



ARIS  
RE 12-31-02  
0-30123

REC'D S.E.C.  
APR 15 2003  
1084

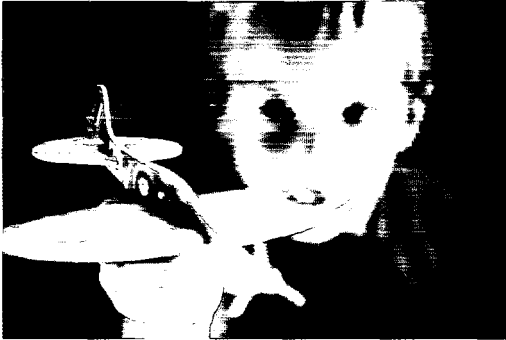
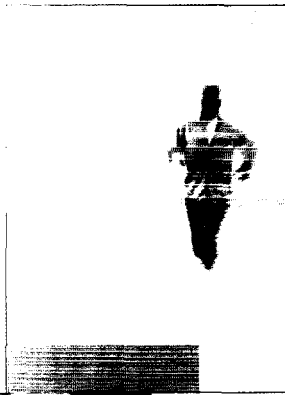


FIRST HORIZON  
PHARMACEUTICAL CORPORATION

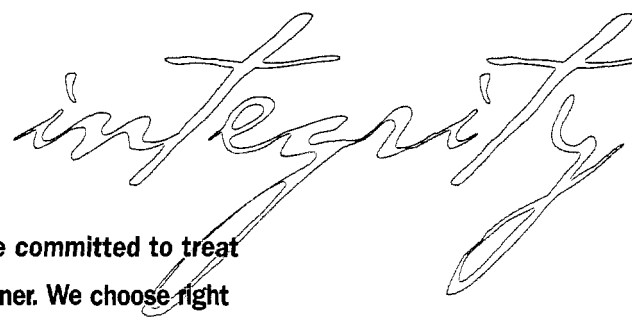
PROCESSED  
APR 16 2003

THOMSON  
FINANCIAL

*Working to deliver a better life.*



**First Horizon Pharmaceutical™ Corporation aspires to be a leader in the specialty pharmaceutical market by acquiring, developing and marketing prescription medicines within our chosen therapeutic areas. We strive to provide effective, high-quality products that improve the health and quality of life of patients while benefiting our shareholders. By placing the needs of the patient first and acting in accordance with our values – Integrity, Accountability, Teamwork, Business Results and Work-Life Balance – we will realize our vision.**



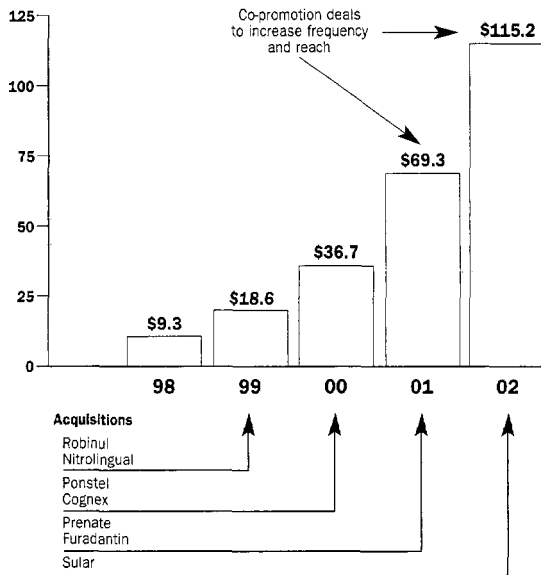
**At First Horizon Pharmaceutical Corporation we believe in integrity. We are committed to treat our employees, customers and shareholders in an honest and respectful manner. We choose right over wrong, ethics over convenience and truth over popularity; we believe in doing the right thing.**

## FINANCIAL HIGHLIGHTS

<u>Year ended December 31,</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>	<u>1999</u>	<u>1998</u>
<i>In thousands, except per share data</i>					
<b>Statement of Operations Data:</b>					
Net revenues	\$ 115,178	\$ 69,290	\$ 36,650	\$ 18,625	\$ 9,252
Cost of revenues	23,967	10,354	5,436	3,140	1,903
Selling, general and administrative expenses	61,843	38,689	24,217	12,546	6,790
Depreciation and amortization expense	14,471	2,724	1,091	424	35
Research and development expense	1,096	1,819	1,784	860	255
Operating income	13,801	15,704	4,122	1,655	269
Interest expense	(2,776)	(4)	(324)	(357)	(13)
Interest income	492	1,874	348	12	4
Other	(7)	4	21	8	(3)
Provision for income taxes	(4,481)	(6,855)	(1,660)	(548)	(121)
Net income before extraordinary items	\$ 7,029	\$ 10,723	\$ 2,507	\$ 770	\$ 136
Extraordinary item, net of taxes	\$ (863)	\$ -	\$ -	\$ -	\$ -
Net income	\$ 6,166	\$ 10,723	\$ 2,507	\$ 770	\$ 136
Net income per share:					
Income before extraordinary item	\$ 0.21	\$ 0.44	\$ 0.15	\$ 0.06	\$ 0.01
Extraordinary item, net of taxes	\$ (0.03)	\$ -	\$ -	\$ -	\$ -
Basic earnings per share	\$ 0.19	\$ 0.44	\$ 0.15	\$ 0.06	\$ 0.01
Income before extraordinary item	\$ 0.21	\$ 0.41	\$ 0.13	\$ 0.06	\$ 0.01
Extraordinary item, net of taxes	\$ (0.03)	\$ -	\$ -	\$ -	\$ -
Diluted earnings per share	\$ 0.18	\$ 0.41	\$ 0.13	\$ 0.06	\$ 0.01

## NET REVENUES

\$ in millions



# accountability

**At First Horizon Pharmaceutical Corporation we believe in accountability. We are committed as employees to be responsible for our personal and professional activities. As a corporation, we offer quality products at a fair price, and are obligated to our investors to provide shareholder value.**

## **DEAR SHAREHOLDERS,**

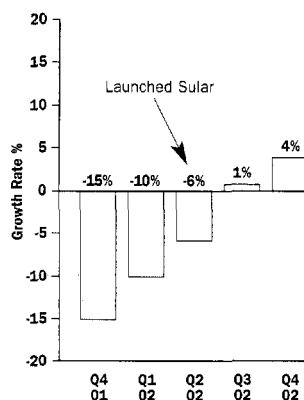
2002 was an important transition year for First Horizon. We expanded our product portfolio with the acquisitions of Sular and Furadantin. We built a larger, more specialized sales force numbering approximately 180 representatives and increased our overall physician reach through the use of our co-promotion partners. Our development efforts were successful as we launched three line extensions to the Tanafed line and received FDA approval for the 60-dose version of Nitrolingual Pumpspray. We faced the challenge of competitive knock-off products to our Tanafed line and Prenate GT as well as challenges associated with sales force realignment. We addressed these challenges and are making progress in executing our business plan.

## **2002 RESULTS**

We began the year by launching Tanafed DM in January as a line extension to our Tanafed line. We further expanded our pediatric franchise with the acquisition of Furadantin. Furadantin is used for the treatment of urinary tract infections and is primarily prescribed by pediatricians.

In February, we announced the acquisition of Sular, our largest acquisition to date. Sular is a differentiated calcium channel blocker that treats hypertension. We financed the acquisition of Sular through a \$152 million credit facility arranged through Deutsche Bank, which was subsequently repaid with the proceeds of a follow-on common stock offering in April.

### **Sular NRx Growth** Quarter over Quarter



Source: IMS NPA Plus report

The acquisition of Sular allowed us the opportunity to specialize and expand our sales force. We began by hiring 50 additional representatives in April. In May we specialized our sales force into two teams. The first team calls on primary care physicians and cardiologists promoting Sular, Nitrolingual Pumpspray and Robinul. The second team calls on pediatricians, OB/GYNs and gastroenterologists promoting our Tanafed line, Prenate GT, Ponstel and Robinul.

# Teamwork

**At First Horizon Pharmaceutical Corporation we believe in teamwork. We believe that teamwork is working together to achieve a common goal, and the ability to direct individual accomplishments toward corporate objectives.**



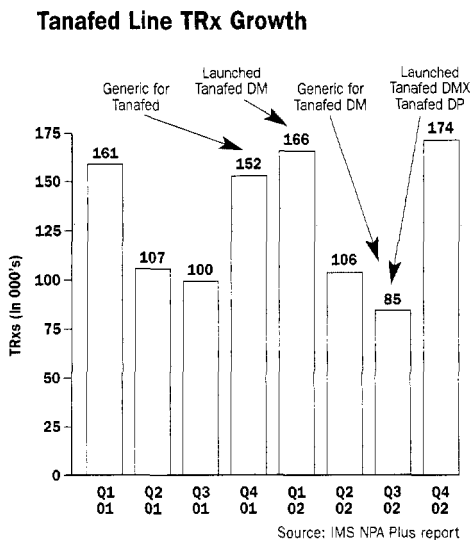
Mahendra G. Shah, Ph.D.  
Chairman, Chief Executive Officer  
and President

With the acquisition of Sular, we also expanded our reach by entering into two co-promotion agreements with PDI. The first agreement provided a convertible sales force of approximately 50 professionals that will promote First Horizon products to select primary care physicians and cardiologists. The second agreement provided over 150 professionals that promoted Sular to primary care physicians. In December 2002, we terminated the second agreement and entered into a new agreement with PDI which provides at least 250 professionals to promote Sular to primary care physicians.

In the second quarter of 2002, two issues impacted our operating results. The first issue was the greater than expected erosion of sales of our Tanafed Suspension and Prenate GT products due to increased substitution by pharmacists with competitor's knock-off products. The second issue was the temporary distraction caused by the sales force realignment in the second quarter, which decreased our product growth rates.

During the second half of the year we made substantial progress in addressing these issues. Beginning with the Tanafed line, we launched Tanafed DP and Tanafed DMX, two line extensions to the Tanafed line, in late September. These products have been formulated using the antihistamine dexchlorpheniramine, a single-isomer of chlorpheniramine. Dexchlorpheniramine provides the same effective relief as chlorpheniramine with about one-half of the antihistamine ingredient. Tanafed DP is a great tasting cold and allergy suspension for children that is dosed twice a day and Tanafed DMX offers the same benefits as Tanafed DP and contains cough suppressant.

We recently received a patent covering Tanafed DP and Tanafed DMX. We believe this patent broadens and



# business results

**At First Horizon Pharmaceutical Corporation we believe in business results. Through the promotion of our existing products, future acquisitions, and development of our employees, we will meet and exceed our financial corporate objectives. It is our passion that allows us to achieve superior results.**

strengthens the intellectual property protection of our Tanafed DP and Tanafed DMX products, and should protect these products against knock-offs.

Switching to the Prenate line, Prenate GT is the only prenatal vitamin that has a gel coating, which provides significant advantages to the patient such as no odor, no taste and is easier to swallow. Our strategic education programs highlighting the benefits of Prenate GT have been well accepted by healthcare

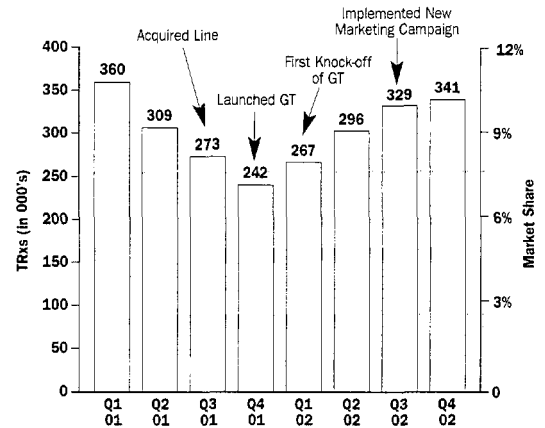
professionals and patients. In October, we extended our contract with ProtoCall for the promotion of Prenate GT. Prescriptions for the product increased in the third and fourth quarters. Prenate GT is one of very few prescription products that I am aware of that has managed to grow in the presence of a knock-off, demonstrating the benefits of the gel coating and the strength of our sales and marketing capabilities.

The second issue that hurt us temporarily in the second quarter was the sales force realignment. As I mentioned before, we used the acquisition of Sular as an opportunity to expand and specialize our internal sales force. This expansion and specialization resulted in a realignment of the sales force.

In November, we learned from the FDA, that our Nitrolingual Pumpspray 60-dose bottle application was

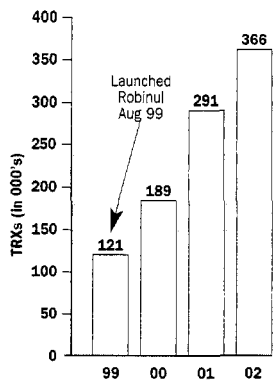
approved. This is an important approval for the brand for two reasons; one, physician's feedback on Nitrolingual Pumpspray 200-dose bottle has been that some patients, especially male patients, find the larger 200-dose bottle sometimes cumbersome to carry, and two, the 200-dose product may not be very efficient for patients who have mild stable angina and therefore occasional angina pectoris. The smaller bottle addresses both concerns and will be an excellent companion product to the currently marketed 200-dose Pumpspray.

**Prenate Line TRx and Market Share Growth**



Source: IMS NPA Plus report

**Robinul TRx Growth**



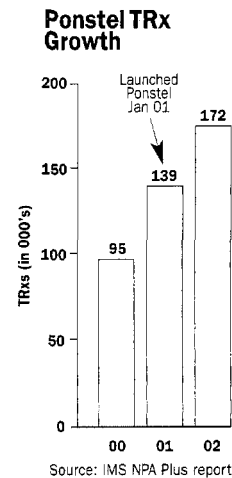
Source: IMS NPA Plus report

# Work-life balance

**At First Horizon Pharmaceutical Corporation we believe in work-life balance. We are committed to provide a harmonious environment that encourages our employees to treat their personal and professional life equally. One must have a strong balance between the two to achieve success.**

In December, we expanded our senior management team with the additions of Jack Spencer as Vice President of Sales and Darrell Borne as Chief Financial Officer.

For the year ended December 31, 2002, net revenues increased 66% to \$115.2 million compared to \$69.3 million for the year ended December 31, 2001. Net income before extraordinary items for the year ended December 31, 2002 was \$7.0 million or 21 cents per share compared to \$10.7 million or 41 cents per share for the year ended December 31, 2001, which reflected the investments that we made in our sales force. As of December 31, 2002, we had approximately \$47 million in cash and no debt.



## 2003 OUTLOOK

2003 will be a pivotal year for our Company as we continue our transition and refocus our organization. Our short- and medium-term success depends on the execution of our sales and marketing strategy. Our best assets are our products and our people, and we are focusing on ways to maximize these assets so they will provide a superior return on investment for our shareholders. Our long-term success will continue to depend on our ability to build a strong product pipeline. To that end, we continue to seek attractive product acquisition and licensing opportunities that fit within our therapeutic/physician focus. We are also looking at partnership opportunities with companies that have late stage products that can be in-licensed and developed with small, targeted investments.

Sincerely,

Mahendra G. Shah, Ph.D.

Chairman, Chief Executive Officer and President

## KEY PRODUCTS



**Tanafed DP™ Suspension** is indicated for the treatment of symptoms related to common colds and allergic rhinitis such as sneezing; stuffy or runny nose; and itchy, watery eyes. The single-isomer technology forming Dexchlorpheniramine allows Tanafed DP Suspension to provide the same efficacy with about half the antihistamine as previous Tanafed products, benefiting both doctor and patient. Tanafed DP Suspension is conveniently BID dosed and is available in a strawberry-banana flavored suspension that children love.



**Tanafed DMX™ Suspension**, containing the antitussive Dextromethorphan, is indicated for the treatment of symptoms related to common colds and allergic rhinitis such as cough; sneezing; stuffy or runny nose; and itchy, watery eyes. The single-isomer technology forming Dexchlorpheniramine allows Tanafed DMX Suspension to provide the same efficacy with about half the antihistamine as previous Tanafed products, benefiting both doctor and patient. Tanafed DMX is conveniently BID dosed and is available in a cotton candy flavored suspension that children love.

**Important Patient Information** As with other drugs in this class, the most frequent side effect of Tanafed DP Suspension and Tanafed DMX Suspension is slight-to-moderate, rare drowsiness. Pseudoephedrine may cause mild central nervous system (CNS) stimulation, especially in those patients who are hypersensitive to sympathomimetic drugs. Sympathomimetic drugs have also been associated with certain untoward reactions including convulsion, CNS depression, arrhythmias, and cardiovascular collapse with hypotension. Dextromethorphan has been associated with mild gastrointestinal disturbances. See full prescribing information on Company's Web site.



