 six products 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, all of which were filed 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 \$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 common stock, or approximately 3% of the total shares of common stock outstanding at December 31, 2002. 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 the products specified in our alliance agreement, IMPAX 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 alliance agreement. The \$22 million is reflected on the balance sheet as a refundable deposit. The refundable deposit was provided in the form of a loan. This loan originally had an 8% annual interest rate. According to the agreement, if IMPAX received tentative or final approval for any of three products, the accrued interest is forgiven and no

future interest will accrue. During 2002, we received tentative approvals for our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets, Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24-hour Extended Release Tablets, and Omeprazole Delayed Released 40mg products and final approvals for our Omeprazole Delayed Release 10mg and 20mg capsules resulting in the reversal of the accrued interest in the fourth quarter of 2002 and no future interest will accrue. Teva will forgive portions of this loan as we achieve milestones relating to the development and launch dates of the products described in our alliance agreement; these milestones, if achieved, will represent the culmination of a separate earnings process. If we fail to achieve the milestones, we will have to repay Teva some or all of the \$22.0 million loan on January 15, 2004. If we miss a milestone, Teva has the option of making us repay 100%, or 50% of the portion of the loan associated with that milestone. If Teva requires us to repay 100% of the portion of the loan related to the missed milestone, Teva's right to market that product will no longer be exclusive. However, if Teva requires us to repay only 50% of the portion of the loan related to the missed milestone, Teva will continue to have an exclusive marketing right for that product. At our option, we may repay Teva any amounts we owe 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 January 15, 2004. However, if any of the shares we issue to Teva as repayment of the loan will cause Teva to own in excess of 19.9% of our outstanding common stock, we will have to repay that portion of the loan in cash.

If we repay the loan in stock, such payment will result in dilution. If we repay all or a portion of the loan in cash, we may seek additional sources of liquidity to fund such payment, as discussed in the "Liquidity and Capital Resources" section of Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations.

As of February 25, 2003, we believe that approximately \$10.5 million of the \$22 million may be forgiven prior to January 15, 2004, although there is no assurance that any of the \$22 million may be ultimately forgiven.

### ***OTC Alliances***

In December 2001, we entered into a License and Supply Agreement granting to Novartis exclusive rights to market an OTC generic Claritin (loratadine) product. 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.

In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth relating to our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets and Loratadine and Pseudoephedrine Sulfate 10mg/240mg 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 milestone payments and a royalty on Wyeth sales.

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

### **MANUFACTURING**

We manufacture our finished dosage form products at our 31153 San Antonio Street, Hayward, California 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 the 31153 San Antonio Street, Hayward, California facility on tablet and capsule manufacturing, which requires less space. The facility currently manufactures Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets, Orphenadrine Citrate 100mg Extended Release Tablets, Sotalol Hydrochloride 80mg, 120mg, 160mg, and 240mg Tablets, Methitest™ (methyltestosterone) Tablets, Minocycline Hydrochloride 50mg, 75mg, and 100mg Capsules, Fludrocortisone Acetate Tablets 0.1mg, Terbutaline Sulfate 2.5mg and 5.0mg Tablets, and Rimantadine Hydrochloride 100mg Tablets. We began full-scale manufacturing in this facility in June 2002 and believe we have sufficient capacity to produce new products in the future. Currently, we are using about one-third of our estimated annual production capacity of up to approximately 1.5 billion tablets and capsules.

Our research and development activities are situated at 30831 Huntwood Avenue, Hayward, California. We believe this proximity allows for a more efficient transfer and scale-up of products from research and development to manufacturing. Currently, our 30831 Huntwood Avenue, Hayward, California facility serves as our research and development center and

analytical development laboratory, and has a pilot plant that can accommodate our current development work. This facility will also provide space for the expansion of our development resources in future years.

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 IMPAX's 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 United States 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 Impax Laboratories, Inc.

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.

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 federal government extensively regulates all pharmaceutical manufacturers, including the FDA, the Drug Enforcement Agency ("DEA"), and various state agencies. 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 (i.e., the "reference drug" or "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 and packaging 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 2003, annual establishment fees for facilities that produce products subject to NDAs are approximately \$209,900, and product listing fees are approximately \$32,400 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 2003, user fees to file an NDA are approximately \$533,400.

*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 reference or listed drug), the FDA ordinarily only requires bioavailability data demonstrating that the generic formulation is bioequivalent to the previously approved reference 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 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 FDCA 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 listed drug are alleged to be invalid, unenforceable, or not infringed, the holder or holders of the brand name drug patents may institute patent infringement litigation. Second, the first company to file an ANDA for a given drug and which certifies that an unexpired patent covering the reference 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.

While the Hatch-Waxman Amendments codify the ANDA mechanism for generic drugs, they also fosters 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. 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 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 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 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. The states and the FDA are still implementing various sections of the PDMA. Nevertheless, 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 methods of reimbursement and fixing of reimbursement levels are under active review by federal, state and local governmental entities, as well as by private third-party reimbursers. At present, the Justice Department and U.S. Attorneys Offices and State Attorneys General have initiated investigations, reviews, and litigation into pharmaceutical pricing and promotional practices. 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.

## **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 28, 2003, we employed approximately 273 full-time employees. Of these employees, approximately 96 are in operations, 80 are in research and development, 49 work in the quality area, 38 are in administration, and 10 work in sales and marketing. 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.

Charles Hsiao	59	Chairman, Co-Chief Executive Officer and Director
Barry R. Edwards	46	Co-Chief Executive Officer and Director
Larry Hsu	54	President and Director
Michael G. Wokasch	51	Chief Operating Officer
Cornel C. Spiegler	58	Chief Financial Officer and Corporate Secretary
May Chu	53	Vice President, Quality Affairs
David S. Doll	44	Senior Vice President, Sales and Marketing

Charles Hsiao, Ph.D. has been Chairman, Co-Chief Executive Officer and Director since December 14, 1999. Dr. Hsiao co-founded Impax Pharmaceuticals, Inc. in 1994, and has served as Chairman, Chief Executive Officer and a Director since its inception. 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 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 Co-Chief Executive Officer since December 14, 1999, and a Director since January 1999. Previously, Mr. Edwards has served as President since August 1998 and Chief Executive Officer since January 1999. 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 President and Director since January 2, 2003, and was President, Chief Operating Officer and Director through January 1, 2003. Dr. Hsu co-founded Impax Pharmaceuticals, Inc. in 1994 and served as its President, Chief Operating Officer and a Director since its inception. 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.

Michael G. Wokasch joined IMPAX on January 3, 2003 as Chief Operating Officer. Mr. Wokasch was a member of the IMPAX Board of Directors from May 2001 to December 2002. Mr. Wokasch has over 20 years pharmaceutical experience in all aspects of the business, including operations, product development and commercialization, distribution, and sales and marketing. Mr. Wokasch served as President of PanVera LLC, a wholly-owned subsidiary of Vertex Pharmaceuticals, from July 2001 until December 2002. Prior to his position at PanVera, he was CEO and President of Gala Design Inc., a biotechnology start-up specializing in production of pharmaceutical proteins from transgenic cattle. In addition, from 1997 to 1999, Mr. Wokasch was Corporate Senior Vice President and Group President of Covance Early Development, which was spun out of Corning, Inc. Throughout his career, Mr. Wokasch has held a variety of senior management positions at

companies such as Promega Corporation, Abbott Laboratories, Bayer Corporation, and Merck & Co. Mr. Wokasch received his B.S. in Pharmacy from the University of Minnesota in 1978.

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 14, 1999. Ms. Chu joined Impax Pharmaceuticals, Inc. in 1996 as Vice President, Analytical and Quality Assurance. From 1985 to 1996, Ms. Chu was employed at Watson Laboratories in the areas of Analytical and QA. 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 February 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 Pharmaceutical. 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 reports, statements and other information we file 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 [www.impaxlabs.com](http://www.impaxlabs.com) 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). 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, an inactive textual reference.

## **ITEM 2. PROPERTIES**

We have four facilities, as follows:

### 30831 Huntwood Avenue - Hayward, California

This 35,125 square foot building is our 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.

### 31153 San Antonio Street - Hayward, California

This 50,400 square foot building 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 and Teva's refundable deposit.

### 1502 Crocker Ave - 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 Huntwood Avenue building. 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.

### 3735 Castor Avenue - Philadelphia, PA

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 on Jasper Street of 1.04 acres, of which 0.50 acres are paved for parking.

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 be prevented from marketing that product if patent litigation is still pending.

Litigation has been filed against us in connection with twelve 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 United States District Court in Wilmington, Delaware claiming that IMPAX's submission of an Abbreviated New Drug Application for Omeprazole Delayed Release Capsules, 10mg 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, 10mg and 20mg, 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 40mg 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 10mg, 20mg, and 40mg Delayed Released Capsules Patent Litigation*, MDL-1291, has been established to coordinate pre-trial proceedings. Both lawsuits filed by AstraZeneca et al. 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 another is invalid. In particular, the '794 patent (omeprazole in combination with clarithromycin in the treatment of *H.pylori*); '305 (combination therapy for *H.pylori* related disease); and the '342 patent (*H.pylori* treatment) were declared invalid either in pre-trial summary proceedings or after the trial described below. The trial court also ruled that the '499 (sulphenamide salt of omeprazole) was not infringed in related summary proceedings. These rulings effectively eliminated these four patents from the trial of these infringement cases, although AstraZeneca may appeal these decisions as part of the overall appeal process in the case.

On October 11, 2002, after a 52-day long trial involving Andrx, Genpharm, Cheminor, and Kremers, the trial judge handling the multidistrict litigation rendered a 277-page opinion that ruled on AstraZeneca's complaints that these four defendants (the "First Wave Defendants") infringed the remaining patents-in-suit. Most importantly, the trial judge ruled that three of the First Wave defendants, Andrx, Genpharm, and Cheminor, infringed the '505 and '230 patents asserted by AstraZeneca in its complaints, and that those patents are valid until 2007. The court construed the specific language of those two related patents and found that each of these three First Wave Defendants proposed to manufacture their generic equivalents of omeprazole using a process that employed an Alkaline Reacting Compound, which the trial court said was defined in the patent to include disodium hydrogen phosphate (a substance also used in Impax's formulation), to create a "stabilizing" alkaline protective "microenvironment" around active omeprazole particles in the "core region." The trial court also construed the language of these patents to require that an inert "subcoating" be "disposed" on the "core." The court said that the language of the patents should be construed to mean that such a "subcoating" might be created "in situ" by some reaction between elements of the "core" and an enteric coating. The court held that the formulations employed by Andrx, Genpharm, and Cheminor met these patent requirements as well, and that these three First Wave defendants thus infringed both the '505 and '230 patents.

In the same ruling, the trial court ruled that the remaining First Wave defendant, Kremers, did not infringe either the '505 or the '230 patent. This defendant's formulation differed from the formulation used by the other First Wave defendants in several respects. Among other things, the trial court's opinion stated that Kremers does not use an Alkaline Reacting Compound in its "core."

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 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 less certain.

In December 2002, following proceedings before a Special Master appointed to supervise discovery in the case, the trial court entered a new scheduling order governing pre-trial proceedings relating to the six Second Wave defendants, including IMPAX. The timing of further proceedings in this litigation may be adversely affected by the appellate proceedings that have been commenced by AstraZeneca and several of the First Wave Defendants. Under the scheduling order entered by the

court, discovery and pretrial proceedings have already commenced, with the parties exchanging additional document requests and interrogatories. Depositions of fact witnesses commenced on February 15, 2003 and, under the scheduling order, must be completed by June 2003. Expert witness depositions will occur thereafter and must be completed by mid-August 2003.

Two of the Second Wave defendants filed Motions for Summary Judgment of Non-Infringement based upon Judge Jones' October 2002 ruling. The trial court has deferred ruling on those motions until discovery is completed.

Under the scheduling order, any further Motions for Summary Judgment must be filed by mid-September 2003 and will be heard by the trial court later in the Fall of 2003. IMPAX may well file a Motion for Summary Judgment of non-infringement following the close of discovery. If the case is not summarily resolved (as by Summary Judgment), the case involving IMPAX will be returned to the U.S. District Court in Delaware for trial. A possibility exists that the case 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, IMPAX will press the court to schedule a date for trial of the case in 2003, but no assurance can be given that trial will commence at any particular time. IMPAX believes, however, that any trial that might be scheduled in the case will commence no later than early 2004. IMPAX is vigorously defending the action brought by AstraZeneca. IMPAX's defense of the action is being conducted under an insurance policy issued by AIG, which pays a portion of the costs of IMPAX's defense of AstraZeneca's suit (see "Insurance" below). In March, 2001, AstraZeneca advised all of the defendants in the multidistrict litigation that four new patents had been added to the FDA's Orange Book as Omeprazole patents. IMPAX filed Paragraph IV certifications asserting that, to its knowledge, its Omeprazole 10mg, 20mg, and 40mg Delayed Released Capsules will not infringe valid claims of the four newly listed patents. The forty-five (45) day period for AstraZeneca to file suit against IMPAX under the four patents expired on August 6, 2001. AstraZeneca did not file suit on these patents against IMPAX or any other generic company that filed Paragraph IV certifications for these patents.