**Nitrolingual® Pumpspray**, a patented oral nitroglycerin spray, is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease. As the only short-acting nitrate available in spray form, Nitrolingual Pumpspray has been shown to provide faster relief, longer duration of action and greater stability compared to nitroglycerin tablets. According to the American Heart Association, angina pectoris affects 6.4 million Americans with approximately 400,000 new cases each year.

**Important Patient Information** Nitrolingual Pumpspray should not be used while taking sildenafil (Viagra®). Nitrolingual Pumpspray should be used with caution if patients have low systolic blood pressure or are undergoing diuretic therapy. Headache is the most commonly reported side effect with nitroglycerin. Patients may also experience episodes of dizziness, weakness, and other related side effects. See full prescribing information on Company's Web site.



**Sular®** is a dihydropyridine (DHP) calcium channel blocker. The extended release tablet form is designed to provide a once-daily dosing schedule and steady plasma nisoldipine concentrations that are essential in the treatment of mild to moderate hypertension. Sular provides consistent 24-hour control, including blunting of the early morning rise in blood pressure. Sular is an ideal adjunctive therapy and can be combined with ACE inhibitors, beta-blockers and diuretics. Sular is safe and well tolerated and is one of the lowest cost calcium channel blockers on the market and the only calcium channel blocker with the same price across all dosages. Sular comes in four strengths: 10, 20, 30 and 40 mg tablets.

**Important Patient Information** Sular is indicated for the treatment of hypertension. In rare cases, some patients, particularly those with severe obstructive coronary artery disease, have developed increased frequency, duration, and/or severity of angina, or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. Safety of Sular in patients with heart failure has not been established. Sular should be administered cautiously in patients over the age of 65 and in those with severe hepatic dysfunction. Because nisoldipine, like other vasodilators, decreases peripheral vascular resistance, careful monitoring of blood pressure during the initial administration and titration of Sular is recommended. Sular should not be taken with grapefruit products or in conjunction with a high-fat meal. The most common adverse events, reported in the U.S. placebo-controlled trials, were peripheral edema, headache, and dizziness. See full prescribing information on Company's Web site.





**Prenate GT™**, the only gel-coated prescription prenatal vitamin, is designed to meet the increased nutritional needs of pregnancy in a gellab form that is easy for patients to take. Due to the large size and unpleasant taste and smell of most prenatal vitamins, many women find it difficult to take their prenatal vitamins as directed by their physician. The gel coating on Prenate GT eliminates the vitamin taste and smell and makes Prenate GT easy to swallow. A nationwide patient preference test confirmed that patients prefer gel-coated Prenate GT to traditional film-coated prenatal vitamins. Recognizing the unique benefits of a gel-coated prenatal, physicians prescribe Prenate GT more than any other prescription prenatal vitamin in the U.S.

Unique Formula  
**Prenate GT™**  
PRENATAL VITAMINS — GEL-COATED TABLETS

**Important Patient Information** Iron-containing products should always be kept out of reach of children. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Please see important product information, including boxed warning on accidental overdose of iron-containing products in children, on Company's Web site.

**Robinul® and Robinul® Forte tablets** are indicated for adjunctive therapy in the treatment of peptic ulcer. Glycopyrrolate is an antispasmodic (anticholinergic) often used as first-line therapy to treat gastrointestinal symptoms such as pain, bloating, gas and spasms. Experts estimate that nearly 20% of the world population suffers from gastrointestinal symptoms, and in the United States this has been reported to account for up to 3.5 million physician visits annually.

  
**ROBINUL®**  
(glycopyrrolate tablets USP, 1 mg)

**Important Patient Information** Robinul and Robinul Forte tablets are not recommended for use in pediatric patients under the age of 12 years. Robinul and Robinul Forte tablets are contraindicated in patients with any of the following conditions: glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, paralytic ileus, intestinal atony of the elderly or debilitated patient, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis, or hypersensitivity to glycopyrrolate. In the presence of high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of Robinul. Robinul may produce drowsiness or blurred vision. See full prescribing information on Company's Web site.

  
**ROBINUL®  
FORTE**  
(glycopyrrolate tablets USP, 2 mg)

**Ponstel®** is a nonsteroidal (fenamate) indicated for the relief of mild to moderate pain in patients over 14 years of age (when therapy will not exceed one week), and for treatment of primary dysmenorrhea. Dysmenorrhea is a very common gynecologic problem, reportedly affecting as many as 90 percent of menstruating women. Fenamates have a dual mode of action — prostaglandin inhibition and blockade — unlike other nonsteroidals, which only inhibit the synthesis of prostaglandins. Ponstel is also the most extensively studied nonsteroidal used to treat menorrhagia, or excessive menstrual blood loss.

**PONSTEL®**  
(mefenamic acid capsules, 250mg)

**Important Patient Information** Ponstel should not be used in patients who experience symptoms of bronchospasm, allergic rhinitis, or urticaria. Ponstel should not be used in patients with aspirin-sensitive asthma. Ponstel is contraindicated in patients with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract and should be avoided in patients with preexisting renal disease, fluid retention, hypertension, or heart failure. If rash occurs, administration of the drug should be stopped. Ponstel should not be used concomitantly with aspirin, methotrexate, ACE inhibitors, furosemide, lithium, warfarin, or antacids. See full prescribing information on Company's Web site.

## EXECUTIVE MANAGEMENT TEAM AND BOARD OF DIRECTORS

**Mahendra G. Shah, Ph.D.**

*Chairman of the Board, Chief Executive Officer and President*

**Jack E. Spencer**

*Vice President of Sales*

**Pierre Lapalme**

*Director*

**Darrell E. Borne**

*Chief Financial Officer, Treasurer and Secretary*

**Jerry N. Ellis**

*Director*

**Jon S. Saxe**

*Director*

**Andrew D. Shales**

*Vice President of Marketing*

**John N. Kapoor, Ph.D.**

*Director*

**Patrick J. Zenner**

*Director*

## CORPORATE INFORMATION

**Corporate Headquarters**

6195 Shiloh Road  
Alpharetta, Georgia 30005

**Stock Market Information**

First Horizon Pharmaceutical Corporation common stock is traded on the Nasdaq National Market under the symbol, FHRX

**SEC Filings**

The Company's annual report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2002 will be sent upon request by writing to:

**Investor Relations Contact**

You may contact investor relations through the Company's Web site [www.firsthorizonpharm.com](http://www.firsthorizonpharm.com)

**Annual Meeting**

The 2003 Annual Meeting of First Horizon Pharmaceutical Corporation will be held on Friday, May 16, 2003. The meeting will begin at 10:00 a.m. Eastern Time, at the Company's headquarters at 6195 Shiloh Road, Alpharetta, GA 30005.

Investor Relations  
First Horizon Pharmaceutical Corporation  
6195 Shiloh Road  
Alpharetta, Georgia 30005

**Transfer Agent and Registrar**

LaSalle Bank N.A.  
135 South LaSalle Street  
Chicago, Illinois 60603

**Web Site Address**

[www.firsthorizonpharm.com](http://www.firsthorizonpharm.com)

**Corporate Counsel**

Arnall Golden Gregory LLP  
2800 One Atlantic Center  
1201 West Peachtree Street  
Atlanta, Georgia 30309

## FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, the following: (i) our ability to meet and exceed our financial corporate objectives through the promotion of our existing products, future acquisitions, and development of our employees, (ii) the ability of a patent to strengthen the intellectual property protection of our Tanafed DP and Tanafed DMX products and to protect these products against knock-offs, (iii) the ability of the 60-dose version of Nitrolingual Pumpspray to address concerns of the 200-dose bottle, (iv) that the 60-dose bottle of Nitrolingual Pumpspray will be an excellent companion product to the currently marketed 200-dose bottle, (v) the success of our sales and marketing strategy, (vi) the ability of our products and people to provide a superior return on investment for our shareholders, (vii) our ability to build a strong product pipeline, (viii) our ability to locate and enter into attractive product acquisition and licensing opportunities, and (ix) our ability to locate and enter into partnerships with companies that have late stage products that can be in-licensed and developed with small, targeted investments. In evaluating all forward-looking statements, you should specifically consider various factors that could cause actual results to vary from those contained in the forward-looking statements. Risks affecting the Company are identified in the "Risk Factors" section of our Form 10-K for the year ended December 31, 2002 filed with the Securities and Exchange Commission on March 18, 2003 and attached herein as part of this Annual Report. We do not undertake to update prescription or market data or our forward-looking statements to reflect future events or circumstances.

## PART I

### ITEM 1. BUSINESS

#### Overview

First Horizon Pharmaceutical Corporation is a specialty pharmaceutical company that markets and sells brand name prescription products. We focus on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. Our strategy is to acquire or license pharmaceutical products that other companies do not actively market and that we believe have high sales growth potential, are promotion-sensitive and complement our existing products. In addition, we intend to develop new patentable formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs. We may also acquire businesses with complementary products or development pipelines as well as late stage development products consistent with our therapeutic focus.

Large multinational companies dominate the U.S. prescription pharmaceutical market. These companies often divest products which, as a result of consolidation or lack of strategic fit, do not meet the threshold level of sales required for continued marketing and promotion, as these companies continue to focus on drugs with annual sales in excess of \$1 billion. Since January 1, 1999, we have acquired and licensed products from AstraZeneca UK Limited, Aventis SA, Bayer AG, Elan Corporation, Pfizer Inc., Sanofi-Synthelabo Inc. and Wyeth. Third parties manufacture all of our products.

Since 1992, we have introduced 17 products. We promote our products through our nationwide sales and marketing force of approximately 180 professionals, targeting high-prescribing cardiologists, obstetricians and gynecologists, pediatricians, gastroenterologists and select primary care physicians. We also contract with third parties to promote our products in order to target a broader number of physicians.

During 2002, we acquired and began to sell Sular, an antihypertensive prescription medication. Sales of Sular during 2002 were below our expectations. Also during 2002, we experienced erosion of sales of our Prenate GT and Tanafed brands due to competition from knock-off products.

We were incorporated in Delaware in July 1992 as the surviving corporation of a merger between Century Pharmaceutical Corporation and Horizon Pharmaceutical Corporation. Our principal office is located at 6195 Shiloh Road, Alpharetta, Georgia 30005 and our telephone number is (770) 442-9707. Our corporate Internet address is [www.firsthorizonpharm.com](http://www.firsthorizonpharm.com). We do not intend for the information contained on our website to be a part of this Annual Report. We make available at this address, free of charge, 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 Securities Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

#### First Horizon Strategy

We believe that our ability to market, acquire and develop brand name prescription products positions us to continue to grow. The key elements of our strategy include:

- Increase product sales through targeted promotion. We seek to increase sales by promoting our products to physicians through our nationwide sales and marketing force. We also contract with third parties to promote our products in order to target a broader number of physicians. In 2002, we entered into or extended co-promotion agreements for our Sular, Nitrolingual Pumpspray, Robinul and Prenate products in order to expand our targeted promotion efforts. In January 2003, we terminated one of our co-promotion agreements for Nitrolingual Pumpspray. We also use direct mail and telemarketing to promote our products.
- Acquire brand name prescription products. We seek to acquire rights to brand name pharmaceutical products that we believe are promotion sensitive, complement our areas of therapeutic focus

and have the potential to leverage our sales infrastructure. In connection with our acquisition of products, we also consider barriers to entry for competitive products including patent protection, complexity of manufacturing processes and patient and physician loyalty. Since January 1, 1999, we have acquired or licensed ten products.

- Develop proprietary products and line extensions. We seek to reduce the costs and risks of development by focusing on drugs that the FDA has already approved. We plan to develop and launch products, including line extensions of our current products, using patent-protected delivery systems or formulations that offer market differentiation and the potential for market exclusivity. In September 2002, we launched Tanafed DP and Tanafed DMX, two line extensions to Tanafed and Tanafed DM. Our current development pipeline includes a line extension to Robinul to treat excessive salivation.
- Acquire businesses with products and development pipelines as well as late-stage development products complementary to ours. We regularly review opportunities to acquire businesses that sell products or have products under development that complement our areas of therapeutic focus. We also review opportunities to acquire and/or license late-stage development products.

## Products

Most of our products treat recurring or chronic conditions or disorders which result in repeat use over an extended period of time and generate consistent revenue streams. Our current key products include:

<u>Product</u>	<u>Year of the Company's Introduction</u>	<u>Product Use</u>
<b>Cardiology:</b>		
Sular . . . . .	2002	Hypertension
Nitrolingual Pumpspray . . . . .	2000	Acute angina
<b>Obstetrics and Gynecology:</b>		
Prenate GT . . . . .	2001	Prescription prenatal vitamin
Prenate Advance . . . . .	2001	Prescription prenatal vitamin
Ponstel . . . . .	2000	Pain and painful menstruation
<b>Pediatrics:</b>		
Tanafed DP . . . . .	2002	Allergy and cold
Tanafed DMX . . . . .	2002	Allergy and cold with cough
<b>Gastroenterology:</b>		
Robinul . . . . .	1999	Adjunctive therapy for peptic ulcer
Robinul Forte . . . . .	1999	Adjunctive therapy for peptic ulcer

### *Sular*

On March 6, 2002, we acquired certain U.S. rights relating to the antihypertensive prescription medication Sular from AstraZeneca. We also entered into a long-term manufacturing, supply and distribution agreement with Sular's manufacturer, Bayer. Sular is a patented, once-a-day treatment for hypertension that competes in the approximately \$16 billion antihypertensives market.

Prior to the acquisition of Sular, our cardiovascular product offering was limited to Nitrolingual Pumpspray, a product for the treatment of acute angina. Sular complements our cardiovascular franchise because the physicians who prescribe our Nitrolingual Pumpspray comprise a large part of the target audience for Sular. In addition, many patients who suffer from acute angina also suffer from hypertension. We believe that Sular offers advantages over other antihypertensives based upon its proven efficacy and

safety, its demonstrated ability to provide twenty-four hour blood pressure control and its relative value on a cost per day basis as compared to other branded antihypertensives.

Nisoldipine, the active ingredient in Sular, belongs to a group of medicines called calcium channel blockers. Calcium channel blockers prevent calcium from entering certain types of muscle cells. Because the muscle cells need calcium to contract, calcium channel blockers prevent the cells from contracting and cause them to relax. Nisoldipine selectively relaxes the muscles of small arteries causing them to dilate but has little or no effect on muscles or the veins of the heart.

Prior to our acquisition of Sular, we believe that Sular had not been actively promoted in the U.S. since 1999. Based on management's experience promoting cardiovascular products and the results of market research we conducted, we believe that it is promotion-sensitive. We launched Sular in the second quarter of 2002 and utilized a launch plan that included:

- Hiring sales professionals. We increased the size of our sales organization by approximately 50 individuals in the second quarter of 2002 to increase our reach to physicians.
- Contracting with an external sales organization. Similar to our promotional strategy for Nitrolingual Pumpspray and Prenate GT, we contracted with an external sales organization to increase the number of physicians we reach with direct selling and sampling efforts.

Sular was developed and patented by Bayer and was approved by the FDA in 1995. In 1996, Bayer granted to Zeneca Limited, a predecessor entity to AstraZeneca, the exclusive right to market, distribute and sell products containing nisoldipine, Sular's active ingredient, in the U.S. As part of this transaction, Bayer has granted to us an exclusive ten-year license to its patents and other intellectual property for the sale of Sular in the U.S. Bayer has also agreed to supply us with Sular during the term of this license. Sular is protected by Bayer's patent covering the composition of its coat core tablet that expires in June 2008 and its patent covering the Sular manufacturing process that expires in 2004.

#### *Nitrolingual Pumpspray*

In February 2000, we began marketing Nitrolingual Pumpspray for which we acquired exclusive distribution rights in the U.S. from Pohl-Boskamp. Nitrolingual Pumpspray is an oral spray of nitroglycerin used for the acute relief or prevention of chest pain associated with angina pectoris that results from heart disease. Pohl-Boskamp holds a patent that was issued in 1993 on the formulation of Nitrolingual that we license. According to the American Heart Association, about 6.2 million Americans suffer from angina pectoris.

The primary competitor to Nitrolingual Pumpspray is nitroglycerin, which is generally prescribed in tablet form. Unlike tablets, which begin to lose their potency immediately upon opening the bottle, Nitrolingual Pumpspray maintains its potency for two years. Further, studies have shown that Nitrolingual Pumpspray provides for more rapid absorption than the tablets. Each metered dose of Nitrolingual Pumpspray provides for consistent delivery of nitroglycerin. Also, unlike the tablets, Nitrolingual Pumpspray requires no special storage or handling to maintain its potency.