#### **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 United States District Court in Chicago, Illinois claiming that IMPAX's submission of an ANDA for Fenofibrate (Micronized) Capsules, 67mg, 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 200mg Fenofibrate (Micronized) capsules. A third action was filed for IMPAX's 134mg Fenofibrate (Micronized) Capsules in March 2001. All three actions seek an injunction preventing IMPAX from marketing its fenofibrate products until January 19, 2009, and an award of damages for any commercial manufacture, use, or sale of IMPAX's fenofibrate product, together with costs and attorney fees.

Abbott and Fournier have filed essentially the same lawsuits against Novopharm and 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, Judge Darrah granted Novopharm's Motion for Summary Judgment of Non-Infringement. The grounds for finding non-infringement by Novopharm were directly applicable to IMPAX. IMPAX filed its own Motion for Summary Judgment of Non-Infringement before Judge Gottschall, the judge who is presiding over the IMPAX case.

In the interim, Abbott appealed Judge Darrah's ruling to the United States Court of Appeals for the Federal Circuit. IMPAX has filed a brief in that appeal as a "friend of court," although IMPAX is not directly a party to the appeal. On March 20, 2003, the Court of Appeals upheld the lower court's decision.

On March 26, 2003, Judge Gottschall ruled that IMPAX's product does not infringe on Abbott's patent. An appeal by Abbott is likely.

IMPAX is vigorously defending the action brought by Abbott Labs under an insurance policy issued by AIG, which pays a portion of the costs of IMPAX's defense of Abbott's suit (see "Insurance" below).

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

Glaxo filed a Complaint (Case No. 00-04403) against IMPAX in the United States 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/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.

All parties attended a Status Conference in July 2001 to discuss the need for a Markman (claim construction) Hearing. IMPAX was successful in convincing the Court that a Markman Hearing was unnecessary because there was no literal infringement and no dispute regarding the Claim Construction proffered by Glaxo. Instead, IMPAX advocated that our Summary Judgment Motion, based upon prosecution history estoppel grounds, be calendared for oral argument. 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.* to the pending Motion for Summary Judgment. An additional Motion for Summary Judgment was brought in early August 2002, requesting Judge Patel apply the District Court for the Eastern District of Virginia's decision limiting the scope of the '798 patent in the *Glaxo v. Excel* case to IMPAX's ANDA formulation.

On August 21, 2002, Judge Patel granted IMPAX's motions for Summary Judgment, stating that "prosecution estoppel bars infringement by equivalents throughout the '798 patent." Glaxo has appealed Judge Patel's decision to the Court of Appeals for the Federal Circuit and that appeal was fully briefed on January 22, 2003. Oral argument will be scheduled for sometime in the first quarter 2003, after which IMPAX expects a decision on the appeal. The defense costs in this litigation are covered under an insurance policy issued by AIG (see "Insurance" below).

Also, Glaxo has decided to settle its Bupropion Hydrochloride 100mg and 150mg 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 United States 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 10mgs of loratadine and 240mgs 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 United States District Court for the District of New Jersey (Case No. 01-0279), alleging that IMPAX's proposed orally-disintegrating loratadine tablets ("Reditabs") infringe claims of the '716 patent. Schering-Plough has sought to enjoin IMPAX from obtaining approval to market its Reditab 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 United States 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 5mgs of loratadine and 120mgs 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 December 2001. Oral argument on two of the Dispositive Motions took place before Judge Bissell on June 26, 2002. On August 8, 2002, Judge Bissell granted Defendants' Motion for Summary Judgment that Claims

1 and 3 of the '716 Patent are inherently anticipated by Schering-Plough's '233 Patent and denied Schering-Plough's Motion for Summary Judgment on Defendants' inherent anticipation defenses and counterclaims. The Court held that Claims 1 and 3 of the '716 patent – the claims of that patent that Schering-Plough asserted against IMPAX in Case Nos. 01-0009, 01-0279, 01-0520 – are invalid. Schering-Plough has appealed Judge Bissell's decision to the U.S. Court of Appeals for the Federal Circuit. The appeal has been fully briefed. The Federal Circuit has not yet scheduled oral argument on the appeal.

In Case No. 01-0009, fact discovery on the '697 patent is completed and expert discovery on the '697 patent was completed on January 24, 2003. The Court has not yet entered a schedule for Briefing Dispositive Motions on the '697 patent. The defense costs in this litigation are covered under an insurance policy issued by AIG (see "Insurance" below).

#### **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 "Aventis") sued IMPAX in the United States 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 60mg of fexofenadine and 120mg of pseudoephedrine hydrochloride, infringe United States 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 60mg/120mg Extended Release Tablet product infringes United States Patent No. 6,399,632. Aventis seeks an injunction preventing IMPAX from marketing its Fexofenadine and Pseudoephedrine Hydrochloride 60mg/120mg 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 60mg/120mg Extended Release Tablet product, together with costs and attorneys' fees.

On March 26, 2002, Aventis filed a virtually identical complaint against IMPAX in the United States District Court for the District of Delaware (Civil Action No. 02-226). The Delaware complaint was filed in case Aventis could not obtain personal jurisdiction over IMPAX in New Jersey. On May 8, 2002, IMPAX moved to dismiss the New Jersey action for lack of personal jurisdiction. On December 18, 2002, IMPAX's Motion to Dismiss the action in New Jersey was denied. On December 19, 2002, a stipulation dismissing the Delaware action without prejudice was filed.

Because of the pending procedural motions, discovery is in its early stages. IMPAX believes, however, that it has strong 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. in New Jersey asserting the same patents against Barr's proposed Fexofenadine and Pseudoephedrine Hydrochloride 60mg/120mg Extended Release Tablet product. The IMPAX case will be coordinated with the Barr case for discovery purposes, but it has not yet been decided whether the two will be consolidated for trial.

#### **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 United States District Court for the Southern District of New York alleging that IMPAX's submission of ANDA No. 76-318 for 80mg OxyContin Tablets infringes three patents owned by Purdue. The Purdue patents are U.S. 4,861,598, U.S. 4,970,075 and U.S. 5,266,331, all directed to controlled release opiod formulations. On September 19, 2002, Purdue filed a second Infringement Complaint regarding IMPAX's 40mg OxyContin generic product. On October 9, 2002, Purdue filed a third Infringement Complaint regarding IMPAX's 10mg and 20mg OxyContin generic products. 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 is currently disputing the jurisdiction of the United States District Court for the Southern District of New York in which Purdue has brought this matter by pursuing a Motion to Dismiss Purdue's action. As of March 21, 2003, the court has not ruled on IMPAX's pending motion. Discovery will begin once this jurisdictional question has been resolved.

Purdue previously has sued Boehringer-Ingelheim/Roxane, Endo and Teva on the same patents. It is possible that one or more of these other defendants will resolve the invalidity issues surrounding the Purdue patents prior to IMPAX going to trial.

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

In June 2002, IMPAX filed suit against Aventis Pharmaceuticals, Inc. in the United States District Court in Wilmington, Delaware, seeking a declaration that the filing of an Abbreviated New Drug Application to engage in a commercial

manufacture and/or sale of Riluzole 50mg Tablets for treatment of patients with amyotrophic lateral sclerosis (“ALS”) does not infringe claims of Aventis’ U.S. Patent No. 5,527,814 (“the ‘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 parties are currently engaged in the discovery phase of the action. 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 U.S. Patent & Trademark Office. Until discovery is completed, no estimate can be given of IMPAX’s likelihood of success on its invalidity and unenforceability defenses.

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 50mg 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 50mg Tablet product for the treatment of ALS in the United States.

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

On January 27, 2003, Abbott Laboratories filed a lawsuit against the Company in the United States District Court in Delaware alleging patent infringement related to IMPAX’s filing of an ANDA for a generic version of Abbott’s Tricor (Fenofibrate) 160mg Tablets. IMPAX believes that it has strong defenses to the claims made by Abbott based on non-infringement.

Abbott has filed the same lawsuits against Novapharm, Teva and Pharmaceutical Resources.

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

On February 24, 2003, Merck & Co., Inc. filed a lawsuit against the Company in the United States District Court in Delaware alleging patent infringement related to IMPAX’s filing of an ANDA for a generic version of Sinemet CR Tablets. IMPAX believes that it has strong defenses to the claims made by Merck based on non-infringement.

Other than the patent litigations 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 FDA that contain Paragraph IV certifications, it is likely we will become involved in additional litigation related to those filings.

#### **INSURANCE**

As part of our patent litigation strategy, we have 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. At present, we believe this insurance coverage is sufficient for our legal defense costs related to these seven ANDAs. Correspondence received from AISLIC indicated that, as of January 14, 2003, one of the policies had approximately \$1,879,000 remaining on the limit of liability and the second of the policies had approximately \$675,000 remaining on the limit of liability. In addition, as per the agreement with Teva, for the six products already filed at the time of the agreement, Teva will pay 50% of the attorneys’ fees and costs in excess of the \$7 million to be paid by AISLIC. For the three products 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.

However, 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 \$10 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, 2002.

### PART II

#### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the NASDAQ National Market under the symbol "IPXL." The following table sets forth the quarterly share price information for the periods indicated below:

	<u>Price Range Per Share</u>	
	<u>High</u>	<u>Low</u>
<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
<u>Year Ended December 31, 2001</u>		
Quarter ended March 31, 2001	\$10.31	\$5.88
Quarter ended June 30, 2001	\$12.60	\$6.25
Quarter ended September 30, 2001	\$17.10	\$10.60
Quarter ended December 31, 2001	\$14.28	\$8.21

As of February 21, 2003, there were approximately 4,174 beneficial owners of 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.

In March 2002 and June 2002, under the terms of a strategic alliance announced in June 2001, we issued an aggregate of 883,068 shares of IMPAX common stock to a subsidiary of Teva Pharmaceutical Industries Ltd. for proceeds to the Company of approximately \$7.5 million. The stock was issued pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933 and Regulation D adopted under such Act.

For information regarding the Company's equity compensation plans, please see Item 12.

#### ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data as of and for each of the five years ended December 31, 2002, 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.

<b>Statement of Operations Data</b> (in thousands, except per share data)	<u>For The Year Ended December 31,</u>				
	<u>1998</u>	<u>1999<sup>(1)</sup></u>	<u>2000</u>	<u>2001</u>	<u>2002</u>
Net revenues <sup>(2)</sup> .....	\$ —	\$ 1,240	\$ 10,170	\$ 6,591	\$ 24,515
Research and development .....	5,127	7,858 <sup>(3)</sup>	11,096	10,972	15,549
Total operating expenses .....	5,267	9,648	25,546	22,252	26,817
Operating loss .....	(5,267)	(9,333)	(25,092)	(25,330)	(20,794)
Net loss .....	(5,222)	(8,949)	(24,961)	(25,111)	(20,040)
Net loss per share (basic and diluted) .....	\$ (0.73)	\$ (1.12)	\$ (0.91)	\$ (0.60)	\$ (0.42)

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 year 2002 do not include certain amounts of amortization

of goodwill that are included in prior years' financial results. See Note 2 to the Company's financial statements for additional information.

Balance Sheet Data	At December 31,				
	1998	1999	2000	2001	2002
Cash, cash equivalents and short-term investments.....	\$ 370	\$ 7,413	\$ 19,228	\$ 35,466	\$ 10,219
Restricted cash.....	—	—	—	—	10,000
Working capital.....	(795)	6,297	17,802	36,180	4,946
Total assets.....	3,408	61,705	67,128	97,612	104,403
Refundable deposit.....	—	—	—	22,876	22,000
Long term debt.....	—	—	1,345	6,868	9,105
Mandatory redeemable convertible preferred stock.....	12,206*	22,000	28,303	7,500	7,500
Accumulated deficit.....	(11,281)	(20,230)	(45,191)	(70,302)	(90,342)
Total stockholders' equity.....	1,682	30,278	30,754	52,448	41,064

\*The convertible preferred stock was not mandatory redeemable in 1998.

(1) 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.

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

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

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

### 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:**

During the year 2000, we adopted 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. If historical data used to calculate these estimates does not properly reflect future activity, our net sales, gross profit, net income and earnings per share could be impacted.

The application of the SAB 101 guidance to the Company’s previous revenue recognition policy requires us to defer revenue recognition from the sale of product until the shipment of product is received and accepted by the customer, rather than recognizing revenue only upon shipment. The change in accounting policy resulted in a cumulative effect adjustment at January 1, 2000, of \$288,000 and also resulted in an increase in revenue and gross margin of \$667,000 and \$288,000, respectively, for the twelve month period ended December 31, 2000.

Revenue from strategic alliances includes up-front payments and milestone payments. Up-front payments are generally deferred and recognized on a straight-line basis over the life of the related agreement. Milestone payments are generally recognized when the requirements set forth in the related agreement are met and such recognition represents a separate earnings process. In evaluating whether a separate earnings process has been met, the Company considers the following criteria: a) level of effort involved in achieving the milestone; b) reasonableness of the milestone payment in relation to the effort expended in achieving the milestone; c) the amount of time that has passed from the up-front payment, if any, to the milestone payment and between various milestones; d) the amount of the payment in relation to the risk involved in achieving the milestone; and e) relationship between the amount of the up-front payment and the first milestone payment.

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

The sales return reserve is calculated using 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 to NDC numbers.

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 will allow the Company to evaluate any customer orders, which have 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 at the time of the Form 10-K filing, management’s expectations, 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, 2002 and 2001, our returns reserve was \$3.1 million and \$1.9 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, 2002 and 2001, our reserves for rebates were \$1.5 million and \$0.9 million, respectively, and at December 31, 2002 and 2001, our reserves for chargebacks were \$1.4 million and \$0.6 million, respectively.

While the determination of reserves for sales rebates and chargebacks does not require significant judgments or estimates, 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 arising are apportioned to inventory and cost of goods sold based upon inventory turnover. The Company considers product costs as inventory once the Company receives FDA approval to market the related products. 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. At December 31, 2002 and 2001, our inventory reserve was \$200,000 and \$150,000 respectively.

**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, 2002 and 2001, the shelf-stock reserve was \$660,000 and \$0, 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, 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, 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. If estimates of fair value less costs to sell are revised, the carrying amount of the related asset is adjusted, resulting in recognition of a charge or benefit to earnings.

**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. 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.

At December 31, 2002 and 2001, 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. We currently market twenty-seven generic pharmaceuticals, which represent dosage variations of twelve different pharmaceutical compounds, and have nineteen applications pending at the FDA, including three tentatively approved, that address \$5.8 billion in U.S. product sales for the twelve months ended December 31, 2002. Thirteen of these filings were made under Paragraph IV of the Hatch-Waxman Amendments. We have approximately seventeen 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. sales of approximately \$3.2 billion for the twelve months ended December 31, 2002.

The major highlights of 2002 operational activity included the following:

- In February 2002, the FDA tentatively approved the Company's ANDA for a generic version of Tricor (Fenofibrate), Micronized Capsules. Tricor is marketed by Abbott Laboratories. The tentative approval covers 67mg, 134mg, and 200mg capsules. Final approval is contingent upon the earlier of (1) the resolution of patent infringement litigation brought by Abbott against IMPAX, or (2) the expiration of the 30-month stay process under the Hatch-Waxman Amendments, and the expiration of any generic marketing exclusivity. Final approval is also dependent upon the FDA's evaluation of any new information it receives subsequent to this tentative approval.

- In February 2002, the FDA accepted our filing of an ANDA for a generic version of Allegra-D (Fexofenadine and Pseudoephedrine Hydrochloride) 60mg/120mg Extended Release Tablets (IMPAX's eighth Paragraph IV filing). In March 2002, Aventis Pharmaceuticals Inc., which markets Allegra-D for the relief of symptoms associated with seasonal rhinitis in adults and children 12 years of age and older, filed a lawsuit against us in the United States District Court in Delaware alleging patent infringement related to our subject filing.
- Also in February 2002, the FDA accepted our filing of an ANDA for a generic version of OxyContin (Oxycodone Hydrochloride) Extended Release 80mg Tablets (IMPAX's ninth Paragraph IV filing). Purdue Pharma L.P. markets OxyContin for the management of moderate-to-severe pain. In April 2002, Purdue Pharma L.P. filed a lawsuit against us alleging patent infringement related to IMPAX's earlier filing of an ANDA for a generic version of OxyContin (Oxycodone Hydrochloride) Extended Release 80mg Tablets.
- In March 2002 and June 2002, under the terms of a strategic alliance announced in June 2001, we issued an aggregate of 883,068 shares of IMPAX common stock to a subsidiary of Teva Pharmaceutical Industries Ltd. for proceeds to the Company of approximately \$7.5 million. Together with the shares sold in 2001, Teva purchased a total of 1,462,083 shares, or approximately 3% of total shares of common stock outstanding at December 31, 2002.
- Also in March 2002, the FDA approved our ANDA to market Fludrocortisone Acetate Tablets 0.1mg, a generic version of Florinef, which is marketed by Monarch Pharmaceuticals, a division of King Pharmaceuticals, as partial replacement for primary and secondary adrenocortical insufficiency in Addison's disease. Our Global Pharmaceuticals division began marketing the product immediately.
- In May 2002, the FDA tentatively approved our ANDAs for generic versions of Claritin-D 24-hour (Loratadine and Pseudoephedrine Sulfate, 10mg/240mg) Extended Release Tablets and Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate, 5mg/120mg) Extended Release Tablets. Schering-Plough Corporation markets both products for the relief of symptoms of seasonal allergic rhinitis (hay fever). In March 2002, Schering-Plough announced that it filed with the FDA an application to switch all of the prescription Claritin formulations to OTC. In August 2002, the United States District Court of New Jersey granted our Motion for Summary Judgment and declared portions of the Schering-Plough Corporation U.S. Patent No 4,659,716 invalid as they relate to our generic Claritin ANDAs. In December 2002, FDA granted Schering-Plough's application to switch all Claritin formulations to OTC. In January 2003, FDA granted final approval to our ANDA for our generic version of Claritin-D 12-Hour (Loratadine and Pseudoephedrine Sulfate, 5mg/120mg) Extended Release Tablets and we immediately began shipment of the product.
- In June 2002, we signed a semi-exclusive Development, License and Supply Agreement with Wyeth, acting through its Wyeth Consumer Healthcare Division, relating to our generic versions of Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate, 5mg/120mg) Extended Release Tablets and Claritin-D 24-hour (Loratadine and Pseudoephedrine Sulfate, 10mg/240mg) Extended Release Tablets for the OTC market.
- Also in June 2002, we signed a non-exclusive Licensing, Contract Manufacturing and Supply Agreement with Schering-Plough Corporation relating to Claritin-D 12-hour (Loratadine and Pseudoephedrine Sulfate) Extended Release Tablets, 5mg/ 120mg for the OTC market. This agreement did not resolve the ongoing patent litigation between Schering-Plough and IMPAX to decide whether we may market our generic Claritin-D 12-hour product, or manufacture such a product for companies other than Schering-Plough prior to the expiration of a Schering-Plough patent in 2004.
- In July 2002, the FDA tentatively approved our ANDA for a generic version of Rilutek (Riluzole) 50mg Tablets. Aventis Pharmaceutical Products, Inc. markets Rilutek for the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease.

We filed a lawsuit in June 2002 against Aventis Pharmaceuticals, Inc. in the United States District Court in Delaware seeking a declaration that Aventis' U.S. Patent No. 5,527,814 is invalid. Aventis filed an Answer and Counterclaim, claiming that our submission of an ANDA for Riluzole 50mg Tablets constituted infringement of U.S. Patent No. 5,527,814, and that our intended marketing activities constituted inducement of infringement of this patent. On October 15, 2002, Aventis filed a motion seeking a Preliminary Injunction enjoining us from marketing Riluzole 50mg Tablets until a final decision is reached by the court in this case. On December 12, 2002, the District Court of Delaware granted the Preliminary Injunction Motion brought by Aventis. Litigation is currently scheduled for trial in October 2003.

On January 30, 2003, we received the final approval from the FDA for our generic version of Rilutek (Riluzole) 50mg tablets.

- In August 2002, the FDA accepted our filing of an ANDA for a generic version of OxyContin (Oxycodone Hydrochloride) Extended Release 40mg Tablets (IMPAX's tenth Paragraph IV filing). In September 2002, Purdue Pharma L.P. filed a lawsuit against us alleging patent infringement. In addition, we amended our ANDA for the 40mg Tablets to include 10mg and 20mg Extended Release Tablets.
- Also in August 2002, the U.S. District Court for the Northern District of California granted our Motion for Summary Judgment of Non-Infringement regarding our ANDAs for Wellbutrin SR and Zyban. GlaxoSmithKline markets Wellbutrin SR for the treatment of depression and Zyban for the cessation of smoking.
- In September 2002, the FDA approved our ANDA for a generic version of Flumadine (Rimantadine Hydrochloride 100mg) Tablets. Forest Laboratories, Inc. markets Flumadine for the prevention and treatment of illness caused by various strains of influenza-A virus in adults. Our Global Pharmaceuticals division began marketing the product during the quarter ended December 31, 2002.
- In November 2002, the FDA granted approval for our ANDA for its 10mg and 20mg strengths and tentative approval for its 40mg strength of Omeprazole Delayed Release Capsules, a generic version of Prilosec. AstraZeneca markets Prilosec for the treatment of duodenal/gastric ulcers and gastro-esophageal reflux disease.
- During December 2002, the FDA accepted our ANDA for a generic version of Tricor (Fenofibrate) 160mg Tablets. Abbott Laboratories, Inc. markets Tricor for treatment of very high serum triglyceride levels. On January 27, 2003, Abbott Laboratories filed a lawsuit against us in the federal district court in Delaware alleging patent infringement.

## Results of Operations

We have incurred net losses in each year since our inception. We had an accumulated deficit of \$90,342,000 at December 31, 2002.

## 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 significant year-over-year increase resulted from increased sales of Fludrocortisone Acetate Tablets 0.1mg, introduced at the end of the first quarter of 2002; Minocycline Hydrochloride 50mg, 75mg, and 100mg Capsules, launched in the third quarter of 2002; Terbutaline Sulfate 2.5mg and 5.0mg Tablets, introduced since July 2001; Rimantadine Hydrochloride 100mg 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 Sales	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 Sales	<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.

According to the 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 is forgiven and no future interest accrues. 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.

## **Year Ended December 31, 2001 Compared to Year Ended December 31, 2000**

### ***Overview***

The net loss for the year ended December 31, 2001 was \$25,111,000 as compared to \$24,961,000 for the year ended December 31, 2000. The increase in the net loss was primarily due to lower sales and higher infrastructure costs related to the new manufacturing facility in Hayward, California and expansion of our sales and marketing capabilities.

### ***Revenues***

The net sales for the year ended December 31, 2001 were \$6,591,000 as compared to \$10,170,000 for the same period in 2000. The lower sales were primarily due to the fact that the Company discontinued certain products during 2000 (the "discontinued products"). These discontinued products accounted for gross sales of approximately \$4,977,000 in 2000. Additionally, the Company experienced higher sales returns expense of approximately \$3,662,000 in 2001. These decreases were partially offset by the introduction of new products in 2001 that had gross sales of approximately \$2,455,000. The following table summarizes the activity in net sales for the year ended December 31, 2001 and 2000:

( in \$000's )	<u>2001</u>	<u>2000</u>
Active products	16,119	8,898
Discontinued products <sup>1</sup>	—	4,977
SAB 101 adjustment <sup>2</sup>	—	<u>667</u>
Gross Sales	16,119	14,542
Less:		
Actual returns	2,841	707
Increase in reserve for product returns	1,684	156
Rebates, chargebacks and other credits	<u>5,003</u>	<u>3,509</u>
Net Sales	<u>6,591</u>	<u>10,170</u>

<sup>1</sup>Due to the consolidation of all manufacturing activities in Hayward, California, a number of products, which represented approximately 35% of our sales for the period, were discontinued in August 2000 and a change in National Drug Code ("NDC") numbers for one of the Lipram products. Regarding the old NDC Lipram, the Company determined that, for customer relations purposes as well as for competitive reasons, it accepted the return of the old NDC Lipram.

<sup>2</sup>See Note 2 to the financial statements for a discussion of this adjustment.

The actual returns of \$2,841,000 included approximately \$1,166,000 of discontinued products. The increase of \$1,684,000 in 2001 returns reserve was the result of our review and analysis of the historical return rates through 2001 and the lag period, adjusted by estimates of the future return rates. The increase in rebates, chargebacks, and other credits was primarily due to sales volume increase and increased competition.

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

The cost of sales for the year ended December 31, 2001 was \$9,669,000 as compared to \$9,716,000 for the same period in 2000. Included in the cost of sales are startup costs of the new manufacturing facility in Hayward, California, and unabsorbed fixed costs due to excess plant capacity in Philadelphia, Pennsylvania. Because of the nature of the sales returns (discontinued products, old NDC numbers, or short-dated products), we concluded the returned inventory had no value to the Company and the products were destroyed.

### ***Gross Margin***

Due primarily to lower net sales and to the increase in the infrastructure costs related to the new manufacturing facility in Hayward, California, we incurred a negative gross margin of \$3,078,000 for the year ended December 31, 2001 as compared to a gross margin of \$454,000 for the same period in 2000.

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

The research and development expenses for the year ended December 31, 2001 were \$11,890,000, less expense reimbursements of \$918,000 by Teva under the strategic alliance agreement signed in June 2001, as compared to \$11,096,000 for the same period in 2000. The increase in 2001 research and development expenses over 2000 was primarily due to higher personnel costs.

### ***Selling Expenses***

The selling expenses for the year ended December 31, 2001 were \$2,186,000 as compared to \$1,346,000 for the same period in 2000. The increase in selling expenses as compared to 2000 was primarily due to additional personnel, advertising, market research, and sales agreement costs.

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

The general and administrative expenses for the year ended December 31, 2001 were \$9,258,000 as compared to \$9,764,000 for the same period in 2000. The decrease in 2001 general and administrative expenses as compared to 2000 was primarily due to lower intangibles amortization caused by the impairment write-off in the third quarter of 2000, and lower patent infringement litigation insurance and related costs, partially offset by higher personnel expenses and professional fees. The amortization of intangibles and goodwill for the year ended December 31, 2001 was \$3,888,000 as compared to \$4,604,000 for the same period in 2000.

### ***Other Operating Income***

The other operating income was \$164,000 for the year ended December 31, 2001 as compared to \$306,000 for the same period in 2000, primarily due to lower license fees earned in 2001.