During the fourth quarter of 2002, the FDA approved a 60-dose application bottle of Nitrolingual Pumpspray. The 60-dose bottle is smaller and more convenient to carry for some patients than the currently marketed 200-dose bottle. We believe that the 60-dose bottle will benefit patients who have mild angina and whose episodes are occasional. We believe the smaller bottle will be an excellent companion product to the currently marketed 200-dose bottle. The launch for the 60-dose bottle is scheduled for the second quarter of 2003.

#### *Prenate Advance and Prenate GT*

In August 2001, we acquired the Prenate line of products from Sanofi-Synthelabo, including Prenate GT, which is a line extension to Prenate Advance that is manufactured using a gel-coating applied with a patent protected manufacturing technology. Prenate GT was also reformulated to include additional vitamins. Prescription prenatal vitamins are generally recommended before, during and after pregnancy so that the mother and the fetus receive adequate amounts of essential vitamins and minerals. The Prenate line has been a market leader of prescription prenatal vitamins based upon total prescriptions written. We believe that the advantages of Prenate GT include easier swallowing and masked taste and smell. During the third quarter of 2002, we implemented strategic education programs targeted to physicians, nurses and pharmacies highlighting the benefits of Prenate GT.

#### *Ponstel*

In April 2000, we acquired exclusive U.S. rights to market, distribute and sell Ponstel from Pfizer. Ponstel is used for the relief of mild to moderate pain for patients 14 years of age and older if therapy will be for less than one week and for primary dysmenorrhea, which is pain associated with menstruation. One class of frequently prescribed pain relievers is nonsteroidal anti-inflammatory drugs, or NSAIDs. Ponstel is a well known NSAID for treating dysmenorrhea and we believe that its advantages are its non-addictive qualities, low stomach-related side effects and efficacy. Primary dysmenorrhea is one of the most frequently encountered gynecological complaints and affects as many as half of postpubescent females.

#### *Tanafed DP and Tanafed DMX*

Our Tanafed line is comprised of liquid cold and allergy products marketed to pediatricians. We believe that pediatricians prescribe our Tanafed products because they are effective and children prefer their taste. We introduced Tanafed DP and Tanafed DMX, two line extensions to Tanafed Suspension and Tanafed DM, in September 2002. Tanafed DP and Tanafed DMX have been formulated using the antihistamine Dexchlorpheniramine. Tanafed DP is a cold and allergy suspension for children that is dosed twice a day and provides for eight to twelve hour relief and Tanafed DMX offers the same benefits and contains a cough suppressant.

#### *Robinul and Robinul Forte*

In January 1999, we acquired exclusive U.S. rights to Robinul and Robinul Forte, which is a higher-strength dosage of Robinul, from Wyeth. Both Robinul and Robinul Forte belong to a class of drugs known as anticholinergics that reduce the motion of the gastrointestinal tract and decrease stomach secretions. The FDA has approved both products for use as a therapy in conjunction with other therapeutics in the treatment of peptic ulcers. Compared to other anticholinergics, the Robinul product line has an overall better side effect profile and is longer acting, thereby requiring fewer doses. We are currently developing a line extension and will seek regulatory approval to use the active ingredient in Robinul to treat symptoms associated with the excessive production of saliva.

#### **Other Products**

In December 2001, we acquired U.S. rights to Furadantin from Elan. Furadantin is indicated for the treatment of urinary tract infections and is prescribed primarily by pediatricians. We launched Furadantin in January 2002. Furadantin is a product well-suited for children because it is formulated in liquid suspension form and has a fruit-flavored taste. Furadantin contains nitrofurantoin, which has no known bacterial resistance and is not known to cause allergic side effects that are well documented with other antibiotics.

In June 2000, we acquired world-wide rights to market, distribute and sell Cognex, as well as rights to a new unapproved controlled release version of Cognex called Cognex CR, from Pfizer. Cognex is used for

the treatment of mild to moderate dementia associated with Alzheimer's disease. Alzheimer's disease is a progressive, degenerative disease that attacks the brain and results in impaired memory, thinking and behavior.

In addition to Tanafed DP and Tanafed DMX, our other products for the treatment of cough, cold and allergy are Defen-LA tablets, Mescolor tablets and the Protuss product line, which includes Protuss liquid, Protuss DM tablets and Protuss-D Liquid.

We sell Zoto-HC ear drops for the treatment of swimmer's ear infections and Zebutal capsules for the treatment of tension headaches.

### **Regulatory Classification**

The FDA approved Sular, Furadantin, Cognex, Ponstel, Nitrolingual Pumpspray, Robinul and Robinul Forte based on new drug application submissions. The FDA also approved an abbreviated new drug application for Zebutal. Prenate is a prescription vitamin and does not have an approved new drug application. However, the FDA has not requested a new drug application on the Prenate line of products because of their long marketing history. We believe our other products are classified by the FDA as drugs that may be marketed without submitting safety and efficacy data at this time because of safety data submitted to the FDA at an earlier time.

### **Product Development**

We seek to maximize the value of drugs by developing new patentable formulations, using new delivery methods and seeking regulatory approval for new indications. Through the use of these distinct formulations and patent-protected delivery systems, we plan to create a marketing advantage over competing drugs. Some of these development projects include line extensions which allow us to extend the life cycles of our products. We expect the strength of extensive literature-based clinical data on the active ingredients in our products under development, current acceptance and usage of the active ingredients in these products by healthcare professionals and the safety profile of the active ingredients in approved products will reduce development costs and risks associated with FDA approval.

We generally seek to contract third parties to formulate, develop and manufacture materials needed for clinical trials and to perform scale-up work. We select third-party contractors that we believe have the capability to commercially manufacture the products. By selecting qualified third parties capable of both developing formulations and providing full-scale manufacturing services, we believe we will be able to shorten development and scale-up times necessary for production. The key advantage to this approach is that the third-party contractor will have the equipment, operational parameters and validated testing procedures already in place for the commercial manufacture of our products.

### ***Migraine Product (FHPC 01)***

We have been developing a proprietary formulation of a product named FHPC 01 for the treatment of migraine headaches, which contains an active ingredient that is currently approved by the FDA for other indications. We entered into a product development agreement and an amended and restated product development agreement with Penwest Pharmaceuticals Co. to develop the product using Penwest's patented TIMERx controlled-release technology. Penwest also granted us the right to reference certain of their FDA filings as necessary for us to submit a new drug application for this product. We developed a once a day formulation for this product and we filed an investigational new drug application for this product on February 17, 2000 which has been accepted by the FDA. We are currently seeking potential development partners to assist us with the development of FHPC 01.

### *Excessive Salivation Product (FHPC 02)*

We are developing a product named FHPC 02 for the treatment of the symptoms associated with the excessive production of saliva primarily in children. This product will be a line extension of our Robinul products. We have entered into an agreement with Mikart to develop a new dosage form and to manufacture the product. On December 29, 2000, we filed an investigational new drug application for this product which has been accepted by the FDA. Excessive salivation, also known as sialorrhea, occurs primarily in patients suffering from cerebral palsy and other neurodevelopmental diseases.

### **Sales and Marketing**

To maximize the effectiveness of our selling efforts, our sales force targets select specialty physicians and high-prescribing primary care physicians. Our sales force seeks to develop close relationships with these physicians and respond to their needs. During the second quarter of 2002, we expanded our sales and marketing force from approximately 130 to approximately 180 professionals nationwide. Also during the second quarter of 2002, we significantly realigned our sales force by forming two specialty groups to optimize productivity. The first specialty group markets Sular, Nitrolingual Pumpspray and our Robinul products to primary care physicians and cardiologists. The second specialty group markets our Prenate GT, Ponstel, Tanafed, and Robinul products to obstetricians and gynecologists, pediatricians and gastroenterologists. In April 2002, we entered into two agreements with PDI to promote certain of our products. Under the first agreement, approximately 50 sales representatives promote and distribute samples of Sular, Nitrolingual Pumpspray and our Robinul products to specified physicians for specified fees. Consistent with the terms of the agreement, we plan to offer employment to these representatives in March 2003. Under the terms of the second agreement, approximately 150 sales representatives promoted and distributed samples of Sular to specified physicians. In December 2002, we cancelled the second agreement entered into in April 2002 and entered into a new co-promotion agreement with PDI, under which PDI agreed to use at least 250 of its sales representatives experienced in marketing cardiovascular products to promote Sular to high prescribing physicians.

We sell our products to pharmaceutical wholesalers (who in turn distribute to pharmacies), chain drug stores, other retail merchandisers and, on a limited basis, directly to pharmacies. For the year ended December 31, 2002, sales to our top three pharmaceutical wholesalers accounted for over 77% of all of our sales. The following wholesalers each accounted for 10% or more of all of our sales: McKesson Corporation (23%), Cardinal Health, Inc. (including the Bindley Western Division) (23%), and AmerisourceBergen (31%).

We have a group of sales professionals that focuses exclusively on building relationships with managed-care organizations that can be leveraged across markets. We continue to strengthen this group to gain access to formularies and develop long-term working relationships with managed care organizations.

For the year ended December 31, 2002 Sular accounted for approximately 26% of our total sales and the Prenate line accounted for approximately 16% of our total sales. For the years ended December 31, 2000, 2001 and 2002, Nitrolingual Pumpspray accounted for approximately 25%, 19% and 13%, respectively, of our total sales. For the years ended 2000, 2001 and 2002, Robinul and Robinul Forte accounted for approximately 20%, 18% and 13%, respectively, of our total sales. In 2000, 2001 and 2002, the Tanafed line accounted for approximately 22%, 29% and 18%, respectively, of our total sales.

Although our business is generally non-seasonal, sales of certain products, such as cough and cold products, increase slightly between October and March due to the cold and flu season. We expect the impact of seasonality to decrease as we acquire or obtain licenses for products that treat chronic conditions. However, we anticipate that the seasonality may continue to affect sales for the foreseeable future.



## **Third-Party Agreements**

### *Sular*

In March 2002, we acquired exclusive U.S. rights to distribute and sell Sular from AstraZeneca and Bayer. The purchase price paid was \$184.3 million in cash, including \$0.6 million in acquisition costs, plus the assumption of liabilities of \$1.9 million related to the return of product shipped prior to the acquisition date. In December 2002, we increased our estimates for assumed liabilities by \$0.7 million. Under the asset purchase agreement, we acquired the regulatory approval to sell Sular in the U.S., current inventory, certain intellectual property (including the trademark Sular), marketing materials for the promotion, advertising and marketing of Sular in the U.S., study materials relating to clinical studies of Sular, and certain of AstraZeneca's contracts relating to the marketing, sale and distribution of Sular. We must pay AstraZeneca up to an additional \$20.0 million upon achievement of certain sales milestones before the third anniversary date of the closing of the transaction.

We entered into a ten-year agreement with Bayer, which appoints us as the exclusive party to sell and distribute Sular in the U.S., provides us with the rights to sell Sular under certain patents and other technical information owned by Bayer, and provides for the manufacture and supply of Sular to us. We pay Bayer for the manufacture and supply of Sular on a unit basis. The unit price to us for Sular may adjust after 2003 based upon changes in the net revenue per unit that we recognize in the sale of Sular. We must also pay Bayer an additional \$10.0 million upon the achievement of a certain sales milestone for Sular if a sales threshold is achieved during the ten year term of the agreement. Under this agreement, we must purchase minimum quantities of Sular from Bayer each year and we must obtain the consent of Bayer prior to selling another product containing the active ingredient in Sular.

Subject to obtaining the consent of Bayer prior to conducting clinical trials for new cardiovascular indications for Sular and in the event that we receive a new drug application approval for these new uses, we may deduct a percentage of the costs incurred to obtain such approval, up to a certain amount, from our payments to Bayer under the agreement for five years following such approval. Bayer will have access to any data that we obtain pursuant to such trials and we will grant Bayer a license to use such data outside of the U. S. at no cost.

In April 2002, we entered into two agreements with PDI to promote Sular. Under the first agreement, approximately 50 sales representatives promote Sular to specified physicians for specified fees. The initial term of this agreement is through April 2003. Under the terms of the agreement, we plan to offer employment to these representatives in March 2003. Under the terms of the second agreement, approximately 150 sales representatives promoted Sular to specified physicians. In December 2002, we cancelled the second agreement and entered into a new agreement with PDI, under which PDI agreed to use at least 250 of its sales representatives who are experienced in marketing cardiovascular products to promote Sular. PDI has agreed to have its sales representatives target certain high-prescribing physicians in exchange for specified fees and certain success fees. This agreement expires on December 31, 2003 but is cancelable commencing in April 2003.

### *Nitrolingual Pumpspray*

In July 1999, we acquired exclusive U.S. rights to distribute, market and sell Nitrolingual Pumpspray from Pohl-Boskamp beginning on February 1, 2000 for five years plus an additional five-year renewal period subject to establishing mutually acceptable minimum sales requirements. Under the agreement, Pohl-Boskamp supplies us Nitrolingual Pumpspray at prices that decrease as volume purchased in each year increases. We must purchase designated minimum quantities in each year of the agreement or pay a fee to keep the agreement in effect. We must also pay a royalty on net sales of the product. Also, Pohl-Boskamp can terminate our distribution agreement for Nitrolingual Pumpspray if we do not sell specified minimum quantities of the product each year, if a company with a product competitive with Nitrolingual Pumpspray acquires direct or indirect influence or control over us, or if a significant change in

our stockholders occurs so that Kapoor-Pharma Investments and our employees, management, directors, and any of their respective affiliates, do not in the aggregate directly or indirectly beneficially own at least 20% of our shares. Our agreement with Pohl-Boskamp prohibits us from selling other products which are indicated for the relief of angina pectoris.

In April 2002, we entered into an agreement with PDI, under which it agreed to use approximately 50 sales representatives to promote Nitrolingual Pumpspray to specified physicians for specified fees. The initial term of this agreement is through April 2003. Under the terms of the agreement, we plan to offer employment to these representatives in March 2003. In September 2001, we entered into a co-promotion agreement with Otsuka to co-promote Nitrolingual Pumpspray. In January 2003, we and Otsuka mutually decided to terminate this agreement as of January 31, 2003.

#### *Prenate Advance and Prenate GT*

In August 2001, we purchased the Prenate line of prescription prenatal vitamins from Sanofi-Synthelabo. We acquired all of Sanofi-Synthelabo's intellectual property, regulatory permits and licenses and contract rights related to Prenate. The purchase price for the acquired assets was \$52.5 million in cash plus the assumption of certain liabilities and payment for product inventory, subject to post-closing adjustments.

We also assumed Sanofi-Synthelabo's Prenate-related contracts, including a contract with Patheon, Inc., to manufacture Prenate Advance tablets and the core tablets for Prenate GT, and a contract with Banner Pharmacaps to manufacture Prenate GT using its patented manufacturing process to create gelatin-enrobed tablets. Banner Pharmacaps has agreed not to use this manufacturing process to make any other prenatal vitamins. The agreement with Patheon is for a term of five years, beginning October 1, 1999. The agreement with Banner Pharmacaps is for a term of five years, beginning May 3, 2001. Under the terms of the supply agreement with Banner Pharmacaps, the Company will pay Banner Pharmacaps a royalty on net sales above a certain amount of net sales.

In September 2001, we entered into a co-promotion agreement with PDI under which it promotes and distributes samples of Prenate GT to specified physicians for specified fees. The initial term of this agreement was through October 2002 and was renewed through April 2003.

#### *Ponstel*

In April 2000, we acquired exclusive rights to market, distribute and sell Ponstel in the U. S. from Pfizer. The total purchase price was \$13.0 million. In April 2000, we also entered into a supply agreement with Pfizer under which Pfizer was to supply us with designated quantities of Ponstel. This agreement expired on March 31, 2001. Pfizer has continued to supply Ponstel to us under the same terms. We believe that Pfizer will fulfill its remaining supply obligations under this supply agreement and will cease supplying Ponstel to us at or about the end of the first quarter of 2003. We pay Pfizer an agreed upon price for the supply of Ponstel.

In December 2000, we signed an agreement with West-ward Pharmaceuticals to manufacture Ponstel after West-ward obtains FDA approval to manufacture the product. We have filed the site transfer application with the FDA and we believe that West-ward will begin supplying the product to us by the third quarter of 2003. This agreement expires in April 2005. We must purchase all of our requirements for Ponstel from West-ward and are subject to minimum purchase requirements. We must pay West-ward a price for Ponstel based on a multiple of West-ward's direct cost of goods sold in the manufacture and supply of the product. In addition, we must pay West-ward milestone payments, as long as no generics have been introduced, upon certain anniversary dates of FDA approval of the manufacture of Ponstel by West-ward.