### ***Restructuring Charges and Non-Recurring Items***

We had no restructuring charges and non-recurring items for the year ended December 31, 2001. For the year ended December 31, 2000, we incurred charges of \$3,646,000 representing a one-time write-off for impairment of \$2,037,000 of intangibles, \$957,000 of inventory, and \$652,000 of equipment due to ceasing manufacturing in the Philadelphia facility and rationalizing the product lines.

### ***Interest Income***

Interest income for the year ended December 31, 2001 was \$1,148,000 as compared to \$758,000 for the same period in 2000, primarily due to increases in cash equivalents and short-term investments from funds received in connection with the Teva refundable deposit and equity investments, and the June 2001 private placement of equity, partially offset by lower interest rates.

### ***Interest Expense***

Interest expense for the year ended December 31, 2001 was \$929,000 as compared to \$339,000 for the same period in 2000, primarily due to the \$876,000 interest accrued in 2001 on the refundable deposit from Teva. The 2001 interest expense is net of \$200,000 in capitalized interest related to the renovation of the San Antonio Street, Hayward, California building.

## ***Net Loss***

The net loss for the year ended December 31, 2001 was \$25,111,000 as compared to \$24,961,000 for the same period in 2000. The increase in net loss was primarily due to lower net sales and higher infrastructure costs related to the new manufacturing facility in Hayward, California and the expansion of our sales and marketing capabilities. Our 2001 net loss was favorably impacted by the absence of restructuring charges and non-recurring items, and lower intangibles amortization in 2001.

## **Liquidity and Capital Resources**

At December 31, 2002, we had \$10,219,000 in cash and cash equivalents as compared to \$15,044,000 at December 31, 2001.

The net cash provided from financing activities for the year ended December 31, 2002 was approximately \$5,006,000, consisting of proceeds of \$7,500,000 from the sale of common stock to Teva, proceeds of \$409,000 from issuance of common stock upon exercise of stock options and warrants, net borrowing of \$6,865,000 from Congress Financial less the transfer of \$10,000,000 to a restricted cash account that serves as collateral for the \$25 million revolving credit facility and term loan agreement signed with Congress Financial in October 2002.

During the year ended December 31, 2002, the sale and maturities of short-term investments of \$20,422,000 funded capital expenditures of approximately \$15,054,000 related to the completion of the manufacturing facility in Hayward, California and the purchases of machinery and equipment required for expansion of our operating capacity. The \$5,368,000 in net cash provided by investing activities and the \$5,006,000 provided by financing activities funded our net cash used in operating activities during the year ended December 31, 2002. The increase in the accounts receivable and inventory was substantially offset by the increase in accounts payable and accrued liabilities. Accounts receivable at December 31, 2002 were \$6,524,000, or \$3,001,000 higher than those at December 31, 2001, with the increase primarily attributable to increased product sales. Most of the Company's major customers have payment terms between 2% 60 days and 2% 90 days. As such, the accounts receivable balance normally represents the previous two to three months of net sales.

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. 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 profitability targets. The interest rates for the revolving loans range from prime rate plus 1% to 1.75%, or eurodollar rate plus 3% to 3.75%, 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, 2002, we borrowed approximately \$3,999,000 against the revolving credit line and \$3,098,000 against the term loan. The revolving credit facility and the term loan agreement have a number of quarterly covenants primarily covering Minimum Tangible Net Worth, and either EBITDA or excess availability and annual capital expenditures limit of \$8 million. At December 31, 2002, all the bank loan covenants were met.

The \$22 million refundable deposit from Teva, less any forgiven amounts upon IMPAX's attainment of certain milestone, if any, is due and payable on January 15, 2004, in cash or equity at our discretion. As previously indicated in Part I, Item 1, as of February 25, 2003, we believe that approximately \$10.5 million of the \$22 million may be forgiven prior to January 15, 2004, although there is no assurance that any of the \$22 million may be ultimately forgiven. These milestone events, if achieved, will represent the culmination of a separate earnings process. If we repay the loan in stock, such payment will result in dilution. If we repay all our portion of the loan in cash, we may seek additional sources of liquidity to fund such payment, as discussed below.

Our capital expenditures planned for 2003 include, primarily, purchases of machinery and equipment, and range between \$2 and \$4 million as compared to approximately \$15,054,000 spent in 2002.

We have no interest rate or derivative hedging contracts and material foreign exchange or commodity price risks. We are also not party to any off-balance-sheet arrangements, other than operating leases.

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 2003, we believe that our existing cash and cash equivalent balances, together with our \$25 million term loan and revolving line of credit, will be sufficient to meet our operational plan for the next twelve months. We may, however, seek additional financing through strategic alliances and/or equity markets to repay the Teva deposit, if required, and to fund our research and development plans, and potential revenues shortfall due to delays in new products introduction. However, we may be unable to obtain such financing.

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.

### **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 effect, if any, of initially applying this Statement will be reported in the Statements of Operations as the cumulative effect of a change in accounting principle. The Company is evaluating the effect this Statement will have on the Company's future financial statements.

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 have not had and are not expected to 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 Company does not expect that this Statement will 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 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company is currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on its results of operations and financial condition.

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 are effective for the current fiscal year, and the Company has included this information in Note 13 to the Company's financial statements. However, 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. 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.

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 2 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. As discussed in Note 13 to the Company's financial statements, IMPAX does not have any relationships with variable interest entities as of December 31, 2002.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 supercedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." This Statement applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), "Reporting Results of Operations Reporting the Effects of Disposal of a Segment of a Business." The provisions of SFAS No. 144 are effective for financial statements issued for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The adoption of SFAS No. 144 did not have a material effect on the Company's results of operations, financial position or cash flows.

In April 2002, FASB issued SFAS No. 145, this Statement rescinds FASB Statement No. 4, Reporting Gains and Losses from Extinguishment of Debt, and an amendment of that Statement, FASB Statement No. 64, Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements. This Statement also rescinds FASB Statement No. 44, Accounting for Intangible Assets of Motor Carriers. This Statement amends FASB Statement No. 13, Accounting for Leases, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The adoption of SFAS No. 145 did not have a material effect on the Company's results of operations, financial position or cash flows.

In June 2002, FASB issued SFAS No. 146, this Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The adoption of SFAS No. 146 did not have a material effect on the Company's results of operations, financial position or cash flows.

## **Risk Factors**

**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 generated minimal revenues to date and have experienced operating losses and negative cash flow from operations since our inception. As of December 31, 2002, our accumulated deficit was \$90,342,000 and we had outstanding indebtedness in an aggregate principal amount of \$35,965,000, including \$22,000,000 due 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 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 twenty-seven generic pharmaceuticals which represent dosage variations of twelve different pharmaceutical compounds. Our revenues from these products for the twelve months ended December 31, 2002 were \$23.8 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 December 31, 2002, we had nineteen ANDAs 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 new drug products. The FDA approval requirements are costly and time consuming. 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 reference or listed drugs), the FDA ordinarily only requires bioavailability data demonstrating that the generic formulation is bioequivalent to the previously approved reference 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 drug. 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 abbreviated new drug application 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. 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 or our own internal standards.

Bioequivalent pharmaceuticals, commonly referred to as generics, are the pharmaceutical and therapeutic equivalents of brand name drugs and are usually marketed under their established nonproprietary drug names rather than by a brand name. Controlled-release drug delivery technologies generally provide more consistent and appropriate drug levels in the bloodstream than immediate-release dosage forms and may improve drug efficacy and reduced side effects by releasing drug dosages at specific times and in specific locations in the body. These technologies also allow for the development of "patient friendly" dosage forms that reduce the number of times a drug must be taken, thus improving patient compliance.

**Approvals for our new drug products may become more difficult to obtain if changes to FDA approval requirements are instituted.**

Some abbreviated application procedures for bioequivalent controlled-release drugs and other products are presently the subject of petitions filed by brand name drug manufacturers, which seek changes from the FDA in the approval requirements for particular bioequivalent 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 or policies may make abbreviated application approvals more difficult and thus may materially harm our business and financial results.

**We have no experience in conducting clinical trials or preparing a New Drug Application which may be required if a drug we develop does not qualify for the FDA's abbreviated applications procedures.**

In order to market a new drug that does not qualify for the FDA's abbreviated application procedures, we may have to conduct extensive clinical trials to demonstrate product safety and efficacy and submit a New Drug Application, or NDA. 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.

**We face significant delays in obtaining FDA approval as a result of patent infringement litigation.**

Patent certification requirements for bioequivalent controlled-release drugs and for some new drugs could also result in significant delays in obtaining FDA approval if patent infringement litigation is initiated by the holder or holders of the brand name patents. We apply our proprietary drug delivery technologies and formulation skills to develop bioequivalent versions of selected controlled-release brand name pharmaceuticals. Specifically, we apply our proprietary processes and formulations to develop a product that will produce the brand product's physiological characteristics but not infringe upon the patents of the owner of the NDA 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 or that such patents are invalid or unenforceable. As required by the Drug Price Competition and Patent 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 such a certification. This is called a Paragraph IV certification.

Once the FDA accepts our ANDA for filing, we must also send notice of a Paragraph IV certification to the NDA owner and patent holder. 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. Brand name companies may obtain additional patents after an ANDA has been filed, but before final marketing approval has been granted, which may result in a new legal challenge and may require submission of a new Paragraph IV certification and trigger a new notice and waiting period requirements. Thus, the developer of bioequivalent products may invest a significant amount of time and expense in the development of these products only to be subject to significant delays and the uncertain results of patent litigation before its products may be commercialized. Patent litigation has been instituted against us with respect to nine of our pending ANDAs relating to our generic controlled-release product candidates.

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.

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

We have, and continue to face substantial patent infringement litigation with respect to our proposed products. As of February 24, 2003, we had nineteen ANDAs pending at the FDA for generic versions of brand name pharmaceuticals. To date, patent litigation has been filed against us in connection with twelve of the ANDAs we have filed containing certifications relating to infringement, validity, or enforceability of patents. In these ANDAs, we have certified that we believe an unexpired patent that is listed with the FDA and covers the brand name product will not be infringed and/or is invalid or unenforceable. Patent litigation is both costly and time consuming. If we are unable to prevail in these litigations or obtain any required licenses, we may be prevented from commercializing our products.

We anticipate that additional legal actions may be filed against us as we file additional ANDAs. Patent litigation may also be brought against us in connection with NDA products that we may pursue. The outcome of patent litigation is difficult to predict. Prior to filing an ANDA or NDA, we evaluate the probability of patent infringement litigation on a case-by-case basis. 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 Pharmaceuticals Curacao N.V., a subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva") for twelve controlled-release generic products. The agreement grants Teva exclusive U.S. marketing rights for six of our products. The six products already filed at the time of the agreement were Omeprazole 10mg, 20mg, and 40mg Delayed Released Capsules (generic of Prilosec), Bupropion Hydrochloride 100mg and 150mg Extended Release Tablets (generic of Wellbutrin SR), Bupropion Hydrochloride 150mg Extended Release Tablets (generic of Zyban), Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets (generic of Claritin-D 12-Hour) and Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24-hour Extended Release Tablets (generic of Claritin-D 24-hour) and Loratadine 10mg Orally Disintegrating Tablets (generic of Claritin Reditabs). Of the six products to be developed at the time the agreement was signed, three have since been filed with the FDA. Teva elected to commercialize a competing product to one of the three products filed since June 2001, which it has 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. 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 that 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.

**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 of our products with 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 not be favorable 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.**

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 three largest product families currently on the market, which accounted for approximately 85% of our net revenues for the twelve months ended December 31, 2002:

<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 Pharmaceutical
Terbutaline Sulfate 2.5mg and 5.0mg Tablets	Neosan Pharma (Brethine)	None
Fludrocortisone Acetate Tablets 0.1mg	Monarch Pharm (Florinef)	Barr Laboratories

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 Pharmaceuticals, 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	Glaxo, Biovail (Wellbutrin SR, Zyban, Wellbutrin OAD)	Andrx Pharmaceuticals, Watson Laboratories, Eon Labs, Excel Pharmaceuticals

<b>Development Product</b>	<b>Brand Competition</b>	<b>Potential Generic Competition</b>
Loratadine and Pseudoephedrine Sulfate Extended Release Tablets	Schering-Plough (Claritin-D 12-hour, Claritin-D 24-hour, Clarinex D)Wyeth (Alavert)	Andrx Pharmaceuticals
Loratadine Orally Disintegrating Tablets	Schering-Plough (Claritin Reditabs, Clarinex Reditabs)Wyeth (Alavert)	CIMA Laboratories, Andrx Pharmaceuticals
Fenofibrate Capsules and Tablets	Abbott Labs (Tricor Tablets)	Teva Pharmaceutical Ind, Ltd., Pharmaceutical Resources
Fexofenadine and Pseudoephedrine Hydrochloride Extended Release Tablets	Aventis Pharma (Allegra-D)	Barr 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 Pharmaceutical Industries, Ltd.

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 related to goodwill and intangibles.**

At December 31, 2002, our goodwill and intangibles were approximately \$28.3 million, or approximately 27% 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. As of December 31, 2002, the carrying value of goodwill was not impaired based on our assessment performed in accordance with accounting principles generally accepted in the United States of America. 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, 2002, we had outstanding indebtedness of approximately \$35,965,000 of which \$13,965,000 bears interest at rates ranging from 2.0% to 8.17% annually. For the year ended December 31, 2002, we paid interest on our indebtedness of approximately \$561,000. Additionally, as of December 31, 2002, we had an accumulated stockholders' deficit of approximately \$90,342,000. We may not be able to maintain adequate capital at any given time, or from time to time in the future.