### *Tanafed DP and Tanafed DMX*

Prior to the fourth quarter of 2002, we had marketed Tanafed Suspension, a liquid cold and allergy product, to pediatricians. In January 2002, we launched Tanafed DM, a line extension to Tanafed Suspension, that contains a cough suppressant. During the second quarter of 2002, we experienced significant erosion of sales of Tanafed Suspension and Tanafed DM due to increased substitution of knock-off products by pharmacies. In response, we launched Tanafed DP and Tanafed DMX, two line extensions to Tanafed Suspension and Tanafed DM, and we ceased selling Tanafed Suspension and Tanafed DM in the fourth quarter of 2002.

In June 2002, we entered into an exclusive distribution agreement with Unisource granting us exclusive rights to sell Tanafed DP and Tanafed DMX in North America and for Unisource to supply Tanafed DP and Tanafed DMX to us through June 2007, subject to an automatic three year renewal. The agreement requires us to purchase all of our Tanafed DP and Tanafed DMX requirements from Unisource and subjects us to minimum purchase requirements. We must pay Unisource for the manufacture and supply of Tanafed DP and Tanafed DMX based upon fixed unit costs.

In June 2002, we entered into an agreement with Jame Fine Chemicals, Inc. for a ten year exclusive license to make, have made, use, distribute, market, promote, advertise and sell pharmaceutical formulations containing the ingredients dextromethorphan tannate and dexchlorpheniramine tannate. Tanafed DP and Tanafed DMX products contain dexchlorpheniramine tannate and Tanafed DMX contains dextromethorphan tannate. The agreement became effective upon the first sale of product containing the ingredients, which occurred in August 2002. We paid a license fee of \$0.5 million in cash in connection with the first sale. We have also committed to fund a maximum royalty of \$2.5 million in installments through March 2005. This royalty is refundable under certain circumstances. A nonrefundable royalty will commence in January 2005.

### *Robinul and Robinul Forte*

In January 1999, we acquired exclusive rights in the U.S. to Robinul and Robinul Forte tablets from Wyeth. We must pay royalties on net sales under our license agreement with Wyeth. We entered into agreements with Mikart, dated April 23, 1999 and January 21, 2001, for Mikart to become qualified under applicable regulations to manufacture and supply our requirements for Robinul. Mikart became qualified by the FDA to manufacture Robinul on December 3, 2001 and began supplying the Robinul products to us in December 2001. Under these agreements, Mikart will manufacture the products for five years from the time Mikart became a qualified manufacturer plus renewal terms of one year until either party elects not to renew. The agreement with Mikart requires that we purchase certain designated minimum quantities.

In January 2002, we entered into a license agreement with Wyeth-Ayerst Canada Inc. and Whitehall-Robins Inc. under which we acquired rights to manufacture, have manufactured for us, market and sell Robinul and Robinul Forte in Canada. When we begin to sell Robinul in Canada, we will pay Wyeth-Ayerst Canada a royalty on net sales of Robinul in Canada. However, we have no intention of selling Robinul and Robinul Forte in Canada at this time.

In April 2002, we entered into an agreement with PDI, under which it agreed to use approximately 50 sales representatives to promote our Robinul products to specified physicians for specified fees. The initial term of this agreement is through April 2003. Under the terms of the agreement, we plan to offer employment to these representatives in March 2003.

### *Other Products*

In June 2000, we acquired world-wide rights to market, distribute and sell Cognex as well as rights to a new unapproved version of Cognex called Cognex CR from Pfizer. We paid \$3.5 million in cash for Cognex. We must pay Pfizer up to \$1.5 million in additional purchase price if we obtain FDA approval to

market Cognex CR in the U. S. At this time, we have no intention of seeking FDA approval to market Cognex CR. In the event that we voluntarily stop selling Cognex for 60 days or more, other than for reasons outside our control, the Federal Trade Commission may order that Cognex revert back to Pfizer and be divested by the FTC to another purchaser.

Under the purchase agreement for the Cognex transaction, we are required to pay royalties upon achieving certain net sales levels of Cognex. We do not expect to pay significant-royalties in the near future.

An affiliate of Pfizer has agreed to manufacture and supply to us either Cognex or the active ingredient in Cognex until June 2003. We pay an agreed upon price for the supply of Cognex and the active ingredient. The supply agreement contains designated quantities of Cognex and its active ingredient that Pfizer's affiliate will supply to us and that we must purchase. We have located a third-party manufacturer to manufacture Cognex for us after it obtains FDA approval to manufacture the product. We have filed the site transfer application with the FDA and we believe that the manufacturer will begin supplying the product to us during the third quarter of 2003.

In December 2001, we acquired the U.S. rights to Furadantin from Elan. The purchase price for the acquired assets was approximately \$15.8 million in cash. Under the agreement, we acquired the assets relating to Furadantin, including the new drug application, trademark and related inventory.

In December 2001, we also entered into a supply agreement with Elan to manufacture and supply Furadantin to us through May 3, 2003. Under the supply agreement, we paid an up-front fee of \$0.2 million. In August 2002, we entered into a manufacturing agreement with another manufacturer for Furadantin, which is currently conducting testing to become qualified to manufacture the product. This agreement expires in August 2007.

Generally, our other products are manufactured under manufacturing and supply agreements which require that we purchase all of our requirements for these products from the manufacturers which are a party to these agreements, including specified minimum purchase quantities of the product for each year. Except for our Defen-LA, Protuss-D and Zoto-HC products, these agreements generally state that the product supplier will provide products only to us.

#### *Migraine Product (FHPC 01)*

In October 1998, we entered into an agreement with Inpharmakon Corporation in which we acquired rights to the proprietary information for the migraine product FHPC 01 for which we completed Phase I clinical studies. The agreement expires on October 31, 2008, but we may renew it indefinitely after expiration. In May 2000, we entered into an amendment to this agreement in which Inpharmakon Corporation released us from all previous claims that Inpharmakon Corporation may have had under the agreement, and deleted the required time within which we must commence clinical trials and file for regulatory approval of the product. Under the amended agreement, we must develop a workable once-a-day formulation for the drug, conduct clinical trials and file for and exert reasonable efforts to obtain regulatory approval for the drug. If we do not obtain regulatory approval of the drug within three years after filing for such approval and thereafter commence and continue to aggressively market and sell the product, Inpharmakon may terminate the agreement. In the event that Inpharmakon terminates the agreement for failure to achieve these milestones, Inpharmakon may purchase rights to develop the drug at our costs to date. In addition to fees that we have previously paid to Inpharmakon under the agreement, we must also pay Inpharmakon up to an aggregate of \$550,000 within thirty days after approval of a new drug application. In the event of commercial sales of the product, we must pay royalties at rates which we believe are within industry customary ranges. If we elect to sell the business opportunity to a third party, we must share the proceeds of the sale with Inpharmakon.

In March 1999, we acquired rights from Penwest Pharmaceuticals Co. to use Penwest's TIMERx controlled-release technology to develop FHPC 01 pursuant to a product development agreement. In

November 2002, we entered into an amended and restated product development agreement with Penwest. Under the Penwest agreements, we have the right to manufacture, use and sell the developed migraine product in North America for a period extending 15 years from the date a new drug application is issued for the product, as well as a license under certain Penwest patents. Under these agreements we are required to pay Penwest up to an aggregate of approximately \$2.6 million of non-refundable fees upon achieving specified development milestones through the first anniversary of the first commercial sale of the product following regulatory approval and royalties upon any sales of the migraine product at rates which we believe are within industry customary ranges. Penwest was able to terminate the product development agreement in the event we failed to timely achieve designated performance milestones within prescribed time periods including the completion of clinical trials by April 2002, applying for FDA approval of the product within six months after completing clinical trials and commercially launching the product within two months after obtaining FDA approval. Penwest was also able to terminate the product development agreement if we failed to either sell specified minimum quantities of the product each year after approval of the product or pay the applicable royalty to Penwest as if we had sold such minimum quantity. We did not complete clinical trials of our migraine product by April 2002, however, in November 2002, we entered into an agreement with Penwest under which Penwest agreed to waive this provision.

#### *Excessive Salivation Product (FHPC 02)*

In January 2001, we entered into a manufacturing and supply agreement with Mikart granting Mikart exclusive rights to manufacture and package our product under development for the treatment of excessive salivation upon approval of the product by the FDA and upon approval by the FDA of the manufacture of the product by Mikart. The term of this agreement expires five years after FDA approval of the new drug application or supplemental new drug application for the product, subject to automatic one-year renewals.

#### **Manufacturers and Single Source Suppliers**

We use third-party manufacturers for the production of our products for development and commercial purposes. Given the general under-utilization of resources, the availability of excess capacity for manufacturing in the marketplace and the lower cost of outsourcing, we intend to continue to outsource our manufacturing for the near term.

Our supply agreement with Pfizer for Ponstel expired March 31, 2001. Pfizer previously has agreed to supply a designated quantity of product for us that we believe will be fulfilled at or about the end of the first quarter of 2003. We have entered into an agreement with a third party to supply us with Ponstel, subject to the manufacturer receiving FDA approval to manufacture Ponstel. We have filed the site transfer application with the FDA and we believe that the manufacturer will begin supplying Ponstel to us by the third quarter of 2003. Our Furosemide supply agreement with Elan expires in May 2003. We have entered into an agreement with a third party to manufacture Furosemide and its active ingredient, which manufacturer is currently conducting stability testing to become qualified to manufacture the product for us. We believe this will be completed during the third quarter of 2003. In approximately 2005, we will need a new source to supply us with the active ingredient in Furosemide. Our Cognex supply agreement expires in June 2003 and our manufacturer has fulfilled its obligation to deliver product to us under the agreement. We have located another manufacturer to supply Cognex to us after it obtains FDA approval to manufacture the product. We have filed the site transfer application with the FDA and we believe that the manufacturer will begin supplying the product to us during the third quarter of 2003.

Under some of our agreements, the manufacturers or other third parties own rights to the products that we have under our marketing licenses. We have not entered into agreements for alternative manufacturing sources for any of our products. Our supplier of Sular has patents on the manufacturing process and composition of its coat core tablet. The suppliers of Nitrolingual Pumpspray and the raw materials for Tanafed DP and Tanafed DMX hold patents relating to their respective products. Banner Pharmacaps holds the patent to the gel-coating technology it uses to manufacture the Prenate GT tablets.

These patents may provide us with a competitive advantage because the patents create a barrier to entry to other companies that might otherwise seek to develop similar products.

### **Trademarks**

Because of the large number of products on the market which compete with our products, we believe that our product brand names are an important factor in establishing product recognition. We applied for a U.S. trademark registration for the mark First Horizon Pharmaceutical. We also have trademark applications pending for the marks ~~Tanafed DM, Tanafed-DP, Tanafed-DMX, Prenate (and-Design), and Prenate-GT~~. Our products are sold under a variety of trademarks registered in the U.S., including Mescolor, Protuss, Zoto-HC (and Design), Defen, Zebutal and Furdantin. We own the U.S. rights to the Cognex trademark and its international counterparts, and the trademarks for Sular (and Design), Tanafed, Prenate Advance, Prenate Ultra, MicroIron, MicroIron II, Prenate 90 and Ponstel. Further, we have been licensed rights to use the trademarks Nitrolingual and Robinul from Pohl-Boskamp and Wyeth, respectively. We have rights to the TIMERx trademark pursuant to our rights to market the product we have under development agreement with Penwest. Our trademark registrations could be challenged by others which could result in the loss of use of one or more of our trademarks. Maintenance of our trademarks requires that we enforce our rights by preventing infringement by third parties, and we may not have the resources to stop others from infringing our trademarks.

### **Patents**

We consider the protection afforded by patents important to our business. We intend to seek patent protection in the U.S. and selected foreign countries where deemed appropriate for products we develop. There can be no assurances that any patents will result from our patent applications, that any patents that may issue will protect our intellectual property or that any issued patents will not be challenged by third parties. In addition, if we do not avoid infringement of the intellectual property rights of others, we may have to seek a license to sell our products, defend an infringement action or challenge the validity of the intellectual property in court, all of which could be expensive and time consuming.

### *Sular*

Pursuant to our distributorship agreement with Bayer, we are afforded patent protection arising from Bayer's patent covering the Sular manufacturing process and Bayer's patent covering the composition of Sular's coat core tablet. These patents expire in 2004 and 2008, respectively. In 2002, we filed two patents relating to Sular's active ingredient and its uses.

### *Nitrolingual Pumpspray*

By virtue of our distribution agreement with Pohl-Boskamp for Nitrolingual Pumpspray, we are afforded patent protection arising from Pohl-Boskamp's 1993 U.S. patent relating to the product. This patent expires in 2010.

### *Tanafed DP and Tanafed DMX*

We entered into an exclusive licensing agreement with the raw material supplier for Tanafed DP and Tanafed DMX in June 2002. This agreement grants us a license to market and distribute Tanafed DP and Tanafed DMX for which the manufacturer has a patent covering the manufacturing process of two of the active ingredients in these products. This patent expires in 2016. In January 2003, we were issued a patent covering compositions for Tanafed DP and Tanafed DMX. This patent expires in 2021. In October 2002, we filed another patent application covering additional compositions for Tanafed DP and Tanafed DMX.

### *Cognex*

We own certain patent rights relating to the use of an active ingredient in Cognex to treat conditions associated with Alzheimer's disease. The U.S. patents expire from 2006 through 2013.

### *Migraine Product (FHPC 01)*

Pursuant to our development agreement with Penwest for a once-a-day migraine product, we are the licensee of certain Penwest patents for the purpose of manufacturing and marketing the product under development. These patents expire from 2008 through 2016.

### *Robinul and Robinul Forte*

In 1999, we filed a U.S. patent application directed to the use of glycopyrrolate for the treatment of certain new indications and abandoned this patent in 2002. Glycopyrrolate is the active ingredient in Robinul and Robinul Forte. In 2002, we filed a patent relating to glycopyrrolate and its uses.

### **Competition**

The market for drugs is highly competitive with many established manufacturers, suppliers and distributors actively engaged in all phases of the business. We believe that competition in the sale of our products is based primarily on brand awareness, price, availability, product efficacy and service. Our brand name pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. Some of our products, including the Prenate line, compete with generic and other competitive products in the marketplace. Some of our products, including Sular, compete with one or more products marketed by very large pharmaceutical companies with much greater financial resources for marketing and selling their products.

Beginning the second quarter of 2002, we experienced significant sales erosion of Prenate GT and our previously marketed Tanafed Suspension and Tanafed DM products due to increased substitution of knock-off products by pharmacies filling prescriptions for Prenate GT, Tanafed Suspension and Tanafed DM. In response to this sales erosion, we launched Tanafed DP and Tanafed DMX, two line extensions to Tanafed Suspension and Tanafed DM, and we ceased selling Tanafed Suspension and Tanafed DM in the fourth quarter of 2002.

We also compete with other pharmaceutical companies for new products and product line acquisitions. These competitors include Forest Laboratories, Inc., Medicis Pharmaceutical Corporation, Watson Pharmaceuticals, Inc., King Pharmaceuticals, Inc., Shire Pharmaceuticals Group plc, Biovail Corporation and other companies that acquire branded product lines from other pharmaceutical companies.

### **Government Regulation**

According to the Federal Food, Drug, and Cosmetic Act ("FDC Act"), all new drugs are subject to premarket approval by the FDA. Applicable FDA law will treat our development of new products and new uses for approved products or the development of any of our line extensions as "new drugs," which requires the submission of a new drug application ("NDA") or a supplemental NDA ("sNDA") (or an abbreviated NDA ("ANDA") if applicable), and approval by the FDA.

The steps required for approval of an NDA or sNDA may include:

- extensive pre-clinical toxicology and pharmacology studies,
- submission to the FDA of an investigational new drug application ("IND"),
- which must become effective before human clinical trials can be commenced,

- a series of preliminary clinical studies to demonstrate safety (Phase I) and optimal dosing and pharmacologic effects (Phase II),
- adequate and well-controlled human clinical trials (Phase III) to establish the safety and effectiveness of the product,
- submission of an NDA or an sNDA to the FDA (typically six to twelve month internal FDA review cycle),
- presentation of NDA data to an FDA Advisory Panel for its recommendation and
- FDA approval of the NDA or sNDA prior to any commercial sale or shipment of the product.

Pre-clinical studies generally include laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological animal studies, to assess quality and safety and provide a basis for design of the human clinical trials. An applicant submits the results of the pre-clinical studies with chemistry, manufacturing and control information and pharmacology and toxicology data in support of the proposed clinical study design to the FDA as a part of an IND and for review by the FDA prior to the commencement of human clinical trials. Unless the FDA says otherwise, the IND will become effective 30 days following its receipt by the FDA; however, the FDA may place an IND on "clinical hold" until the sponsor generates and supplies the FDA with additional data, which prohibits the sponsor of the IND from commencing with clinical studies.

Clinical trials involve the administration of the investigational new drug to humans under the clinical study protocols that had been submitted to the FDA in the IND. The conduct of the clinical trials is subject to extensive regulation including compliance with good clinical practices, obtaining informed patient consent, sponsor monitoring and auditing of the clinical, laboratory and product manufacturing sites and review and approval of each study by an Institutional Review Board. Clinical trials are typically conducted in three sequential Phases, although Phases may overlap. In Phase I, the investigational new drug usually is administered to 20-50 healthy human subjects and is tested for safety. Phase II usually involves studies in a limited patient population (50-200 patients) to:

- determine the initial effectiveness of the investigational new drug for specific indications,
- determine dosage tolerance and optimal dosage and
- identify possible adverse effects and safety risks.

When an investigational new drug is found to be effective to that point and to have an acceptable safety profile in Phase II evaluation, Phase III trials are undertaken to further evaluate clinical effectiveness and to further test for safety within an expanded patient population of usually 200 or more patients. The FDA reviews both the clinical plans and the results of the trials and may require the study to be discontinued at any time if there are significant safety issues or lack of efficacy. In some cases, the FDA can request Phase IV clinical studies to be conducted as a condition of approval of the NDA, to be performed after the NDA approval with a timeframe. These studies can be designed to obtain additional safety and efficacy data, detect new uses for or abuses of a drug, or determine effectiveness for labeled indications under conditions of widespread usage. These studies can involve significant additional expenses, and failure to perform these Phase IV studies within the FDA-stated timeframe can result in the FDA withdrawing the NDA approval.

Once the FDA has approved an NDA, the holder of the NDA may request changes to the product or manufacturing through a supplement to the original NDA, termed an sNDA. The format, content and procedures applicable to NDA supplements are generally the same as those for NDAs. However, the only information required in a supplement is that needed to support the requested change. If the NDA or sNDA is based on new clinical investigations that are essential to the approval of the application, other than bioavailability studies, it may qualify for a three-year period of marketing exclusivity, distinct from



any applicable patent protection that may exist. In such a case, the FDA may accept for filing, but will not approve a generic product for three years from the date of that application's approval. The FDA may also require user fees in excess of \$0.3 million for prescription drug NDAs or sNDAs. Supplements proposing to include a new indication for use in pediatric populations are not subject to user fees unless the supplement contains clinical data.

Another form of an NDA is the so-called "505(b)(2)" NDA, which applicants submit pursuant to Section 505(b)(2) of the FDC Act. This type of NDA permits the cross-referencing of safety and effectiveness studies that the applicant has not conducted, or been granted a right of reference by the sponsor of the animal or human studies, submitted in a prior NDA or in the literature which utilized the same drug. In addition, the FDA recommends a 505(b)(2) NDA for a modification, such as a new dosage form or drug delivery form, of a previously approved drug (but not that held by the 505(b)(2) applicant), which requires more than merely bioequivalence data. This 505(b)(2) NDA is similar to a full NDA, except that, under conditions prescribed by the FDA, it may be supported in whole or in part by one or more animal and human study investigations in the originator NDA or those published in scientific literature in lieu of the applicant's clinical trials. We intend to submit this type of NDA application to market potential product line extensions or new uses of already-approved products. Payment of user fees may also be required by the FDA.

In addition, if we submit a 505(b)(2) NDA or ANDA, the FDA will require us to certify as to any patent which covers the drug for which we seek approval. If there is a patent in existence, a certain type of certification commonly referred to as a "paragraph 4 certification," is made and proper notice to the patent holder of our intent to market the drugs is given, and the patent holder makes an infringement claim within a specified time period, then the FDA will not approve our marketing application for 30 months or until the patent litigation is resolved, whichever occurs sooner. In addition, distinct from patent considerations, approval of a generic type of ANDA could be delayed because of the existence of five or three years of marketing non-patent exclusivity afforded by the FDA for the innovator drug or 180 days of non-patent exclusivity afforded to the first applicant to submit an ANDA with a paragraph 4 certification; however, in certain proscribed cases, this non-patent exclusivity may not prevent the submission and approval of competitor applications. A patent holder can, however, sue for infringement under traditional patent law.

The least burdensome application for new drug approval is the ANDA, which may apply to a new drug that is shown to be bioequivalent to a drug previously approved by the FDA for safety and effectiveness and listed as the drug to which bioequivalence must be shown. An applicant may submit an ANDA for products that are the same as an approved originator drug regarding active ingredient(s), route of administration, dosage form, strength and conditions of use recommended on the labeling. The ANDA requires only bioequivalence data and other technical and manufacturing information, but typically no safety and effectiveness studies.

Even after obtaining regulatory approval, such approval may require post-marketing (Phase IV) testing and surveillance to monitor the safety of the product. In addition, the product approval may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. At present, companies cannot export pharmaceutical products that cannot be lawfully sold in the U. S. unless certain statutorily prescribed conditions are met.

FDA regulations require that we report adverse events suffered by patients, submit new marketing and promotional materials, submit changes we plan to make to the product manufacturing or labeling and comply with recordkeeping requirements and requirements relating to the distribution of drug samples to physicians. In the event that we do not comply with the FDA requirements, the manufacture, sales and distribution of our products may be suspended, and we may be prevented from obtaining FDA approval of new products.

Our third-party manufacturers must adhere to FDA regulations relating to current good manufacturing practice ("cGMP") regulations, which include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned and salvaged products. Ongoing compliance with cGMP procedures, labeling and other regulatory requirements are monitored through periodic inspections and market surveillance by state and federal agencies, including the FDA. It is also our obligation to periodically monitor the FDA compliance of our third-party manufacturers. Failure by our third-party manufacturers to comply with these rules could result in sanctions being imposed, including fines, injunctions, civil penalties, suspension or withdrawal of FDA approvals, seizures or recalls of products, operating restrictions and criminal prosecutions. In addition, we rely upon our third-party manufacturers to provide many of the documents that we use to comply with our FDA reporting requirements for Sular, Ponstel, Robinul, Robinul Forte, Nitrolingual Pumpspray, Cognex and Furadantin.

In addition, we are subject to fees under the Prescription Drug User Fee Act for new drug applications for new drug products and sNDAs for new uses, except that we may qualify for a waiver of the fee for our first new drug application. We will be responsible for paying these fees for NDAs, sNDAs and subsequent submissions, unless we receive approval from the FDA for a waiver, reduction or refund. We are also subject to regulation under other federal and state laws, including the Occupational Safety and Health Act and other environmental laws and regulations, national restrictions on technology transfer and import, export and customs regulations. In addition, some of our products that contain controlled substances, such as Protuss and Protuss-D, are subject to Drug Enforcement Administration requirements relating to storage, distribution, importation and sampling procedures. We have registered with the Drug Enforcement Administration under the Controlled Substances Act which establishes, among other things, registration, security and recordkeeping requirements. We must also comply with federal and state anti-kickback and other healthcare fraud and abuse laws.

In addition, whether or not we obtain FDA approval, we must obtain approval of a pharmaceutical product by comparable governmental regulatory authorities in foreign countries prior to the commencement of clinical trials and subsequent marketing of such product in these countries. The approval procedure varies from country to country, and the time required may be longer or shorter than that required for FDA approval.

### **Orphan Drug Designation**

We may request orphan drug status for some of our products under development. Orphan drug designation may be granted to those products developed to treat diseases or conditions that affect fewer than 200,000 persons in the U.S. or that affect more than 200,000 persons in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug in the U. S. for such disease or condition will be recovered from sales in the U. S. of such drug. Under the law, the developer of an orphan drug may be entitled to seven years of market exclusivity following the approval of the product by the FDA, exemption from user fee payments to the FDA and a tax credit for the amount of money spent on human clinical trials. However, we must be the first to receive FDA marketing approval to receive market exclusivity under the orphan drug statute should there be a competitor with a similar molecular entity pursuing the same intended clinical use. Although we may get market exclusivity under the Orphan Drug Act, the FDA will allow the sale of a molecularly equivalent drug which is clinically superior to or a molecular entity different from another approved orphan drug, although for the same indication, during the seven-year exclusive marketing period. It is also possible that a competitor might try to undermine any exclusivity provided by promoting a product for an off-label use that is the otherwise protected product. We cannot be sure that any of our products under development would ultimately receive orphan drug designation, or that the benefits currently provided by this designation, if we were to receive it, will not

subsequently be amended or eliminated. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

### **Reimbursement**

Our ability to market our products successfully will depend in part on the extent to which reimbursement for the costs of the products will be available from government health administration authorities, private health insurers and managed care organizations in the U.S. and in any foreign markets where we may sell our products. Third-party payors can affect the pricing or relative attractiveness of our products by regulating the reimbursement they provide on our products and competing products. Insurance carriers may not reimburse healthcare providers for use of our products used for new indications. Domestic and foreign government and third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products.

### **Backlog**

As of December 31, 2002, we had no material backlog.

### **Insurance**

We maintain a product liability insurance policy. We do not maintain separate business interruption insurance, however our property and casualty insurance policy provides for payment for lost inventory and lost sales in the event of loss from damage to our property.

### **Employees**

We had 249 full-time employees as of December 31, 2002, including 186 sales and marketing employees in the field and 63 in management, finance and administration. We also maintain active independent contractor relationships with various individuals with whom we have consulting agreements. We believe our employee relations are good. None of our employees is subject to a collective bargaining agreement.

## RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this Annual Report. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial also may become important factors that affect us.*

*If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline.*

### Risks Related to Our Business

**Our operating results are substantially dependent upon the contribution of Sular, which has been below expectations since we acquired the product and which has adversely effected our operating results.**

Sales of Sular, which we acquired in March 2002, accounted for approximately 26% of our total net sales for 2002. We have not realized the sales growth for Sular that we anticipated when we acquired it in March 2002. According to IMS Health's National Prescription Audit Plus™ data, new Sular prescriptions decreased 29.5% and total Sular prescriptions decreased 27.4% for the year ended December 31, 2002 compared to the year ended December 31, 2001. New Sular prescriptions decreased 11.8% and total Sular prescriptions decreased 13.0% for the quarter ended December 31, 2002 compared to the quarter ended December 31, 2001. As a result, our growth has suffered and our net sales and net income for 2002 were lower than we anticipated.

Our sales and marketing program for Sular has been successful in achieving increased numbers of new prescriptions of Sular, but total prescriptions of Sular have not increased commensurate with the increases we have obtained in new prescriptions. For example, new prescriptions increased 4.4% and total prescriptions decreased 0.7% for the month ended January 2003 compared to the month ended December 2002 according to IMS Health's National Prescription Audit Plus™ data. We believe the inability to sustain the increases in new prescriptions through to increases in total prescriptions is due to limitations imposed by the size of our sales force promoting Sular. However, the failure of users of Sular to refill their Sular prescriptions may be due to other causes of which we are not aware which could have an adverse effect on our operating results.

Although we have developed a detailed strategy to market and sell Sular, and we have seen a stemming of the declines in Sular prescriptions and an increase in new prescriptions during the third and fourth quarters of 2002, there is no assurance that we will be able to reverse the Sular prescription declines.

**Unexpected increases in 2002 year-end quantities of Sular on hand with wholesalers may adversely affect sales of Sular during 2003.**

We learned in mid-December 2002 that wholesalers had increased trade levels of Sular significantly in October 2002 and November 2002, presumably in anticipation of future price increases. This unexpected spike in the level of trade inventories and the lower than expected total prescription performance of Sular resulted in a higher level of trade inventories than targeted by us. Although we have developed a plan to manage the trade inventory level of Sular, we expect that the high level of Sular inventory in the trade will adversely affect our operating results in the first quarter of 2003 and possibly in subsequent periods.

**The potential growth rate for Sular may be limited by slower growth for the class of drugs to which Sular belongs.**

The growth rate of calcium channel blocker products such as Sular has slowed recently. This reduced growth rate may be due to the following:

- published studies showing that other classes of drugs treating hypertension have health benefits in addition to controlling blood pressure,

- the introduction of new classes of drugs treating hypertension, and
- a reduction in the number of companies actively promoting calcium channel blockers and therefore informing the market about them.

These industry factors could adversely affect sales of Sular.

**Sales of Prenate GT have been adversely affected by the introduction of competitive products.**

Commencing during the second quarter of 2002, we experienced significant erosion of Prenate GT sales due to increased substitution of knock-off products by pharmacies filling prescriptions for Prenate GT. This substitution caused us to report lower than expected net revenues and net income during the second quarter. We have responded to this sales erosion by implementing a strategic education program to physicians and nurses detailing the advantages of Prenate GT over knock-off products. However, there is no assurance that this program will protect us from sales erosion from knock-off products now or in the future. According to IMS Health's National Prescription Audit Plus™ data, substitution rates as measured by new dispensed prescriptions captured by Prenate GT and knock-off products were 28.2% for the quarter ended June 30, 2002, 31.9% for the quarter ended September 30, 2002 and 35.4% for the quarter ended December 31, 2002. Any further competition from knock-off products could decrease growth of Prenate GT and decrease net revenues and profits.

In addition, the Prenate line of products, which contain folic acid, are sold as a prescription multiple vitamin supplement. These types of prenatal vitamins are typically regulated by the FDA as prescription drugs, but the products are not covered by a new drug application, which would require the submission of safety and efficacy data to the FDA. As a result, competitors may be, and have been, more easily and rapidly able to introduce products competitive with the Prenate line of products.

**The shelf life of Prenate GT increases the likelihood of returns of Prenate GT, thereby reducing net sales.**

Prenate GT has a short shelf life. Because this shelf life is shorter than the shelf life of our other products, it increases the likelihood that our customers will return the product to us as it nears the expiration of its shelf life. This could cause us to record greater allowances for returns, which are recorded as reductions of our net revenues and therefore adversely affect our operating results.

**Sales of our Tanafed products have been adversely affected by the introduction of competitive products.**

Commencing in the second quarter of 2002, we experienced significant erosion of sales of Tanafed Suspension and Tanafed DM due to increased substitution of knock-off products by pharmacies filling prescriptions for Tanafed Suspension and Tanafed DM. This substitution caused us to report lower than expected net revenues and net income during the second quarter. We have responded to this sales erosion by (i) launching Tanafed DP and Tanafed DMX, two line extensions to the Tanafed line, in September 2002 and (ii) receiving a patent covering the compositions of Tanafed DM, Tanafed DP and Tanafed DMX. When we launched Tanafed DP and Tanafed DMX in September 2002, our goal was to capture 50% of the new prescriptions in their respective market niches by year-end. Tanafed DMX and Tanafed DP captured 78.8% and 41.7%, respectively, of the weekly dispensed new prescriptions for products in their respective market niches for the week ending December 27, 2002 according to IMS Health's National Prescription Audit Plus™ data. While we have exceeded our capture rate goals for Tanafed DMX, our capture rates for Tanafed DP have been below expectations. We may not be able to increase prescriptions of Tanafed DP to the levels which we had originally expected, which may adversely affect our growth of revenues and profits.

**The FDA recently issued a notice which may cause us to incur increased expenses and adversely affect our ability to continue to market and sell our Tanafed products.**

In late 2002, the FDA issued a notice about various cough and cold combination products which includes our Tanafed DP and Tanafed DMX products. We are in the process of evaluating the effect of this

notice on us. This notice may require that we obtain FDA approval of our Tanafed products before 2005 in order to be able to thereafter continue to market and sell these products as prescription products as we do currently. We may potentially be required to conduct clinical studies on our Tanafed products or reformulate the Tanafed products in order to obtain FDA approval to continue to market and sell these products after 2004 as prescription drugs. This may cause us to incur significant development expenses. If we have not obtained FDA approval for these products prior to 2005, we may be required to cease selling these products or sell these products over-the-counter. Selling these products over-the-counter will cause us to lose third party reimbursement for these products and encounter increased competition in the marketing and sale of these products.

**Periodic emphasis of our sales force on one or more of our products and other factors from time-to-time adversely affect sales of other of our products.**

From time-to-time as we introduce or launch new products, we may focus our sales force on the sale of these new products. An unintended consequence of focusing our sales force on new products may be reduced focus on the selling of other products which from time-to-time has resulted in reduced sales of these other products. Other factors may from time-to-time adversely affect the performance of our sales force such as distractions of our sales force caused by the realignment of our sales force. Any failure by us to effectively manage our sales force may adversely affect sales of our products.