As of December 31, 2002, we had approximately \$10.2 million in cash and cash equivalents, and \$10.0 million in restricted cash that serves as collateral for the \$25 million revolving credit facility and loan agreement with Congress Financial. Although we estimate that these funds will be sufficient for at least the next twelve months of operations at our planned expenditure levels, these funds may not be sufficient. 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, our stockholders, or at all. In the event that adequate funds are not available, our business operations and plans may need to be modified. The lack of additional capital could result in less money being spent on research and development programs, fewer products being developed and at a slower pace, and fewer drug applications being filed with the FDA.

**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.**

In August 1999, the FDA proposed to amend its regulations relating to 180-day marketing exclusivity for which certain bioequivalent drugs may qualify. In its proposal, the FDA explained that, to qualify for exclusivity, a pharmaceutical company must be the first generic applicant to file an ANDA with the FDA in a substantially complete form, rather than the first company to successfully challenge a patent. We believe we were first to file with the FDA on only one ANDA. We cannot predict whether or what changes the FDA may make to its regulations. In March 2000, the FDA issued new guidelines regarding the timing of approval of ANDAs following a court decision in patent infringement actions and the start of the 180-day marketing exclusivity period provided for in the Hatch-Waxman Amendments applicable to generic pharmaceuticals. These guidelines could result in us not being able to utilize all or any portion of the 180-day marketing exclusivity period on ANDA products we were first to file on, depending on the timing and outcome of court decisions in patent litigation. We are unable to predict what impact, if any, the FDA's new guidelines may have on our business or financial condition. 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 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.

**We face uncertainties related to clinical trials that 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, we must demonstrate through clinical trials that these products are safe and effective for use. We have limited experience in conducting and supervising clinical trials. A number of difficulties 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 that 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 would 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 litigations; and
- the addition or loss of customers, including strategic partners.

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.

**Restrictive FDA regulations govern the manufacturing and distribution of our products.**

In addition to requiring FDA approval prior to marketing any of our products, we are subject to FDA regulations regarding the development, manufacture, distribution, labeling and promotion of prescription drugs. In addition, the FDA requires that certain records be kept and reports be made, mandates registration of drug manufacturers and listing of their products, and has the authority to inspect manufacturing facilities for compliance with their current Good Manufacturing Practices. Our business and financial results could be materially harmed by any failure to comply with manufacturing and other requirements.

Other requirements exist for controlled drugs, such as narcotics, which are regulated by the U.S. Drug Enforcement Administration (“DEA”). Further, 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. The DEA has similar authority and may also pursue monetary penalties. Our business and financial results could be materially harmed by these requirements or FDA or DEA actions.

**We will need an effective sales organization to market and sell our future brand 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 four 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, Particle Dispersion 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 that 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.

As of December 31, 2002, we had \$7 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 January 14, 2003, one of the policies had approximately \$1,879,000 remaining on the limit of liability and the second of the policies had approximately \$675,000 remaining on the limit of liability. At present, we believe this remaining insurance coverage is sufficient for our defense costs related to these seven ANDAs. In addition, as for the agreement with Teva for the six products already filed at the time of the agreement, Teva will pay 50% of the attorneys' fees and costs in excess of the \$7 million we expect to be paid by AISLIC. For the three products 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.

This insurance coverage may not be sufficient to cover any liability resulting from alleged or proven patent infringement. Additionally, 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.

**We may be subject to product liability litigation and any claims brought against us could have a material adverse effect upon 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 that covers us for liability of up to \$10 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, 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 upon us.

**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, or a limited number of suppliers. Approximately 35% of our 2002 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, or fluctuations in currency exchange rates; and
- uncertainty regarding recourse to a dependable legal system for the enforcement of contracts and other rights.

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 273 employees as of February 28, 2003, 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 and Co-Chief Executive Officer, Barry R. Edwards, our Co-Chief Executive Officer, Larry Hsu, our President, Michael Wokasch our Chief Operating Officer, 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 four facilities: the Hayward (Huntwood Avenue), California, 35,125 square foot facility which serves as our corporate headquarters and our primary development center; the Hayward (San Antonio Street), California, 50,400 square foot facility which serves as our primary manufacturing center and a 14,400 square foot administrative office and warehouse facility in Hayward, California and the Philadelphia, Pennsylvania, 113,000 square foot facility which serves as our center for sales and marketing, packaging, warehousing and distribution.

We recently completed construction of our Hayward (San Antonio Street), California manufacturing center. This new manufacturing facility will need to be in compliance with current Good Manufacturing Practices and inspected. 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, results of operations or 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 employee count from 150 as of March 1, 2002 to 273 as of February 28, 2003. The number of ANDAs pending approval at the FDA has increased from 11 at June 2001 to 19 at February 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.

**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, including holders of shares purchased in this offering, will result. At December 31, 2002, we had 75,000 shares outstanding of our Series 2 Preferred Stock that are convertible, at any time, at the option of their holders into an aggregate of 1,500,000 shares of our common stock. The shares of preferred stock also have anti-dilution protections if we were to issue stock for a price below stated levels (\$5.00 per share for the Series 2 Preferred Stock), which could make them convertible into additional shares of common stock. In addition, the Series 2 Preferred Stock is subject to redemption, mandatorily on March 31, 2005, or at the option of the holder upon the occurrence of certain events. In either case, we can elect to pay the redemption price of \$100 per share of Series 2 Preferred Stock by issuing shares of common stock at a discount of 10% from the then current market price of the common stock. In addition, we borrowed \$22 million from Teva. This refundable deposit will be forgiven if we achieve certain milestones relating to the development of certain products. If we fail to achieve the milestones, the refundable deposit will become payable on January 15, 2004, in cash or, at our option, by the issuance of our common stock at a price equal to the average closing sale price for the common stock measured over the ten trading days ending two days prior to the date on which the common stock is acquired by Teva. However, if any of the shares we issue to Teva as repayment of the loan will cause Teva to own in excess of 19.9% of our outstanding common stock, we will have to repay that portion of the loan in cash.

**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 47,874,614 shares outstanding as of December 31, 2002 of which approximately 20.2 million shares were owned by our officers and directors or their affiliates and are considered restricted shares. Substantially all of these approximately 20.2 million shares have been registered for sale under the Securities Act of 1933 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, as of December 31, 2002 we had 75,000 shares of Series 2 Preferred Stock outstanding, convertible into an aggregate 1,500,000 shares of common stock, outstanding warrants to purchase 2,548,266 shares of common stock, and outstanding stock options to purchase 4,625,525 shares of common stock. The common stock into which the outstanding 75,000 shares of Series 2 Preferred Stock are convertible has been registered for sale under the Securities Act of 1933 and, subject to certain limitations, may be sold at any time without restriction. None of the shares underlying the warrants have yet been registered for sale under the Securities Act of 1933, but substantially all of the warrants have registration rights entitling the holders to register the underlying shares under the Securities Act of 1933 in certain instances upon exercise of the warrants, which would allow those shares of common stock to be sold without restriction. The shares underlying the stock options have been registered under the Securities Act of 1933 and, subject to certain limitations, may be sold upon exercise of the stock options without restriction. In addition, on December 31, 2002 we had 4,616,597 shares of common stock available for issuance under employee benefit plans in addition to the 4,625,525 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 five stockholders who beneficially own approximately 41% of our outstanding common stock and who can exercise significant influence over all matters requiring stockholder approval.**

As of December 31, 2002, our present directors, executive officers and their respective affiliates and related entities beneficially owned approximately 44% of our outstanding common stock and common stock equivalents. 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. They may also receive additional shares of our common stock if, pursuant to the mandatory or optional redemption provisions of our preferred stock, we redeem our preferred stock by electing to issue common stock in lieu of paying the cash redemption price. 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 closing sale price of our stock during the past year has ranged from a high of \$13.72 during the quarter ended March 31, 2002 to a low of \$2.75 during the quarter ended December 31, 2002.

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 financial results of us and our competitors;
- future sales of substantial amounts of common stock by shareholders; and
- economic and other external factors.

**We have and may in the future issue additional preferred stock that 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 (except that the rights, preferences, and privileges may not be more favorable to the stockholder than the Series 2 Preferred Stock, without the approval of holders of the Series 2 Preferred Stock). 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 on our common stock.**

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, 2002. The Company's debt instruments at December 31, 2002, are subject to fixed interest rates and principal payments. We believe that the fair value of our fixed rate long-term debt and refundable deposit approximates its carrying value of approximately \$31 million at December 31, 2002. While changes in market interest rates may affect the fair value of our fixed 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**

There have been no changes in or disagreements with accountants on accounting and financial disclosure matters.

**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 from our definitive proxy statement to be filed pursuant to Regulation 14A, related to the Registrant's 2003 Annual Meeting of Stockholders, to be held on May 15, 2003 (the "2003 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 from our 2003 Proxy Statement.

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

The following table details information regarding the company's existing equity compensation plans as of December 31, 2002:

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.....	4,625,525	\$4.85	4,138,789
Equity Compensation Plans not approved by security holders <sup>(1)</sup> ..	<u>22,192</u>	<u>—</u>	<u>477,808</u>
Total.....	<u>4,647,717</u>		<u>4,616,597</u>

<sup>(1)</sup> See page F-21, Note 16 for information on IMPAX Employee Stock Purchase Plan.

The remaining information required under this Item is incorporated herein by reference from our 2003 Proxy statement.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required under this Item is incorporated herein by reference from our 2003 Proxy Statement.

## ITEM 14. CONTROL AND PROCEDURES

Within ninety days prior to the date of this Annual Report on Form 10-K, the Company, under the supervision and with the participation of our management, including our principal executive officers and our principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officers and our principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or submit 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. In addition, subsequent to the date of the evaluation of our disclosure controls and procedures, there were no significant changes in our internal controls, or in other factors that could significantly affect these controls.

Company's management, including the Co-Chief Executive Officers and Chief Financial Officer, does not expect that its Disclosure Controls or its "internal controls and procedures for financial reporting" ("Internal Controls") will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the

degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## 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>
Reports of Independent Accountants.....	F-2
Balance Sheets as of December 31, 2002 and 2001 .....	F-3
Statements of Operations for each of the three years in the period ended December 31, 2002 .....	F-4
Statements of Stockholders Equity for each of the three years in the period ended December 31, 2002 .....	F-5
Statements of Cash Flows for each of the three years in the period ended December 31, 2002 .....	F-6
Notes to Financial Statements.....	F-7 to F-25

#### 2. FINANCIAL STATEMENT SCHEDULES

The following financial statement schedule of Impax Laboratories, Inc. for each of the years ended December 31, 2002, 2001 and 2000 should be read in conjunction with the Financial Statements, and related notes thereto, of Impax Laboratories, Inc.

	<u>Page Number</u>
Schedule II – Valuation and Qualifying Accounts	S-1

Schedules other than those listed above 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>
- 10.6 The Company's 1995 Stock Incentive Plan. <sup>(1) (4)</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 5mg/120mg 12-hour Extended Release Tablets) and Claritin-D 24 (Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24-hour Extended Release Tablets). <sup>(10)</sup>
- 10.61 Supply Agreement between Schering-Plough (Loratadine and Pseudoephedrine Sulfate 5mg/120mg 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>
- 23.1 Consent of PricewaterhouseCoopers LLP. <sup>(13)</sup>
- 99.1 Certification of Chairman and Co-Chief Executive Officer <sup>(13)</sup>
- 99.2 Certification of Co-Chief Executive Officer <sup>(13)</sup>
- 99.3 Certification of Chief Financial Officer <sup>(13)</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 Yearly 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 Yearly 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 Yearly 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 with 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 with 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> Filed herewith.

(b) Reports on Form 8-K.

No reports on Form 8-K were filed during the last quarter of the year ended December 31, 2002.

## SIGNATURES

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

IMPAX LABORATORIES, INC.  
(Registrant)

By /s/ BARRY R. EDWARDS  
Co-CHIEF EXECUTIVE OFFICER

Date: March 27, 2003

By s/s CORNEL C. SPIEGLER  
CHIEF FINANCIAL OFFICER

Date March 27, 2003

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.

/s/ CHARLES HSIAO, Ph.D. Chairman, Co-Chief Executive Officer and Director  
(Charles Hsiao, Ph.D.)

/s/ BARRY R. EDWARDS Co-Chief Executive Officer and Director  
(Barry R. Edwards) (Principal Executive Officer)

/s/ LARRY HSU, Ph.D. President and Director  
(Larry Hsu, Ph.D.)

/s/ CORNEL C. SPIEGLER Chief Financial Officer and Corporate Secretary  
(Cornel C. Spiegler) (Principal Financial and Accounting Officer)

/s/ LESLIE Z. BENET, Ph.D. Director  
(Leslie Z. Benet, Ph.D.)

s/s ROBERT L. BURR Director  
(Robert L. Burr)

s/s DAVID J. EDWARDS Director  
(David J. Edwards)

s/s NIGEL FLEMING, Ph.D. Director  
(Nigel Fleming, Ph.D.)

s/s MICHAEL MARKBREITER Director  
(Michael Markbreiter)

s/s OH KIM SUN Director  
(Oh Kim Sun)

s/s PETER R. TERRERI Director  
(Peter R. Ferreri)





**CERTIFICATION OF  
CHIEF FINANCIAL OFFICER**

I, Cornel C. Spiegler, CFO, certify that:

1. I have reviewed this annual report on Form 10-K for the twelve months ended December 31, 2002 of Impax Laboratories, Inc.
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact, or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading, with respect to the period covered by this annual report.
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report.
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant, and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the Audit Committee of registrant's Board of Directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize, and report financial data, and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls, or in other factors that could significantly affect internal controls, subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

\_\_\_\_\_  
/s/ Cornel C. Spiegler

Cornel C. Spiegler  
Chief Financial Officer

\_\_\_\_\_  
March 27, 2003

**IMPAX LABORATORIES, INC.**

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## 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 54 present fairly, in all material respects, the financial position of Impax Laboratories, Inc. at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) on page 54 present fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and the financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule 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>2002</b>	<b>2001</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,219	\$ 15,044
Short-term investments	—	20,422
Accounts receivable, net	6,524	3,523
Inventory	10,478	3,488
Prepaid expenses and other assets	973	1,506
Total current assets	28,194	43,983
Restricted Cash	10,000	—
Property, plant and equipment, net	37,065	24,334
Investments and other assets	807	574
Goodwill, net	27,574	27,574
Intangibles, net	763	1,147
Total assets	<b>\$ 104,403</b>	<b>\$ 97,612</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of long-term debt	\$ 861	\$ 232
Accounts payable	7,529	3,996
Notes payable	3,999	—
Accrued expenses and deferred revenues	10,859	3,575
Total current liabilities	23,248	7,803
Long term debt	9,105	6,868
Refundable deposit	22,000	22,876
Deferred revenues	1,486	117
	55,839	37,664
Commitments and contingencies		
Mandatory redeemable convertible Preferred Stock:		
Series 2 mandatory redeemable convertible Preferred Stock, \$0.01 par value		
75,000 shares outstanding at December 31, 2002, and 2001, redeemable at \$100 per share	7,500	7,500
	7,500	7,500
Stockholders' equity:		
Redeemable convertible Preferred Stock	—	—
Common stock, \$0.01 par value, 75,000,000 shares authorized and 47,874,614 and 46,680,047 shares issued and outstanding at December 31, 2002, and 2001, respectively	479	466
Additional paid-in capital	131,085	122,957
Unearned compensation	(158)	(673)
Accumulated deficit	(90,342)	(70,302)
Total stockholders' equity	41,064	52,448
Total liabilities and stockholders' equity	<b>\$ 104,403</b>	<b>\$ 97,612</b>

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>2002</u>	<u>2001</u>	<u>2000</u>
Net sales	\$ 23,758	\$ 6,591	\$ 10,170
Other Revenue	<u>757</u>	<u>—</u>	<u>—</u>
Total Revenues	\$ 24,515	\$ 6,591	\$ 10,170
Cost of sales	<u>18,492</u>	<u>9,669</u>	<u>9,716</u>
Gross margin (loss)	6,023	(3,078)	454
Research and development	16,254	11,890	11,096
Less: Reimbursements from Teva	<u>(705)</u>	<u>(918)</u>	<u>—</u>
Research and development, net	15,549	10,972	11,096
Selling Expenses	2,836	2,186	1,346
General and administrative	8,396	9,258	9,764
Other operating income, net	(36)	164	306
Restructuring charges and non-recurring items	<u>—</u>	<u>—</u>	<u>3,646</u>
Net loss from operations	(20,794)	(25,330)	(25,092)
Interest income	644	1,148	758
Interest (expense)	<u>110</u>	<u>(929)</u>	<u>(339)</u>
Net loss before cumulative effect of accounting change	<u>\$ (20,040)</u>	<u>\$ (25,111)</u>	<u>\$ (24,673)</u>
Cumulative effect of accounting change (SAB 101)	—	—	(288)
Net loss	<u>\$ (20,040)</u>	<u>\$ (25,111)</u>	<u>\$ (24,961)</u>
Net loss per share before cumulative effect of accounting change	<u>\$ (0.42)</u>	<u>\$ (0.60)</u>	<u>\$ (0.90)</u>
Net loss per share (basic and diluted)	<u>\$ (0.42)</u>	<u>\$ (0.60)</u>	<u>\$ (0.91)</u>
Weighted average common shares outstanding	<u>47,444,364</u>	<u>41,555,818</u>	<u>27,538,989</u>

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

**IMPAX LABORATORIES, INC.**  
**STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**FOR THE PERIOD FROM JANUARY 1, 2000 THROUGH DECEMBER 31, 2002**  
**(dollars and shares in thousands, except per share amounts)**

	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, 2000.....	24,807	\$ 248	\$ 51,730	(\$ 1,470)	(\$20,230)	\$30,278
Sale of Common Stock.....	2,739	27	16,473	-	-	16,500
Conversion of Series 1B Preferred Stock.....	3,801	38	5,659	-	-	5,697
Conversion of Series 2 Preferred Stock.....	600	6	2,994	-	-	3,000
Exercise of warrants and options.....	348	4	507	-	-	511
Expenses related to sale of stock.....	-	-	(728)	-	-	(728)
Fair value of stock option issued to consultant....	-	-	105	(105)	-	-
Amortization of unearned compensation.....	-	-	-	457	-	457
Net loss.....	-	-	-	-	(24,961)	(24,961)
Balance at December 31, 2000.....	<u>32,295</u>	<u>\$323</u>	<u>\$76,740</u>	<u>(\$1,118)</u>	<u>(\$45,191)</u>	<u>\$30,754</u>
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>

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>2002</u>	<u>2001</u>	<u>2000</u>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (20,040)	\$ (25,111)	\$ (24,961)
Adjustments to reconcile net loss to net cash used by operating activities:			
Depreciation and amortization	2,707	5,828	5,955
Non-cash compensation charge (warrants and options)	515	498	457
Non-cash asset impairments	-	-	3,646
Other	-	-	(11)
Change in assets and liabilities:			
Accounts receivable	(3,001)	(1,942)	2,211
Inventory	(6,990)	(539)	(1,884)
Prepaid expenses and other assets	300	(1,018)	(143)
Accounts payable and other liabilities	<u>11,310</u>	<u>4,407</u>	<u>(1,274)</u>
Net cash used in operating activities	<u>(15,199)</u>	<u>(17,877)</u>	<u>(16,004)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(15,054)	(16,575)	(3,563)
Purchases of short-term investments	-	(32,232)	(18,569)
Sale and maturities of short term investments	<u>20,422</u>	<u>19,590</u>	<u>10,789</u>
Net cash provided by (used in) investing activities	<u>5,368</u>	<u>(29,217)</u>	<u>(11,343)</u>
<b>Cash flows from financing activities:</b>			
Notes payable borrowings (repayments)	3,999	(2,425)	572
Additions to long-term debt	3,150	5,770	-
Repayment of long-term debt	(284)	(159)	(473)
Proceeds from issuance of preferred stock (net of expense)	-	-	14,902
Proceeds from sale of common stock (net of expense)	7,500	24,831	15,870
Proceeds from issuance of common stock (upon exercise of stock options and warrants) and sale of common stock under ESPP	409	673	511
Reversal of previous year expenses related to sales of stock (net)	232	-	-
Refundable deposit from Teva	-	22,000	-
Restricted Cash Account with Congress Financial	<u>( 10,000)</u>	<u>-</u>	<u>-</u>
Net cash provided by financing activities	<u>5,006</u>	<u>50,690</u>	<u>31,382</u>
Net (decrease) increase in cash and cash equivalents	(4,825)	3,596	4,035
Cash and cash equivalents, beginning of the year	<u>15,044</u>	<u>11,448</u>	<u>7,413</u>
Cash and cash equivalents, end of year	<u>10,219</u>	<u>15,044</u>	<u>11,448</u>

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

**NOTES TO FINANCIAL STATEMENTS**  
**YEARS ENDED DECEMBER 31, 2002, 2001, AND 2000**

**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. Certain information and disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations; however, the Company believes that the disclosures are adequate to make the information presented not misleading. It is suggested that these financial statements be read in conjunction with the notes included in this report.

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. The Company is currently marketing twenty-seven generic pharmaceuticals, which represent dosage variations of twelve different pharmaceutical compounds, and has nineteen Abbreviated New Drug Applications (ANDAs) under review with the Food and Drug Administration (FDA), addressing more than \$5.8 billion in U.S. product sales in the twelve months ending December 31, 2002. Thirteen of these ANDAs were filed under Paragraph IV of the Hatch-Waxman Amendments. The Company has approximately seventeen other products in various stages of development for which applications have not yet been filed. The products are generic versions of brand name pharmaceuticals that had U.S. sales of \$3.2 billion in the twelve months ending December 31, 2002.

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 generated minimal revenues to date and have experienced operating losses and negative cash flow from operations since our inception. As of December 31, 2002, our accumulated deficit was \$90,342,000 and we had outstanding indebtedness in an aggregate amount of \$35,965,000, including the \$22,000,000 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.

As discussed further in Note 12, the \$22 million refundable deposit from Teva, less any forgiven amounts upon IMPAX's attainment of certain milestones, if any, is due and payable on January 15, 2004, in cash or equity at our discretion. As of February 25, 2003, we believe that approximately \$10.5 million of the \$22 million may be forgiven prior to January 15, 2004, although there is no assurance that any of the \$22 million may be ultimately forgiven. These milestone events, if achieved, will represent the culmination of a separate earnings process. If we repay the loan in stock, such payment will result in dilution. If we repay all or a portion of the loan in cash, we may seek additional sources of liquidity to fund such payment, as discussed below.

Although our existing cash and cash equivalents are expected to decline during the remainder of 2003, we believe that our existing cash and cash equivalent balances, together with our \$25 million term loan and revolving line of credit, will be sufficient to meet our operational plan for the next twelve months. We may, however, seek additional financing through strategic alliances and/or equity markets to repay the Teva deposit, if required, and to fund our research and development plans, and potential revenues shortfall due to delays in new products introduction. However, we may be unable to obtain such financing.

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 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 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.

### ***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 three major customers, Amerisource-Bergen, Cardinal Health, and McKesson, that account for approximately 57% of total sales for the year ended December 31, 2002. At December 31, 2002, accounts receivable from these three customers, represent approximately 64% of total trade receivables. Approximately 35% of the Company's net sales were attributable to one product family, which is supplied by a vendor, Eurand America, Inc., under an exclusive licensing agreement that expires in 2007.

### ***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 arising are apportioned to inventory and cost of goods sold based upon inventory turnover. The Company considers product costs as inventory once the Company receives FDA approval to market the related products. 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.

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.

### ***Investments***

The Company's investments in other than cash equivalents are classified as "held-to-maturity" 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 11) and management's intention with respect to holding these securities. At December 31, 2002, the cost of the Company's investments approximates fair value.

### ***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. 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.

### ***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. If estimates of fair value less costs to sell are revised, the carrying amount of the related asset is adjusted, resulting in recognition of a charge or benefit to earnings.

### ***Revenue Recognition***

During the year 2000, we adopted 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.

The application of the SAB 101 guidance to the Company's previous revenue recognition policy requires it to defer revenue recognition from the sale of product until the shipment of product is received and accepted by the customer, rather than recognizing revenue only upon shipment. The change in accounting policy resulted in a cumulative effect adjustment at January 1, 2000, of \$288,000 and also resulted in an increase in revenue and gross margin of \$667,000 and \$288,000, respectively, for the twelve month period ended December 31, 2000.

Revenue from strategic alliances includes up-front payments and milestone payments. Up-front payments are generally deferred and recognized on a straight-line basis over the life of the related agreement. Milestone payments are generally recognized when the requirements set forth in the related agreement are met and such recognition represents a separate earnings process. In evaluating whether a separate earnings process has been met, the Company considers the following criteria: a) level of effort involved in achieving the milestone; b) reasonableness of the milestone payment in relation to the effort expended in achieving the milestone; c) the amount of time that has passed from the up-front payment, if any, to the milestone payment and between various milestones; d) the amount of the payment in relation to the risk involved in achieving the milestone; and e) relationship between the amount of the up-front payment and the first milestone payment.

### ***Returns***

The sales return reserve is calculated using historical lag period (that is, the time between when the product is sold and when it is ultimately returned) 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 to NDC numbers. Our returned goods policy requires prior authorization for the returns, 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 allowed 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 also review the level of pipeline inventory at major wholesalers to assess the reasonableness of our estimate of future returns. 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, 2002 and 2001, the shelf-stock reserve was \$660,000 and \$0, respectively.

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

Shipping and handling fees related to sales transactions when billed to customers are recorded as sales revenue. Shipping and handling costs which are recorded in selling expense were \$195,000, \$132,000, and \$126,000 in 2002, 2001 and 2000, 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, as amended by SFAS No. 138, did not have and will not have a material impact on the results of operations, financial position or cash flows as it is the Company's policy to not enter into any transactions involving derivative instruments.