**We may not be able to increase our sales to compensate for the decrease in sales of our non-promoted products.**

According to IMS Health's National Prescription Audit Plus™ data, total prescriptions of our non-promoted products decreased 32% for the year ended December 31, 2002 as compared to the year ended December 31, 2001. In addition, we experienced greater rates of returns for some non-promoted products in the quarter ended December 31, 2002 which significantly reduced fourth quarter 2002 net sales of these products. We plan to compensate for this decline in revenues by acquiring new products and increasing sales of our existing actively promoted products. In addition, our recent loss of two former executives who formerly were a significant component of our acquisition team may adversely affect our ability to complete acquisitions until we locate a replacement for these individuals. However, there is no assurance that we will be able to locate attractive acquisition candidates, successfully complete an acquisition or increase sales of actively promoted products.

**Introductions by us of line extensions of our existing products may require that we make unexpected changes in our estimates for future product returns and reserves for obsolete inventory which would adversely affect our operating results.**

Part of our business strategy includes the introduction of line extensions of our existing products to create marketing advantages and extend the life cycles of our products. From time-to-time we may seek to introduce line extensions on an unexpected and expedited basis before we are able to reduce the levels of inventories of product which may be rendered obsolete or otherwise adversely affected by the line extension. This may require us to increase our estimate for returns of product on hand at wholesalers which is recorded as a reduction of our net revenues and increase our reserve for inventory in our warehouse which is recorded as a cost of revenues. Accordingly, the introduction of line extensions may adversely affect our operating results.

**There is a risk that we may incur charges for intangible asset impairment.**

When we acquire the rights to manufacture and sell a product, we record the aggregate purchase price, along with the value of the product related liabilities we assume, as intangible assets. We use the assistance of valuation experts to help us allocate the purchase price to the fair value of the various intangible assets we have acquired. Then, we must estimate the economic useful life of each of these intangible assets in order to amortize their cost as an expense in our statement-of operations over the

estimated economic useful life of the related asset. The factors that drive the actual economic useful life of a pharmaceutical product are inherently uncertain, and include patent protection, physician loyalty and prescribing patterns, competition by products prescribed for similar indications, future introductions of competing products not yet FDA approved, the impact of promotional efforts and many other issues. We use all of these factors in initially estimating the economic useful lives of our products, and we also continuously monitor these factors for indications of appropriate revisions.

In assessing the recoverability of our intangible assets, we must make assumptions regarding estimated undiscounted future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than its carrying value, an impairment loss will be recognized in an amount equal to the difference. If these estimates or their related assumptions change in the future, we may be required to record impairment changes for these assets. We review intangible assets for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If we determine that an intangible asset is impaired, a non-cash impairment charge would be recognized.

As circumstances after an acquisition can change, the value of intangible assets may not be realized by us. If we determine that an impairment has occurred, we would be required to write-off the impaired portion of the unamortized intangible assets, which could have a material adverse effect on our results of operations in the period in which the write-off occurs. In addition, in the event of a sale of any of our assets, we cannot be certain that our recorded value of such intangible assets would be recovered.

**Our launch of a smaller size of Nitrolingual Pumpspray may not be successful.**

We plan to launch a 60-dose bottle of Nitrolingual Pumpspray during the second quarter of 2003. We believe that the smaller size bottle will offer the advantages of the currently marketed 200-dose bottle and that it will offer the convenience of a smaller bottle and provide additional advantages to patients with mild stable angina. We believe that these benefits will provide an excellent companion product to the 200-dose bottle. There is no assurance that we will be able to launch the 60-dose bottle of Nitrolingual Pumpspray in the second quarter of 2003 or that the launch will be successful.

**Our growth will suffer if we do not acquire rights to new products and integrate them successfully.**

We depend on acquisitions of rights to products from others as our primary source for new products. Risks in acquiring new products include the following:

- we may not be able to locate new products that we find attractive and complementary to our business and
- the price to acquire or obtain a license for these products may be too costly to justify the acquisition.

We often face significant competition from other pharmaceutical companies in acquiring rights to products, which makes it more difficult to find attractive products on acceptable terms.

**There is uncertainty regarding a potential reorganization plan.**

Our short and medium-term success depends on the execution of our sales and marketing strategy and to achieve this, we intend to implement a reorganization plan that streamlines our business and invests in sales growth while managing our operating expenses. We have not yet finalized this plan and if we do not develop a successful reorganization plan, our financial results could continue to be below expectations. Components of our reorganization plan could include restructuring expenses that would reduce our earnings for the period in which such expenses are incurred.

**We may encounter problems in the manufacture of our products that could limit our ability to sell our products.**

*We depend entirely on third parties to manufacture our products.*

Third parties manufacture all of our products, and we do not currently have manufacturing facilities, personnel or access to raw materials to independently manufacture our products. Except for any contractual rights and remedies which we may have with our manufacturers, we have no control over the availability of our products or their quality or cost to us. We do not maintain alternative manufacturing sources for any of our products, and we may not be able to locate alternative manufacturers on commercially acceptable terms in the event of a manufacturing interruption or termination of an existing manufacturing agreement. We do not currently have business interruption insurance with respect to adverse events that could occur at third-party manufacturers' facilities. Furthermore, due to the patent held on Nitrolingual Pumpspray by our supplier, Pohl-Boskamp, no alternative source for Nitrolingual Pumpspray exists. A third party holds the patents for the manufacturing process for raw materials in Tanafed DP and Tanafed DMX; Banner Pharmacaps, Inc. holds the patent for the gel-coating process used in manufacturing Prenate GT. Bayer holds the patents for the manufacturing process and composition of the coat core tablet for Sular. In the event that these suppliers of Nitrolingual Pumpspray, Tanafed DP and Tanafed DMX, Prenate GT or Sular ceased to supply product to us, there is no assurance that we would be able to locate another manufacturer who would be able to manufacture the products without violating such patents or who could manufacture the products on commercially reasonable terms.

*We may encounter interruptions in our supply of Ponstel.*

Our Ponstel supply agreement with Pfizer expired on March 31, 2001. Although Pfizer has continued to supply Ponstel and its raw material to us under the same terms, we believe that Pfizer will fulfill its obligations under the agreement to supply designated quantities of Ponstel at or about the end of the first quarter of 2003.

In December 2000, we signed an agreement with a third-party to manufacture and supply us with Ponstel upon receiving FDA approval. We have filed the transfer site application with the FDA and we anticipate that the manufacturer will begin supplying Ponstel to us by the third quarter of 2003. There is no assurance that the manufacturer will not experience delays in receiving FDA approval, that it will ultimately receive FDA approval or be able to supply us with Ponstel by the third quarter of 2003. We believe that we will have enough inventory of Ponstel to continue selling Ponstel through the third quarter of 2003. However, if demand increases or if our replacement manufacturer is delayed in supplying us with product, we may experience interruptions in the supply of inventory requiring us to at least temporarily cease selling the product. In addition, the new manufacturer has located a third-party to manufacture the raw material for Ponstel before we exhaust the raw material that Pfizer is expected to supply to us. Although, we believe that we have enough of the raw material for Ponstel to satisfy our expected requirements for two years, there is no assurance that the alternative raw material manufacturer will receive FDA approval or be able to manufacture and supply the raw material in Ponstel before we exhaust our supply of the raw material. Pfizer previously encountered difficulties in manufacturing the raw material for Ponstel that caused delays in supplying us with the product. Any delay in implementing this replacement manufacturing for Ponstel or its raw material would limit our ability to sell it, which could reduce our profitability.

*We may encounter interruptions in our supply of Furadantin.*

Our Furadantin supply agreement expires in May 2003. We are not sure that we will have enough inventory of Furadantin to continue selling Furadantin after this agreement expires because Elan has experienced manufacturing delays that have not been resolved. This could cause us to cease selling the product or limit our ability to sell it. In August 2002, we entered into an agreement for the manufacture of



Furadantin by a third-party manufacturer that is conducting stability testing to become qualified to manufacture the product. There is no assurance that the third-party manufacturer will receive FDA approval or be able to manufacture and supply us with Furadantin by May 2003. If demand increases or our replacement manufacturer is delayed in supplying us with product, we may experience interruptions in the supply of inventory requiring us to at least temporarily cease selling the product. In addition, in approximately 2005, we will need a new source to supply us with the active ingredient in Furadantin. Any delay in implementing this replacement manufacturing for Furadantin or locating a new source for its active ingredient or qualifying the new manufacturer to use the active ingredient from the new source would limit our ability to sell it, which could reduce our profitability.

*We may encounter interruptions in our supply of Cognex.*

Our Cognex supply agreement expires in June 2003 and our manufacturer has fulfilled its obligation to deliver product to us under the agreement. We are not sure that we will be able to continue selling Cognex because we are out of inventory for one strength of the product and the remaining shelf life on the other strengths is less than our customers typically require. This could cause us to cease selling the product or limit our ability to sell it, which could reduce our profitability. The short shelf life also increases the likelihood that our customers will return the product to us. This could cause us to record greater allowances for returns, which are recorded as reductions of our net revenues and therefore adversely affect our operating results.

We have located a third-party manufacturer to manufacture and supply us with Cognex upon receiving FDA approval. We filed a site transfer application with the FDA and we believe that the manufacturer will begin supplying Cognex to us during the third quarter of 2003. If our replacement manufacturer is delayed in supplying us with product, we may experience additional interruptions in the supply of inventory requiring us to at least temporarily cease selling the product. There is no assurance that the third-party manufacturer will receive FDA approval or be able to manufacture and supply us with Cognex during the third quarter of 2003. Any delay in implementing replacement manufacturing for Cognex would significantly limit our ability to sell it, which could reduce our profitability.

*Our existing supply agreements may prohibit us from entering into potentially more favorable supply relationships with others.*

Our third-party manufacturing agreements for our Sular, Nitrolingual Pumpspray, Robinul, Robinul Forte, Tanafed DP, Tanafed DMX, Zebutal, Protuss, Ponstel and Prenate products require that we purchase all of our product requirements from the manufacturers that are a party to those agreements. This prevents our entering into more advantageous manufacturing agreements with other manufacturers for these products.

**Part of our growth strategy is to acquire businesses, which subjects us to additional risks.**

An element of our growth strategy is to acquire businesses with products that complement our current products, and we have evaluated and discussed such opportunities with interested parties in the past. In addition to the risks that we face in locating and integrating new product acquisitions, we may face the following risks:

- we may realize substantial acquisition-related expenses, including the amortization of long-lived assets, which would reduce our net income in future years,
- we may lose key employees and customers as a result of changes in management and
- our investigation of potential acquisition candidates may not reveal problems and liabilities associated with the businesses, technologies or products that we acquire.

In addition, if we conduct acquisitions using convertible debt or equity securities, the increased number of shares could result in lower earnings per share.

**We face generic and other competition that could lower prices and unit sales.**

Sular competes with products that are generic to other calcium channel blockers. Nitrolingual Pumpspray competes with a generic tablet product. Companies introduced knock-off products to our Prenate GT product which has caused a significant sales erosion particularly in the second quarter of 2002, and in 2002, two companies introduced products that compete with Tanafed Suspension and Tanafed DM which caused significant sales erosion primarily in the second quarter of 2002. Our Zebutal capsules, Protuss liquid, Protuss-DM tablets, Protuss-D liquid, Zoto-HC ear drops and Mescolor tablets are not protected by patents and face competition from less expensive products. In addition, competitors could develop generic or other products to compete with our Furadantin, Robinul, Robinul Forte and Ponstel products, which are not protected by patents. Third-party payors can require substitution and pharmacists can substitute generic or other competitive products for our products even if physicians prescribe them. Government agencies, third-party payors and pharmacies often put pressure on patients to purchase generic or other products instead of brand-name products as a way to reduce healthcare costs. Any further increase in the amount of generic and other competition against any one or more of our products could further lower prices and unit sales.

**Strong competition exists for our products, and competitors have recently introduced new products and therapies that could make some of our products obsolete.**

Our Protuss and Tanafed lines, Zebutal, Defen-LA, Ponstel, Prenate, Sular and Furadantin products compete against products sold over-the-counter or by prescription that in some cases are marketed by much larger pharmaceutical companies with greater financial resources for marketing and manufacturing. For example, Pfizer sells a hypertension product called Norvasc which in 2002 had a 39.2% share of the calcium channel blocker market based on prescriptions according to IMS Health's National Prescription Audit Plus™ data. Also, based on the regulatory status of our Prenate products, Protuss, Tanafed, Zebutal, Defen-LA, Zoto-HC and Mescolor products, barriers to entry for competing products are low, which makes it easier for companies to enter the market. Competitors are developing new products and have developed new surgical procedures to treat angina. Competitors are also developing new products to treat short term pain and have recently developed new pain therapies. These new products and procedures may reduce demand for our products. The high level of competition in our industry could force us to reduce the price at which we sell our products or require us to spend more to market our products.

**A small number of customers account for a large portion of our sales and the loss of one of them, or changes in their purchasing patterns, could result in reduced sales.**

We sell most of our products to a small number of wholesale drug distributors. For the year ended December 31, 2002, sales to McKesson Corporation, Cardinal Health Inc., (including the Bindley Western Division) and AmerisourceBergen Corporation represented 23%, 23%, and 31%, respectively, of our total sales. The small number of wholesale drug distributors, consolidation in this industry or financial difficulties of these distributors could result in the combination or elimination of warehouses, which could temporarily increase returns of our products or, as a result of distributors reducing inventory levels, delay the purchase of our products.

**If our products under development fail in clinical studies, if we fail or encounter difficulties in obtaining regulatory approval for new products or new uses of existing products, or if our development agreements are terminated, we will have expended significant resources for no return.**

We have completed Phase I clinical trials of our migraine headache and excessive salivation products under development and filed INDs with the FDA. If we cannot obtain FDA approval for these or other products which we may seek to develop in the future, our rate of sales growth may suffer. We do not have

the experience or the capability to undertake clinical and other studies to obtain FDA approval for new products or new uses of already-approved products. As a result, we rely on third parties to formulate, develop and manufacture the materials needed for clinical trials for our products under development to treat migraine headache and excessive salivation. We also rely on third parties to conduct clinical trials for us. If our products are not successful in clinical trials or we do not obtain FDA marketing approval, we will have expended significant resources with no return. Our ongoing clinical studies might be delayed or halted for various reasons, including:

- these products are not shown to be effective,
- we do not comply with requirements concerning the investigational new drug application requirements or protection of the rights and welfare of human subjects,
- patients experience unacceptable side effects or die during clinical trials,
- patients do not enroll in the studies at the rate we expect and
- product supplies are delayed or are not sufficient to treat the patients in the studies.

**We or third parties may violate government regulations.**

Many government agencies regulate our business, including the following:

- the FDA,
- foreign regulatory authorities,
- the Drug Enforcement Administration,
- the Consumer Product Safety Commission,
- the Occupational Safety and Health Administration,
- the Centers for Medicare and Medicaid Services,
- the Environmental Protection Agency and
- state, local and foreign governments.

We may incur significant expenses to comply with regulations imposed by these agencies. In addition, all of our third-party manufacturers and product packaging companies are subject to inspection by the FDA and, in appropriate cases, the Drug Enforcement Administration and foreign regulators. From time to time, some of our third-party manufacturers have received warning letters from the FDA concerning noncompliance with manufacturing requirements. If our third-party manufacturers do not comply with FDA regulations in the future, they may not deliver products to us or we may have to recall products. Even if manufacturing deficiencies observed by the FDA do not relate to our products, our third-party manufacturers may be delayed in manufacturing and supplying our products to us in a timely manner until they address their compliance issues with the FDA.

**If third-party payors do not adequately reimburse patients for our products, doctors may not prescribe them.**

Because our products are sold by prescription, we depend on third-party payors, such as the government, private healthcare insurers and managed care organizations, to include these products on their lists of products for which third-party payors will reimburse patients. Third-party payors regularly challenge the pricing of medical products and services by substituting cheaper products on their approved lists. Because our Zebutal, Protuss, Zoto, Mescolor, Robinul, Ponstel and Furadantin products are susceptible to generic competition and because of products that compete with Sular, Prenate, Nitrolingual Pumpspray, Tanafed DP and Tanafed DMX and Ponstel, we face an increased risk of third-party payors

substituting these products. If third-party payors remove any of these products from their lists or choose not to pay for our product prescriptions, patients and pharmacies may not continue to choose our products.