### ***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".

If the Company had elected to recognize compensation expense based upon the fair value at the grant dates for awards under its plans, the Company's loss would have been increased to the pro forma amounts indicated below (in thousands):

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. 123, "Accounting for Stock Based Compensation," the Company's loss would have been increased to the pro forma amounts indicated below (in thousands):

	<u>For the Year Ended December 31, 2002</u>		<u>For the Year Ended December 31, 2001</u>		<u>For the Year Ended December 31, 2000</u>	
	As Reported	Pro Forma	As Reported	Pro Forma	As Reported	Pro Forma
Net loss	(\$20,040)	(\$26,426)	(\$25,111)	(\$26,561)	(\$24,961)	(\$25,892)
Net loss per common share (basic and diluted)	(\$0.42)	(\$0.56)	(\$0.60)	(\$0.64)	(\$0.91)	(\$0.94)

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 4.39%, 4.30%, and 5.48% for the years ended December 31, 2002, 2001, and 2000, respectively. The expected stock price volatility for the year ended December 31, 2002, was 50%. The weighted average fair value of options granted during 2002, 2001, and 2000 was \$3.18, \$4.43, and \$2.66, 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.

Mandatory redeemable convertible stock of 1,500,000 shares (on an as-converted basis), warrants to purchase 2,548,266 shares, and stock options to purchase 4,625,525 shares were outstanding at December 31, 2002, 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 effect, if any, of initially applying this Statement will be reported in the Statements of Operations as the cumulative effect of a change in accounting principle. The Company is evaluating the effect this Statement will have on the Company's future financial statements.

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 have not had and are not expecting to 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 Company does not believe that this Statement will 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 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company is currently evaluating the effect that the adoption of EITF Issue No. 00-21 will have on its results of operations and financial condition.

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 are effective for the current fiscal year, and the Company has included this information in Note 13 to the Company’s financial statements. However, 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. We reviewed all material agreements and concluded that all indemnifications are excluded from FIN No. 45 scope of interpretation since they relate primarily to our own future performance and do not require any contingent payments.

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 2 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.

In August 2001, the FASB issued SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets.” SFAS No. 144 supercedes SFAS No. 121, “Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of.” This Statement applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), “Reporting Results of Operations Reporting the Effects of Disposal of a Segment of a Business.” The provisions of SFAS No. 144 are effective for financial statements issued for fiscal years beginning after December 15, 2001, and, generally, its provisions are to be applied prospectively. The adoption of SFAS No. 144 did not have a material effect on the Company’s results of operations, financial position or cash flows.

In April 2002, FASB issued SFAS No. 145. This Statement rescinds FASB Statement No. 4, Reporting Gains and Losses from Extinguishment of Debt, and an amendment of that Statement, FASB Statement No. 64, Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements. This Statement also rescinds FASB Statement No. 44, Accounting for Intangible Assets of Motor Carriers. This Statement amends FASB Statement No. 13, Accounting for Leases, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The adoption of SFAS No. 145 did not have a material effect on the Company’s results of operations, financial position or cash flows.

In June 2002, FASB issued SFAS No. 146, this Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The adoption of SFAS No. 146 did not have a material effect on the Company’s results of operations, financial position or cash flows.

### **NOTE 3 – RELATED PARTY TRANSACTIONS:**

As of December 31, 2000, the Company had accrued \$400,000 of compensation payable to two key employees in recognition of past services rendered; this amount was paid during 2001.

**NOTE 4 – ACCOUNTS RECEIVABLE**

Gross receivables and related deductions at December 31, 2002, 2001 and 2000 are set forth below:

(in \$000's)	<u>Year 2002</u>	<u>Year 2001</u>	<u>Year 2000</u>
Gross accounts receivable	\$ 9,827	\$ 5,112	\$ 1,948
Less: Accrued rebates	(1,525)	(886)	(181)
Less: Accrued chargebacks	(1,373)	(580)	(144)
Less: Other deductions	<u>(405)</u>	<u>(123)</u>	<u>(42)</u>
Net accounts receivable	<u>\$ 6,524</u>	<u>\$ 3,523</u>	<u>\$ 1,581</u>

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

Chargebacks and Rebates Accruals activity for the years ended December 31, 2002, 2001 and 2000, is set forth below.

**CHARGEBACKS ACCRUAL**

(in \$000's)	<u>Year 2002</u>	<u>Year 2001</u>	<u>Year 2000</u>
Beginning Balance	\$ 580	\$ 144	\$ 552
Add: Provision related to sales made in current period	4,632	1,938	1,838
Less: Credits issued during the current period	<u>(3,839)</u>	<u>(1,502)</u>	<u>(2,246)</u>
Ending Balance	<u>\$ 1,373</u>	<u>\$ 580</u>	<u>\$ 144</u>

**REBATES ACCRUAL**

(in \$000's)	<u>Year 2002</u>	<u>Year 2001</u>	<u>Year 2000</u>
Beginning Balance	\$ 886	\$ 181	\$ 532
Add: Provision related to sales made in current period	4,095	2,052	1,341
Less: Credits issued during the current period	<u>(3,456)</u>	<u>(1,347)</u>	<u>(1,692)</u>
Ending Balance	<u>\$ 1,525</u>	<u>\$ 886</u>	<u>\$ 181</u>

**NOTE 5 – INVENTORY**

Inventory consists of the following:

	<u>2002</u>	December 31,	<u>2001</u>
		(in thousands)	
Raw Materials .....	\$ 7,122		\$ 2,004
Work-in-Process .....	365		-
Finished goods .....	<u>3,191</u>		<u>1,634</u>
	10,678		3,638
Less: Reserve for obsolete inventory and net realizable value	<u>200</u>		<u>150</u>
	<u>\$ 10,478</u>		<u>\$ 3,488</u>

**NOTE 6 – PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consists of the following:

	Estimated useful life (years)	2002	December 31, 2001
			(in thousands)
Land .....	—	\$ 1,970	\$ 1,970
Building and building improvements .....	15	22,190	9,802
Equipment .....	7 - 10	13,757	8,321
Office furniture and equipment .....	5	1,161	722
Construction in progress .....	—	<u>3,869</u>	<u>7,316</u>
		42,947	28,131
Less: Accumulated depreciation		<u>5,882</u>	<u>3,797</u>
		<u>\$ 37,065</u>	<u>\$ 24,334</u>

Depreciation expense was \$2,323,000, \$1,940,000, and \$1,351,000 for the years ended December 31, 2002, 2001, and 2000, respectively.

#### NOTE 7 – INTANGIBLES

Intangibles consist of the following:

	Estimated useful life (years)	2002	December 31, 2001
			(in thousands)
Product rights and licenses .....	3 - 8	\$ 2,691	\$ 2,691
Less: Accumulated amortization		<u>1,928</u>	<u>1,544</u>
		<u>\$ 763</u>	<u>\$ 1,147</u>

Amortization expense was \$384,000, \$388,000, and \$4,604,000 for the years ended December 31, 2002, 2001, and 2000, respectively. Expected amortization for 2003 and 2004 is \$384,000 and \$379,000, respectively. The existing intangible assets will be fully amortized by December 31, 2004.

#### NOTE 8 – ACCRUED EXPENSES AND DEFERRED REVENUES

	2002	December 31, 2001
		(in thousands)
Sales returns .....	\$ 3,100	\$ 1,900
Accrued salaries and payroll related expenses .....	984	388
Accrued shelf stock price protection .....	660	—
Patent infringement and other legal expenses .....	516	354
Accrued royalty and gross profit sharing expense .....	446	121
Accrued Medicaid rebates .....	275	77
Accrued taxes.....	270	153
Accrued professional fees .....	331	207
Other accruals.....	644	309
Deferred revenues.....	<u>3,633</u>	<u>66</u>
	<u>\$ 10,859</u>	<u>\$ 3,575</u>

During the years ended 2002, 2001, and 2000, the Company has received product returns, for primarily expired product of \$1,262,000, \$2,840,000, and \$707,000, 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 \$1,900,000 at December 31, 2001 to \$3,100,000 at December 31, 2002. Therefore, the total expense recognized for the years ended December 31, 2002, 2001, and 2000 was \$2,462,000, \$4,524,000, and \$923,000 respectively.

Reserve for Sales Returns activity for the years ended December 31, 2002 and 2001 is set forth below:

## RESERVE FOR SALES RETURNS

(in \$000's)	<u>Year 2002</u>	<u>Year 2001</u>
Beginning Balance	\$ 1,900	\$ 216
Add: Current provision related to sales made in current period	1,633	1,363
Add: Current provision related to sales made in prior periods	829	3,162
Less: Actual returns in current period of sales in current period	( 4)	( 444)
Less: Actual returns in current period of sales in prior periods	<u>(1,258)</u>	<u>(2,397)</u>
Ending Balance	<u>\$ 3,100</u>	<u>\$ 1,900</u>

### NOTE 9 – 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>2002</u>	December 31, (in thousands)	<u>2001</u>
Net operating losses .....	\$ 34,100		\$ 28,802
Deferred start-up and organization costs .....	–		847
Research and development credit .....	2,764		2,068
Other .....	<u>4,974</u>		<u>1,683</u>
Total gross deferred tax assets .....	41,838		33,400
Deferred tax liability			
Tax depreciation and amortization in excess of book depreciation .....	(260)		(705)
Valuation allowance .....	<u>(41,578)</u>		<u>(32,695)</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, 2002, 2001, and 2000, 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, 2002, the Company had a net operating loss-carryforward totaling approximately \$85,249,000, which expires from 2009 through 2022. The Company also had research and development expenditure tax credits totaling approximately \$2,764,000 at December 31, 2002, which begin to expire in 2011. As indicated above, these losses and credits will have limitations. Of the \$85 million, approximately \$60 million will be currently available as of December 31, 2002, to offset any potential future taxable profits, with the remainder being fully available by December 31, 2004.

### NOTE 10 – NOTES PAYABLE

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. 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 profitability targets. The interest rates for the revolving loans range from prime rate plus 1% to 1.75%, or eurodollar rate plus 3% to 3.75%, 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, 2002, we borrowed approximately \$3,999,000 against the revolving credit line and \$3,098,000 against the term loan. The rate of the revolving credit line at December 31, 2002 was 5.25% and the rate of the term loan at December 31, 2002 was 5.75%. The revolving credit facility and the term loan agreement have a number of quarterly covenants primarily covering minimum tangible net worth, and either EBITDA or excess availability and annual capital expenditures limit of \$8 million. At December 31, 2002, all the bank loan covenants were met.

**NOTE 11 – LONG TERM DEBT**

	<u>2002</u>	December 31, (in thousands)	<u>2001</u>
2% loan payable to PIDA (No.1) in 180 monthly installments of \$6,602 commencing June 1, 1994, through May 1, 2009.....	\$ 477		\$ 546
3.75% loan payable to PIDA (No. 2) in 180 monthly installments of \$5,513 commencing September 1, 1997, through August 1, 2012.....	536		581
5% loan payable to DRPA in 120 monthly installments of \$3,712 commencing September 1, 1997, through August 1, 2007.....	185		219
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 .....	2,422		2,458
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 .....	3,248		3,296
Loan payable to Congress Financial in 60 monthly installments of \$52,500 commencing December 1, 2002, through November 30, 2007, at prime interest rate plus 1.5% .....	3,098		—
	<u>\$ 9,966</u>		<u>\$ 7,100</u>
Less: Current portion of long-term debt	861		232
	<u>\$ 9,105</u>		<u>\$ 6,868</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 30831 Huntwood Avenue, Hayward facility. The 7.50% Cathay Bank loan is collateralized by land, building and building improvements in the 31153 San Antonio Street, Hayward facility.

The Congress Financial 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, 2002, are as follows, in thousands:

2003 .....	\$ 861
2004 .....	868
2005 .....	881
2006 .....	894
2007 .....	855
Thereafter.....	<u>5,607</u>
Total	<u>\$ 9,966</u>

We believe that the fair value of our fixed rate long-term debt and refundable deposit approximates its carrying value of approximately \$31 million at December 31, 2002.

The interest paid during the years ended December 31, 2002, 2001, and 2000 was approximately \$561,000, \$224,000, and \$339,000, respectively.

**NOTE 12 – REFUNDABLE DEPOSIT**

In June 2001, we entered into a strategic alliance agreement with a subsidiary of Teva for twelve controlled-release generic pharmaceutical products. Teva (Nasdaq: TEVA), headquartered in Israel, is among the top 40 pharmaceutical companies and among the largest generic pharmaceutical companies in the world. Over 80% 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. marketing rights for six of our products pending approval at the FDA and six products under development at the time the agreement was signed. Of the six products under development, three have been filed with the FDA. Teva elected to commercialize a competing product to one of the three 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 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 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 and revenue generation for our products. 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 six products 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 we expect to be paid by our patent litigation insurer. For three other products, all of which were filed 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 \$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 common stock, or approximately 3% of the total shares of common stock outstanding at December 31, 2002. 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 acquires the common stock. However, on the date Teva completes its first sale of any one of six of the products specified in our alliance agreement, IMPAX 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 alliance agreement. The \$22 million is reflected on the balance sheet as a refundable deposit. The refundable deposit was provided in the form of a loan. This loan originally had an 8% annual interest rate. According to the agreement, if IMPAX received tentative or final approval for any of three products, the accrued interest is forgiven and no future interest accrues. During 2002, we received tentative approvals for our Loratadine and Pseudoephedrine Sulfate 5mg/120mg 12-hour Extended Release Tablets, Loratadine and Pseudoephedrine Sulfate 10mg/240mg 24-hour Extended Release Tablets, and Omeprazole 40mg Delayed Release Capsules and final approvals for our Omeprazole 10mg and 20mg Delayed Release Capsules resulting in the reversal of the accrued interest in the fourth quarter of 2002 and no future interest will accrue. Teva will forgive portions of this loan as we achieve milestones relating to the development and launch dates of the products described in our alliance agreement; these milestones, if achieved, will represent the culmination of a separate earnings process. If we fail to achieve the milestones, we will have to repay Teva some or all of the \$22.0 million loan on January 15, 2004. If we miss a milestone, Teva has the option of making us repay 100%, or 50% of the portion of the loan associated with that milestone. If Teva requires us to repay 100% of the portion of the loan related to the missed milestone, Teva's right to market that product will no longer be exclusive. However, if Teva requires us to repay only 50% of the portion of the loan related to the missed milestone, Teva will continue to have an exclusive marketing right for that product. At our option, we may repay Teva any amounts we owe 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 January 15, 2004. However, if any of the shares we issue to Teva as repayment of the loan will cause Teva to own in excess of 19.9% of our outstanding common stock, we will have to repay that portion of the loan in cash. If we repay all or a portion of the loan in cash, additional sources of liquidity will be pursued, as discussed in Note 1.

As of February 25, 2003, we believe that approximately \$10.5 million of the \$22 million may be forgiven prior to January 15, 2004, although there is no assurance that any of the \$22 million may be ultimately forgiven.

## **NOTE 13 – COMMITMENTS AND CONTINGENCIES**

### ***Leases***

Since November 1, 2002, the Company leases approximately 14,400 square feet of office space at 1502 Crocker Avenue, Hayward, California, through December 31, 2005; the annual rent (including operating expenses) is approximately \$135,000. Rent expense for the years ended December 31, 2002, 2001 and 2000 was \$56,000, \$463,000, and \$165,000, 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 2007. Future minimum lease payments under the non-cancelable operating leases are as follows (in thousands):

Year Ended December 31	
2003	\$ 243
2004	223
2005	211
2006	20
2007	<u>2</u>
Total minimum lease payments	<u>\$ 699</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, 2002.

### ***Patent Litigation***

As part of our patent litigation strategy, we have 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. At present, we believe this insurance coverage is sufficient for our legal defense costs related to these seven ANDAs. Correspondence received from AISLIC indicated that, as of January 14, 2003, one of the policies had approximately \$1,879,000 remaining on the limit of liability and the second of the policies had approximately \$675,000 remaining on the limit of liability. In addition, as per the agreement with Teva, for the six products already filed at the time of the agreement, Teva will pay 50% of the attorneys' fees and costs in excess of the \$7 million to be paid by AISLIC. For the three products 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.

However, 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 14 – MANDATORY 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, 2002 and December 31, 2001, respectively, and are classified as Mandatory Redeemable Convertible Preferred Stock. The remaining authorized but unissued shares could be issued with or without mandatory redemption or conversion features. During 2001, 163,030 shares of Series 1 Preferred Stock and 45,000 Shares of Series 2 Preferred Stock were converted into 10,040,871 and 900,000 shares of Common Stock, respectively.

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.

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 15 – 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>
1,755,266	\$0.75 to \$2.00 per share
770,000	\$2.01 to \$4.00 per share
<u>23,000</u>	\$4.01 to \$6.00 per share
<u><u>2,548,266</u></u>	

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

In connection with a deferred compensation agreement in 1998 with the Company's founders, the Company issued warrants to purchase 1,734,616 shares of Common Stock for \$0.75 per share. Such warrants, which are included in the above table, expire in 2003. In addition, 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 1A Preferred Stock, and warrants to purchase 225,000 shares of common stock at \$4.00 per share to Bear Stearns Small Cap Value in conjunction with a previous private equity financing. The Company determined that the fair value of the warrants at the date of grant was \$260,000 and has charged this amount to expense in 1998 in accordance with APB Opinion No 25. Bear Stearns Small Cap Value exercised its warrants in 2002.

##### ***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; \$578,000, \$472,000 and \$446,000 of the unearned compensation was amortized to expense during the years ended December 31, 2002, 2001, and 2000,

respectively. During 2002, the Company granted options to three consultants to purchase common stock at market price. As a result of the grant, the Company recorded approximately \$86,000 of unearned compensation and expensed approximately \$63,000 during the year ended December 31, 2002. The Company amortizes unearned compensation over the vesting period of the underlying option.

## **NOTE 16 – 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 \$195,000, \$40,000, and \$36,000 in matching contributions under this plan for the year ended December 31, 2002, 2001, and 2000, 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 2002, 15,990 shares of common stock were sold by the Company to its employees under this Plan for net proceeds of \$89,741.

### ***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 \$54,000 in matching contributions under this plan for the year ended December 31, 2002. The Plan has cash surrender value of \$97,552 and a deferred compensation liability of \$104,519 as of December 31, 2002.

## **NOTE 17 – 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 (“NSO”) 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. 425,738 and 563,010 options were outstanding at December 31, 2002 and 2001, 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. 765,658 and 801,298 options were outstanding at December 31, 2002 and 2001, 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. 311,800 and 313,800 options were outstanding at December 31, 2002 and 2001, 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. 3,069,829 and 1,606,961 options were outstanding at December 31, 2002 and 2001, 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. At December 31, 2002, 3,947,000 shares were outstanding.

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:

	2002		2001		2000	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options Outstanding at January 1	3,285,069	\$3.88	3,187,330	\$2.56	2,589,622	\$1.62
Granted	1,679,934	\$6.56	593,000	\$9.81	859,501	\$5.31
Exercised	(192,293)	\$1.08	(364,728)	\$1.56	(179,529)	\$1.71
Cancelled	(147,185)	\$9.00	(130,533)	\$5.35	(82,264)	\$3.59
Options outstanding at December 31	<u>4,625,525</u>	\$4.85	<u>3,285,069</u>	\$3.88	<u>3,187,330</u>	\$2.56
Options exercisable at December 31	<u>1,754,538</u>		<u>1,195,366</u>		<u>924,322</u>	
Options available for grant at December 31	<u>4,138,789</u>		<u>1,674,538</u>		<u>2,137,036</u>	

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

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	857,816	5.61	\$0.75	707,840	\$0.75
\$0.82 - \$ 2.06	357,080	6.08	\$0.90	273,685	\$0.92
\$2.19 - \$ 5.63	1,618,995	7.92	\$4.79	706,896	\$4.10
\$6.50 - \$11.95	1,791,634	9.03	\$7.83	66,117	\$9.42
\$0.30 - \$11.95	<u>4,625,525</u>	<u>7.69</u>	<u>\$4.85</u>	<u>1,754,538</u>	<u>\$2.46</u>

## NOTE 18 – RESTRUCTURING CHARGES

In August 2000, the Company ceased manufacturing operations at its Philadelphia facility and consolidated all manufacturing activities at its facility in Hayward, California. The Philadelphia facility continues as the Company's packaging, repackaging and distribution of finished products center. Additionally, a review of all manufactured products was undertaken in order to rationalize the product line consistent with these changes. This action was taken to utilize the Company's resources in the most economic way and to resolve long-standing regulatory issues with the Philadelphia facility. The following amounts were written-off as restructuring charges and unusual items in August 2000:

- Intangibles: \$2,037,000. As a result of a decision to discontinue nineteen products, the assets associated with these products were assessed (on a held for disposal basis) for impairment in accordance with SFAS 121. As there were no future cash flows and no anticipated buyers, the write-off represents the net book value of the intangibles associated with the products discontinued. None of these intangibles were sold. Two of the previously discontinued products were re-introduced approximately twelve months later. Intangibles associated with these two products had a net book value of \$0 at the date they were discontinued and, accordingly, were not part of the \$2,037,000 intangibles write-off in August 2000.
- Inventory: \$957,000. This represents the book value of inventory for the products discontinued; this inventory was destroyed in 2000.
- Equipment: \$652,000. This represents the difference between the net book value and the market value to be obtained by selling such equipment in the used equipment market. Substantially all the equipment has been disposed of as of December 31, 2002.

## NOTE 19 – SUBSEQUENT EVENTS

On January 30, 2003, IMPAX was granted by the FDA final approval to the Company's ANDA for a generic version of Rilutek (Riluzole 50mg) tablets. Aventis markets Rilutek for the treatment of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease.

On January 31, 2003, FDA granted IMPAX final approval to the Company's ANDA for a generic version of Claritin-D 12-Hour (Loratadine and Pseudoephedrine Sulfate 5mg/120mg) 12-hour Extended Release Tablets. FDA approved the 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.

On February 24, 2003, IMPAX announced that Merck & Co. Inc. has filed a lawsuit against the Company in the federal district court in Delaware alleging patent infringement related to IMPAX's filing of an Abbreviated New Drug Application (ANDA) for a generic version of Sinemet CR tablets. Sinemet CR is used to treat patients with Parkinsonism, and is exclusively distributed in the U.S. by Bristol-Myers Squibb Company. U.S. sales of Sinemet CR and the currently marketed generic equivalent were approximately \$154 million in the 12 months ended December 31, 2002, according to IMS Health data. The FDA accepted for review IMPAX's application to market a generic version of Merck's Sinemet CR in December 2002. IMPAX's submission includes a Paragraph IV certification stating the Company believes its product does not infringe upon Merck's listed Sinemet CR patents.

On March 26, 2003, the United States District Court in Chicago, Illinois ruled that our ANDA submission for a bioequivalent version of Tricor Capsules does not infringe Abbott's patent.

## NOTE 20 – SUPPLEMENTARY QUARTERLY DATA (UNAUDITED)

The following is the summary of the unaudited quarterly results of operations for the fiscal years 2002, 2001 and 2000:

(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> It includes additional reserve amounts.

(dollars in thousands except share and per share data)	Year 2001			
	For The Quarter Ended			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Gross Sales:				
Active products	2,737	2,275	3,731	4,171
New NDC Lipram	<u>520</u>	<u>616</u>	<u>717</u>	<u>1,352</u>
Total	3,257	2,891	4,448	5,523
Less:				
Rebates	(459)	(268)	(531)	(794)
Chargebacks	(316)	(282)	(506)	(834)
Returns <sup>1</sup>	(448)	(1,058)	(1,337)	(1,682)
Other credits	<u>(262)</u>	<u>( 147)</u>	<u>( 416)</u>	<u>( 188)</u>
Net Sales	1,772	1,136	1,658	2,025
Gross margin (loss)	<u>(504)</u>	<u>(856)</u>	<u>(589)</u>	<u>(1,129)</u>
Net loss	\$ (5,338)	\$ (6,150)	\$ (6,769)	\$ (6,854)
Net loss per share (basic and diluted)	\$ (0.16)	\$ (0.15)	\$ (0.15)	\$ (0.15)
Weighted Average Common Shares Outstanding	33,951,876	41,138,673	45,943,604	46,680,047

<sup>1</sup> It includes additional reserve amounts.

(dollars in thousands except share and per share data)	Year 2000			
	For The Quarter Ended			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
Gross Sales:				
Active products	2,008	2,013	2,065	1,837
New NDC Lipram	—	—	311	664
Discontinued products <sup>1</sup>	1,580	1,934	1,463	—
SAB 101 Adjustment	<u>667</u>	<u>—</u>	<u>—</u>	<u>—</u>
Total	4,255	3,947	3,839	2,501
Less:				
Rebates	(325)	(239)	(177)	(405)
Chargebacks	(480)	(468)	(436)	(276)
Returns <sup>2</sup>	(137)	( 90)	( 172)	( 464)
Other credits	<u>(128)</u>	<u>( 242)</u>	<u>( 277)</u>	<u>( 56)</u>

Net Sales	3,185	2,908	2,777	1,300
Gross margin (loss)	<u>833</u>	<u>322</u>	<u>(144)</u>	<u>(557)</u>
Net loss	\$ (4,392)	\$ (5,147)	\$ (9,618)	\$ (5,804)
Net loss per share (basic and diluted)	\$ (0.18)	\$ (0.21)	\$ (0.38)	\$ (0.20)
6 Weighted Average Common Shares Outstanding	24,808,129	24,900,197	25,094,236	29,544,225

<sup>1</sup> There were no discontinued products sold after August 2000.

<sup>2</sup> Includes additional reserve amounts.

IMPAX LABORATORIES, INC.

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS  
YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000  
(in thousands of dollars)

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	Balance at Beginning of Year	Additions, Costs and Expense	Deductions, Write-offs	Balance at End of Year
Inventory reserves:				
Year ended December 31, 2002	\$ 150	\$ 198	\$ 148	\$ 200
Year ended December 31, 2001	\$ 430	\$ 69	\$ 349	\$ 150
Year ended December 31, 2000	\$ 90	\$ 412	\$ 72	\$ 430
Deferred tax valuation allowance:				
Year ended December 31, 2002	\$ 32,695	\$ 8,883	\$ –	\$ 41,758
Year ended December 31, 2001	\$ 24,191	\$ 8,504	\$ –	\$ 32,695
Year ended December 31, 2000	\$ 18,701	\$ 5,490	\$ –	\$ 24,191



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