**We depend on highly trained management, and we may not be able to keep current management or hire qualified management personnel in the future.**

We currently have a limited number of key regulatory, technical and management personnel. Our reliance on a limited number of key personnel has increased due to our recent loss of the services of two former key executives. Additional losses of any of our existing personnel and the failure to identify and hire a suitable replacement for these two executive positions which are currently open within our Company could hurt our ability to develop and market products and acquire new products. If we are able to sustain our rate of growth, we may need to attract new operational and marketing personnel, and we may have difficulty hiring personnel at an acceptable cost. We believe that the managerial activities required for product acquisitions and introductions, together with other duties, may cause management to have insufficient time to integrate new products while simultaneously continuing to effectively market existing products. Failure to do this successfully could limit our ability to sell existing and new products.

**Product liability claims and product recalls could limit sales and increase costs.**

Side effects could occur from the use of our products. Side effects or marketing or manufacturing problems pertaining to any of our products could result in product liability claims or adverse publicity. The defense of these claims would be expensive, and could result in withdrawal of approval to market the product or recall of the product. These problems often occur with little or no notice in connection with the sale of pharmaceutical products.

**An adverse judgment in the securities class action litigation in which we and certain directors and executive officers are defendants could have a material adverse effect on our results of operations and liquidity.**

Our Company and Mahendra G. Shah, Ph.D., our Chief Executive Officer, a former officer and all but one of our directors are defendants in a putative class action lawsuit initiated on August 22, 2002 in the United States District Court for the Northern District of Georgia and in two subsequently filed lawsuits based upon substantially the same claims. Plaintiffs in the securities class action litigation have alleged in general terms that we violated Sections 11 and 12(a)(2) of the Securities Act of 1933 and that we violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by allegedly issuing a series of materially false and misleading statements to the market in connection with our public offering on April 24, 2002 and thereafter, relating to the sales of two of our products, Tanafed Suspension and Prenate GT. The complaints also allege controlling person liability on behalf of certain of our officers under Section 15 of the Securities Act of 1933 and Section 20 of the Securities Exchange Act of 1934. The plaintiffs in these lawsuits seek an unspecified amount of compensatory damages, in an amount to be proven at trial. Due to the inherent uncertainties involved in litigation, we are unable to predict the outcome of this litigation and an adverse result could have a material adverse effect on our financial position and results of operations.

**The incurrence of debt could reduce our growth and profitability.**

In February 2003, we entered into a credit facility for a \$20.0 million revolving loan. We expect that we may borrow under this revolving loan and other debt we may incur in the future to finance acquisitions to implement our growth strategy and/or for general corporate purposes. Significant debt could:

- limit our operating flexibility as a result of requirements by lenders,
- require us to use a large portion of our cash flow from operations for debt service payments that could reduce profits and would reduce the availability of our cash flow to fund operations, product

acquisitions, the expansion of our sales force and facilities and research and development efforts, and

- limit acquisitions of products or companies due to restrictive covenants under our senior secured credit facility with which we must comply as long as it is in effect.

**We expect to require additional funding, and if we cannot obtain it, our sales, profits, acquisitions and development projects could suffer.**

We expect to need additional funds to acquire or obtain licenses for new products, develop and test new products and potentially to acquire other businesses. We may seek funding through public and private financing and may seek to incur debt or to issue shares of our stock either to finance the transaction or as consideration for a transaction. Adequate funds for these purposes, whether through the financial markets or from other sources, may not be available when we need them or on terms acceptable to us. Insufficient funds could cause us to delay, scale back or abandon some or all of our product acquisitions, licensing opportunities, marketing programs, product development programs, potential business acquisitions and manufacturing opportunities.

**Competitors could offer a product competitive with Sular.**

A patent addressing the composition of the active ingredient in Sular expired in 1998. Therefore, a competitor could introduce a product competitive with Sular containing its same active ingredient, although Sular remains protected under patents addressing the manufacturing process and composition of its coat core tablet.

**If we do not secure or enforce patents and other intellectual property rights, we could encounter increased competition that would adversely affect our operating results.**

We do not hold patent rights covering all of the products we are distributing and do not in some cases have the right to enforce patents our licensors hold. Patent rights do not protect our Robinul, Ponstel and Furadantin products from competition. We obtained exclusive distribution rights in the U.S. to distribute our Nitrolingual Pumpspray, Tanafed DP and Tanafed DMX products but have no or only limited rights to enforce the patents relating to Nitrolingual Pumpspray. We have a license from Penwest Pharmaceuticals Co. to use the patented TIMERx technology in our migraine product under development. Subject to the satisfaction of certain conditions, we obtained exclusive supply rights from the manufacturer holding a manufacturing process patent used for the gel-coating on Prenate GT. We obtained exclusive U.S. distribution rights to Sular from Bayer. Bayer holds the patents for the manufacturing process and composition of the coat core tablet for Sular. Any exclusivity afforded by any of these patents or rights could cease because we have no rights or only limited rights to enforce patents or to require enforcement actions by the owners of the patents. Proceedings involving our rights in patents or patent applications could result in adverse decisions. In addition, the confidentiality agreements required of our employees and third parties may not provide adequate protection for our trade secrets, know-how and other proprietary information which we rely on to develop and sell our products. If any of our employees or third parties disclose any of our trade secrets or know-how, we could encounter increased competition.

**Our products could infringe the intellectual property rights of third parties, which could require us to pay license fees or defend litigation that would be expensive or prevent us from selling products.**

The manufacture, use or sale of our products may infringe on the patent, trademark and other intellectual property rights of others. Patent and trademark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we do not avoid alleged infringement of the intellectual property rights of others, we may need to seek a license to sell our products, defend an infringement action or challenge the validity of the intellectual property in court, all of which could be expensive and time consuming. In addition, if we are found liable for infringing a patent, we may have to stop selling one or more of our products and pay damages.

Even though most of our product agreements under which we license intellectual property rights from others contain provisions that allow us to recover costs and damages if we have to defend or are found liable for infringing a patent of a third party, the agreement under which we obtained rights to Nitrolingual Pumpspray does not contain these indemnification provisions. It could be very costly if we have to defend the patents or trademarks covering our products, including Nitrolingual Pumpspray, or if we were found liable for infringement.

**The regulatory status of some of our products makes these products subject to increased competition and other risks.**

The regulatory status of our Protuss, Protuss-D, Protuss-DM, Zoto-HC, Tanafed DP, Tanafed DMX, Mescolor and Defen-LA products allows third parties to more easily introduce competitive products, and may make it more difficult for us to sell these products in the future. Currently, an FDA program allows us, in our opinion, to manufacture and market these products and permits others to manufacture and market the same and similar products without submitting safety or efficacy data. These markets are already highly competitive and, except for a license to certain of the raw materials in Tanafed DP and Tanafed DMX and for a patent covering compositions in Tanafed DP and Tanafed DMX, we do not hold rights in patents protecting us against such competitive pressures. This results in increased competition because other companies can enter the market without having to submit safety and efficacy data to sell competing products. On several occasions, the FDA has considered changing the classification of these types of drugs from prescription to over-the-counter use, and a new rule permits sponsors to utilize foreign over-the-counter experience data to establish a product as safe and effective for over-the-counter use in the U.S. If the FDA does change the classification, we might have to reformulate these products, submit safety and efficacy data on our products which could be costly, or we might have to discontinue selling these products if the FDA does not approve our marketing application. We could lose third-party reimbursement for these products and face increased competition. The FDA recently issued a notice that may require us to obtain FDA approval to continue to sell our cough and cold products by prescription after 2004.

In addition, the FDA considers these products and our Prenate line of products to be new drugs, but has indicated its intent to exercise enforcement discretion and not pursue regulatory action unless certain conditions occur. If these conditions were to materialize, or the FDA disagreed with our conclusions about the regulatory status of these products, we might be required to submit a new drug application and/or cease marketing until the FDA grants approval to do so. The FDA could also, at any time, promulgate new regulations or policies to require the submission of a new drug application for each of these products.

**We face risks under one of our development agreements because the other party to the agreement is a related party.**

John N. Kapoor, Ph.D., who is one of our directors and who is affiliated with our largest stockholder, is trustee of a trust which beneficially owns 50% of the common stock of Inpharmakon Corporation, a party to one of our product development agreements. Mahendra G. Shah, Ph.D., our Chairman and Chief Executive Officer, was a director and Chairman of Inpharmakon through the end of 2000. Thus, our development agreement with Inpharmakon was not the result of arm's length negotiations. Generally, directors and officers have a fiduciary duty to manage their company in a manner beneficial to the company and its stockholders. An action based on the corporate opportunities of Inpharmakon may be detrimental to our interests, which may create real or apparent conflicts of interest.

In the past, the other owner of Inpharmakon has required us to renegotiate some of the terms of our development agreement by seeking to terminate the agreement. We subsequently entered into an amendment to this agreement in which we and Inpharmakon released each other from all previous claims or disputes under the agreement. Conflicts between us and Inpharmakon may develop in the future and may not be resolved in our favor. For example, Inpharmakon has in the past alleged that we have breached our development agreement. In addition, Inpharmakon may have the ability to prevent us from entering into

new arrangements for our migraine product under development. If Inpharmakon sought to prevent such new arrangements, we could lose our rights to the migraine project. Under some circumstances, if Inpharmakon terminates the agreement, it will have rights to develop and market our migraine product under development using the data and information that we have developed and for which we have expended significant resources.

**Pohl-Boskamp can terminate our rights to Nitrolingual Pumpspray.**

Nitrolingual Pumpspray is one of our key products. Pohl-Boskamp can terminate our distribution agreement for Nitrolingual Pumpspray if we do not purchase specified quantities of the product from Pohl-Boskamp each year, if a company with a product competitive with Nitrolingual Pumpspray acquires direct or indirect influence or control over us, or if a significant change in our stockholders occurs so that Kapoor-Pharma Investments and our employees, management and directors, and any of their respective affiliates, do not in the aggregate directly or indirectly beneficially own at least 20.0% of our shares. These provisions could reduce the price some investors might be willing to pay for our shares of common stock, and could delay or prevent a third party from acquiring us.

**We have limited experience selling products in other countries.**

In 2001, we entered into agreements for the distribution of Cognex in certain European countries and rely exclusively on our third-party distributors to comply with foreign regulatory requirements. In addition, we recently acquired rights to market, sell and distribute our Robinul products in Canada, but have not yet entered into any agreements with third-parties to sell Robinul in Canada and do not have government approval to sell Robinul in Canada. We have limited experience selling products outside the U. S., are not familiar with registering or obtaining regulatory approvals outside of the U. S. and have no international marketing presence or sales force. International sales of Cognex pursuant to our distribution agreements and our sales and marketing plans for Robinul in Canada subject us to other inherent risks, including registration requirements and differing regulatory and industry standards, reduced protection for intellectual property rights in some countries, fluctuations in currency exchange rates and import or export licensing requirements.

**Our financial statements as of and for the two years ended December 31, 2001 and 2000 included in this Form 10-K were audited by Arthur Andersen LLP, which has been found guilty of obstruction of justice and may be the subject of additional litigation.**

Arthur Andersen LLP has been found guilty of obstruction of justice with respect to its activities in connection with Enron Corp. and may be the subject of additional litigation. In the event that Arthur Andersen LLP dissolves, liquidates or does not otherwise continue in business, it may have insufficient assets to satisfy any claims that may be made by investors with respect to financial statements which it has audited. In addition, Arthur Andersen LLP has not consented to the inclusion of their report dated February 12, 2002 in this Form 10-K, and as a result, only a copy of such report has been included. Because Arthur Andersen LLP has not consented to the inclusion of their report in this Form 10-K, you may not be able to recover against Arthur Andersen LLP for any information included in financial statements that it has audited.

**Risks Related to our Common Stock**

**Our stock price has declined substantially, has been volatile and could decline further.**

The market price for our securities has declined substantially and has been highly volatile. Various factors, including factors that are not related to our operating performance, may cause significant volume and price fluctuations in the market. The following factors may cause fluctuations in our stock price:

- failure to meet financial estimates or expectations of securities analysts,

- failure to increase Sular prescriptions,
- the introduction of knock-offs to our products,
- fluctuations in operating results,
- rates of product acceptance,
- timing or delay of regulatory approvals, including our line extension of Robinul to treat symptoms associated with excessive salivation,
- our third-party manufacturers experience interruptions in the supply of raw materials or encounter regulatory problems, and
- developments in or disputes regarding patent or other proprietary rights.

**Existing officers, directors and our principal stockholder owns a substantial block of stock that may allow them to elect directors and direct the outcome of matters requiring stockholder approval.**

As of March 15, 2003, our officers, directors and our principal stockholder beneficially owned approximately 30.0% of our outstanding common stock. As of March 15, 2002, Kapoor-Pharma Investments, L.P. owned approximately 26.0% of our outstanding common stock. Accordingly, Kapoor-Pharma Investments holds significant control or influence over our policies and acts. John N. Kapoor, Ph.D., one of our directors, is President and sole stockholder of EJ Financial Enterprises, Inc. EJ Financial Enterprises is the managing general partner of Kapoor-Pharma Investments. In addition, a trust of which Dr. Kapoor is trustee is a partner of Kapoor-Pharma Investments.

**Anti-takeover provisions could discourage a third party from making a takeover offer that could be beneficial to stockholders.**

Some of the provisions in our restated certificate of incorporation and bylaws, our Shareholder Protection Rights Plan, and the anti-takeover provisions under Delaware law could delay or prevent a third party from acquiring us or replacing members of our board of directors, even if the acquisition or the replacements would be beneficial to our stockholders. These provisions could also reduce the price that certain investors might be willing to pay for shares of our common stock and result in the market price being lower than it would be without these provisions. Our charter and other documents contain anti-takeover devices including:

- only one of the three classes of directors is elected each year,
- we have adopted a shareholder rights plan that is designed to protect us from coercive takeover attempts,
- stockholders cannot amend our bylaws unless at least two-thirds of the shares entitled to vote approve the amendment,
- our board of directors can issue shares of preferred stock without stockholder approval under any terms, conditions, rights and preferences that the board determines and
- stockholders must give advance notice to nominate directors or to submit proposals for consideration at stockholder meetings.

## **ITEM 2. PROPERTIES**

On December 31, 2001, we entered into a lease for a 101,120 square foot office and warehouse facility in Alpharetta, Georgia. Our facility includes space for offices and a warehouse. This lease expires on May 31, 2009.



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

On November 7, 2001, Ethex Corporation and Ther-Rx, both Missouri corporations, filed a complaint against us in the Circuit Court of St. Louis County, Missouri. The complaint alleged that we made false and misleading statements about our Prenate products and about Ethex and Ther-Rx's products in the course of our advertising and promotion of the products in violation of the Lanham Act and under Missouri state law. The complaint sought unspecified monetary damages and an injunction against further violations, certain corrective actions and a declaratory judgment. In April 2002, we filed a counter-claim to this suit and in May 2002, we filed a lawsuit against KV Pharmaceutical Corporation in the Eastern District of Missouri. In November 2002, these lawsuits were dismissed after each party agreed to release and discharge the other from all claims relating to past or future verbal or written advertising, marketing or promotion of products.

A putative class action lawsuit was filed in the U.S. District Court for the Northern District of Georgia on August 22, 2002 (and two subsequent lawsuits have been filed based upon substantially the same allegations) against the Company, members of our Board of Directors, an officer and a former officer (the "Company-related Defendants") and representatives of our underwriters for our public offering completed on April 24, 2002. The complaints generally allege that we issued a series of materially false and misleading statements to the market in connection with our public offering on April 24, 2002 and thereafter, relating to the sales of two of our products, Tanafed Suspension and Prenate GT. The complaints assert that the defendants violated Section 11 and that we violated Section 12(a)(2) of the Securities Act of 1933. The complaints further allege violations by us and Company-related Defendants of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaints also allege controlling person liability on behalf of certain of our officers under Section 15 of the Securities Act and Section 20 of the Securities Exchange Act.

The plaintiffs in these class action lawsuits seek unspecified compensatory damages in an amount to be proven at trial. We believe these cases will be consolidated into one putative class action lawsuit. We deny the claims made in the lawsuits and intend to vigorously defend against these claims. Due to the inherent uncertainties involved in litigation, we are unable to predict the outcome of this litigation and an adverse result could have a material adverse effect on our financial position and results of operations.

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

No matters were submitted to a vote of our stockholders during the quarter ended December 31, 2002.

**PART II**

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

Our common stock began trading on the Nasdaq National Market on May 31, 2000. Our trading symbol is "FHRX." The following table lists, for the periods indicated, the high and low sale prices per share for our common stock as reported on the Nasdaq National Market.

	<u>High</u>	<u>Low</u>
<b>2001</b>		
First Quarter .....	\$19.42	\$11.17
Second Quarter .....	21.40	12.75
Third Quarter .....	26.03	19.23
Fourth Quarter .....	30.88	21.07
<b>2002</b>		
First Quarter .....	\$32.00	\$19.41
Second Quarter .....	26.75	18.24
Third Quarter .....	18.25	3.51
Fourth Quarter .....	7.48	2.48

On September 24, 2001, we completed a three-for-two stock split. The stock split was effected in the form of a stock dividend paid on September 24, 2001 to stockholders of record on September 10, 2001. The high and low sale prices per share of common stock have been retroactively adjusted to reflect the stock split.

On February 28, 2003, the last reported sale price for our common stock on the Nasdaq National Market was \$2.06 per share. As of February 28, 2003, there were approximately 198 holders of record of our common stock.

**Equity Compensation Plan Information**

The following table provides information as of December 31, 2002 with respect to shares of First Horizon common stock that may be issued under existing equity compensation plans.

	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans(1) (excluding securities reflected in column(a)) (c)
2002 Stock Plan Approved by Stockholders .....	287,000	\$ 7.06	2,193,564
2000 Stock Plan Approved by Stockholders .....	2,023,595	\$18.49	0
1997 Stock Option Plan Approved by Stockholders .....	900,199	\$ 1.51	0
Employee Stock Purchase Plan Approved by Stockholders .....	N/A	N/A	705,275
<b>Total</b> .....	<b>3,210,794</b>		<b>2,898,839</b>

(1) The aggregate number of shares of common stock available under the 2002 Stock Plan for grants of options, grants of stock awards and stock sales during any fiscal year of the Company is generally

(i) seven percent (7%) of the outstanding shares of common stock on the last day of the immediately preceding fiscal year of the Company, as such number is determined by the Company to calculate the fully diluted earnings per share of such preceding fiscal year and as such number may be further adjusted pursuant to certain corporate transactions, if applicable, reduced by (ii) the number of shares of common stock for which grants of awards have been made under the 2002 Stock Plan.

#### **Dividend Policy**

We have not declared or paid any cash dividends since our inception. We currently intend to retain our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Our current credit facility prohibits the payment of any dividends or other distributions on any shares of our stock.

#### **ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data is qualified by reference to and should be read in conjunction with our financial statements and the related notes and other financial information included elsewhere in this Annual Report and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data has been derived from our financial statements which have been audited by Deloitte & Touche LLP, independent public accountants, for the year ended December 31, 2002 and by Arthur Andersen LLP, independent public accountants, for the years ended December 31, 1998, 1999, 2000 and 2001. These results may not be indicative of future results. Our results of operations include contributions from products we acquired only from their respective acquisition date. We acquired Sular in March 2002, Furadantin in December 2001, the Prenate line of products in August 2001, Ponstel in

April 2000, Cognex in April 2000, Nitrolingual Pumpspray in July 1999, and the Robinul line of products in January 1999.

	Year Ended December 31,				
	1998	1999	2000	2001	2002
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Net revenues	\$9,252	\$18,625	\$36,650	\$69,290	\$115,178
Cost of revenues	1,903	3,140	5,436	10,354	23,967
Selling, general and administrative expense	6,790	12,546	24,217	38,689	61,843
Depreciation and amortization expense	35	424	1,091	2,724	14,471
Research and development expense	255	860	1,784	1,819	1,096
Operating income	269	1,655	4,122	15,704	13,801
Interest expense	(13)	(357)	(324)	(4)	(2,776)
Interest income	4	12	348	1,874	492
Other	(3)	8	21	4	(7)
Provision for income taxes	(121)	(548)	(1,660)	(6,855)	(4,481)
Extraordinary item, net of taxes	—	—	—	—	\$ (863)
Net income	<u>\$ 136</u>	<u>\$ 770</u>	<u>\$ 2,507</u>	<u>\$10,723</u>	<u>\$ 6,166</u>
Net income per share:					
Basic	<u>\$ 0.01</u>	<u>\$ 0.06</u>	<u>\$ 0.15</u>	<u>\$ 0.44</u>	<u>\$ 0.19</u>
Diluted	<u>\$ 0.01</u>	<u>\$ 0.06</u>	<u>\$ 0.13</u>	<u>\$ 0.41</u>	<u>\$ 0.18</u>

	As of December 31,				
	1998	1999	2000	2001	2002
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 425	\$ 220	\$14,228	\$ 53,458	\$ 47,409
Total assets	2,933	11,078	50,083	170,150	352,932
Total debt	603	3,699	221	—	—
Total stockholders' equity	956	3,616	38,572	143,364	305,683

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

The following discussion and related financial data should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report.

##### Overview

We are a specialty pharmaceutical company that markets and sells brand name prescription products. We focus on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. Our strategy is to acquire or license pharmaceutical products that other companies do not actively market and that we believe have high sales growth potential, are promotion-sensitive and complement our existing products. In addition, we intend to develop new patentable formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs. We may also acquire businesses with complementary products or development pipelines as well as late stage development products consistent with our therapeutic focus.

Since January 1, 1999, we have acquired or licensed products from AstraZeneca, Aventis, Bayer, Elan, Pfizer, Sanofi-Synthelabo and Wyeth. These acquisitions have included the following: Sular, a hypertension product acquired in 2002, Furadantin, a pediatric urinary tract infection product acquired in 2001, the Prenate line of prenatal vitamins acquired in 2001, Ponstel, a product for the treatment of pain and painful menstruation acquired in 2000, Nitrolingual Pumpspray, a product for the treatment of acute angina acquired in 1999, and the Robinul line of products, an adjunctive therapy for the treatment of peptic ulcers, acquired in 1999.

During 2002, we acquired and began to sell Sular, an antihypertensive prescription medication. Sales of Sular during 2002 were below our expectations. Also during 2002, we experienced erosion of sales of our Prenate GT and Tanafed brands due to competition from knock-off products.

## Results Of Operations

### Years Ended December 31, 2002 and December 31, 2001

Net revenues were \$115.2 million for the year ended December 31, 2002, as compared to \$69.3 million for the year ended December 31, 2001. Net revenues for 2002 are comprised of (1) net revenues from products sales, (2) a reduction in the recorded liability for estimated future returns of our Ponstel and Cognex products and related increase in net revenues, and (3) an accrual for estimated future returns of our Tanafed Suspension products and related decrease in net revenues. Net revenues for 2001 have no comparable adjustments for changes in estimates of liabilities for future product returns.

	2002	2001
	(In millions)	
Net revenue from product sales . . . . .	\$116.3	\$69.3
Reduction of product returns accrual . . . . .	2.7	—
Accrual for Tanafed . . . . .	(3.8)	—
Net revenues . . . . .	\$115.2	\$69.3

Net revenues from product sales increased \$47 million, or 68%, over the year ended December 31, 2001 to \$116.3 million for the year ended December 31, 2002. Net revenues from product sales of existing products (namely, all of the Company's products other than those launched or acquired after December 31, 2000) decreased \$18.2 million to \$46.6 million for the year ended December 31, 2002, as compared to the year ended December 31, 2001. This decrease is due to lower net sales of Tanafed Suspension and our non-promoted Cognex and cough and cold products, partially offset by an increase in net sales of the Robinul line and Nitrolingual Pumpspray. Net revenues from sales of products launched or acquired after December 31, 2000 were \$69.7 million for the year ended December 31, 2002. We acquired the Prenate line in August 2001, Furadantin in December 2001 and Sular in March 2002. We launched the Tanafed line extensions, Tanafed DM, Tanafed DP and Tanafed DMX in January 2002, September 2002 and September 2002, respectively.

According to IMS Health's National Prescription Audit Plus™ data, new and total prescriptions of Sular for the quarter ended December 31, 2002 increased 4.2% and 1.6%, respectively, compared to the quarter ended September 30, 2002. According to IMS Health's National Prescription Audit Plus™ data, new and total prescriptions of Sular decreased 29.5% and 27.4%, respectively, for the year ended December 31, 2002 compared to the year ended December 31, 2001, while new and total prescriptions of Sular decreased 11.8% and 13.0%, respectively, for the quarter ended December 31, 2002, compared to the quarter ended December 31, 2001. We continue to manage the levels of trade inventories of Sular. Wholesalers who purchase our products increased the levels of trade inventories significantly in October and November of 2002, presumably in anticipation of future price increases. We plan to reduce our shipments of Sular and thereby seek to reduce the levels of trade inventories of Sular in the first quarter of

2003. Net revenues of Sular by the Company in 2002 since its acquisition in March 2002 were approximately \$30.2 million.

Net revenues of the pediatric and OB/GYN franchise products, which include the Prenate line, the Tanafed line, Furadantin and Ponstel, were approximately \$48.1 million for the year ended December 31, 2002 compared to approximately \$29.3 million for the year ended December 31, 2001.

We experienced erosion of sales of our Tanafed Suspension and Tanafed DM line of products during 2002 due to increased competition from knock-off products resulting from pharmacists substituting such knock-off products for prescriptions of our Tanafed Suspension and Tanafed DM line of products. In response to the knock-off products, we launched two line extensions, Tanafed DP and Tanafed DMX, in September 2002. In January 2003 we were issued a U.S. patent that contains claims which protect Tanafed DM, Tanafed DP and Tanafed DMX against knock-off products. When we launched Tanafed DP and Tanafed DMX in September 2002, our goal was to capture 50% of the new prescriptions in their respective market niches by the end of 2002. We have exceeded our goal for Tanafed DMX but did not achieve our goal for Tanafed DP. According to IMS Health's NPA Plus7™ data, Tanafed DMX captured 79% of the weekly-dispensed new prescriptions for products including Tanafed DM, Tanafed DM knock-off products and Tanafed DMX for the week ending December 27, 2002. Over the same period, Tanafed DP captured 42% of the weekly-dispensed new prescriptions for products including Tanafed Suspension, Tanafed Suspension knock-off products and Tanafed DP according to IMS Health's NPA Plus7™ data. Total dispensed prescriptions of the Tanafed line increased 13.9% for the quarter ended December 31, 2002, compared to the quarter ended December 31, 2001 according to IMS Health's National Prescription Audit Plus™ data.

We acquired the Prenate line in August 2001, introduced Prenate GT in September 2001 and experienced erosion of sales of the products included in our Prenate line during 2002 due to increased competition from knock-off products resulting in pharmacists substituting such knock-off products for prescriptions of our Prenate line of products. Total dispensed prescriptions of Prenate GT increased 10% for the quarter ended December 31, 2002 as compared to the quarter ended September 30, 2002. The substitution rates, as measured by new dispensed prescriptions captured by Prenate GT and knock-off products, were 31.9% for the quarter ended September 30, 2002 and 35.4% for the quarter ended December 31, 2002 (Source: IMS Health's National Prescription Audit Plus™ data).

According to IMS Health's National Prescription Audit Plus™ data, total prescriptions of our Ponstel and Robinul products each increased 24% and 26%, respectively, for the year ended December 31, 2002 as compared to the year ended December 31, 2001. Total prescriptions decreased 2.3% for Ponstel and increased 0.2% for Robinul for the quarter ended December 31, 2002 as compared to the quarter ended September 30, 2002. We believe this slowing in growth in the fourth quarter of 2002 was due to the reduced levels of promotion of these products caused by the launch of the Tanafed line extensions during the second half of 2002. We have subsequently balanced and refocused our selling approach to all of the promoted products for 2003.

We do not report independent market data on prescriptions of Nitrolingual Pumpspray because we believe such data does not capture prescriptions from some of the non-retail channels. Sales of Nitrolingual Pumpspray continue to increase. However, these sales in 2002 were approximately 10% below our goals primarily in the second and third quarter of 2002 because of the increased focus of our sales force on the launch of Sular during these quarters.

Total prescriptions of our non-promoted products decreased 32% for the year ended December 31, 2002 as compared to the year ended December 31, 2001 according to IMS Health National Prescription Audit Plus™ data. The most significant portion of this decline occurred in the quarter ended December 31, 2002. In addition, we experienced greater rates of returns for certain of our non-promoted products in the quarter ended December 31, 2002, which significantly reduced fourth quarter 2002 net sales of these products. Because sales of the Company's non-promoted products are seasonal to the cough and cold

seasons, the absolute dollar impact of these trends was more pronounced in the fourth quarter than in earlier periods. We plan to compensate for this decline in revenues by acquiring new products and increasing sales of our existing actively promoted products.

In connection with the acquisition of rights for Robinul, Ponstel, Cognex, Prenate, Furadantin and Sular we assumed certain liabilities for returns of product shipped by the seller prior to the acquisition date. At the respective acquisition dates, we estimated the amount of the assumed liabilities based on actual sales return data from the seller and included that amount in the allocation of the total purchase price. We periodically review the estimated liability. Generally, no adjustment is made to the reserve until two to three years subsequent to the acquisition due to the lag time between when a product is sold and when it is returned. During 2002 we determined that the established reserves for Robinul, Ponstel and Cognex were in excess of the currently expected returns. As a result of the revised estimate, we reduced the liability and increased net revenues by \$2.7 million during 2002. In December 2002, we also determined that the established reserve for Sular was insufficient compared to expected future returns. As a result, the estimate for assumed liabilities was increased by \$0.7 million.

As a result of our launch of Tanafed DP and Tanafed DMX, we anticipated higher than normal returns of Tanafed Suspension. As of December 31, 2002, we estimate that additional returns will total approximately \$3.8 million and have provided for this amount as a deduction of revenue.

Cost of revenues for 2002 were \$24.0 million and was comprised of cost of revenues from product sales of \$22.1 million as increased by an allowance for obsolete inventory for existing Tanafed Suspension and Prenate GT inventory totaling \$1.9 million due to the introduction of product line extensions in the third quarter of 2002 and decreased sales rates. Costs of revenues for the year ended December 31, 2001 of \$10.4 million do not include a comparable allowance for obsolete inventory.

	<u>2002</u>	<u>2001</u>
	(In millions)	
Cost of revenues from product sales . . . . .	\$22.1	\$10.4
Charge for Prenate GT obsolescence . . . . .	.7	—
Charge for Tanafed Suspension obsolescence . . . . .	<u>1.2</u>	<u>—</u>
Total cost of revenues . . . . .	\$24.0	\$10.4

Cost of revenues from product sales increased \$11.7 million, or 113%, to \$22.1 million for the year ended December 31, 2002 compared to \$10.4 million for the year ended December 31, 2001.

For the year ended December 31, 2002 gross margin, defined as net revenue from product sales less cost of revenues from product sales as a percentage of net revenue from product sales, was 81% compared to 85% for the year ended December 31, 2001. This decrease in gross margin resulted primarily from the change in product sales mix and Sular having a lower gross margin as compared to our other products.

Selling, general and administrative expenses increased \$23.1 million, or 60%, for the year ended December 31, 2002 to \$61.8 million, compared to \$38.7 million for the year ended December 31, 2001. As a percentage of net revenues from product sales, selling, general and administrative expenses were 53% for the year ended December 31, 2002, as compared to 56% for the year ended December 31, 2001. Selling related expenses increased due to increased royalty expense due to higher net revenues of our Nitrolingual Pumpspray, Robinul and Zebutal products on which we pay royalties, the expansion of our sales force in April 2002, and higher training and marketing cost related to the launch of Furadantin, Sular, Tanafed DP, Tanafed DM and Tanafed DMX during 2002. Selling expenses also increased due to the outside commission and co-promotion expenses paid to Professional Detailing, Inc. ("PDI") for our Prenate co-promotion and the new Sular, Nitrolingual Pumpspray and Robinul co-promotion which began in the second quarter of 2002.

General and administrative expenses for the year ended December 31, 2002 increased due to increased support staff and operating expenses at our corporate headquarters, higher insurance costs, and higher state and local tax expense. During 2002 we recorded estimated expenses for state and local taxes associated with prior periods of \$0.6 million. We have not yet settled the amount of our obligations for such taxes. These increased expenses were partially offset by lower bad debt expense.

Depreciation and amortization expense increased \$11.8 million, to \$14.5 million for the year ended December 31, 2002 compared to \$2.7 million for the year ended December 31, 2001. This increase resulted from higher amortization expense related to the acquisition of Prenate in August 2001, Furadantin in December 2001, and Sular in March 2002 as well as increased depreciation expense for new furniture, computer equipment and leasehold improvements at our new corporate headquarters.

Research and development expense decreased \$0.7 million, or 39%, to \$1.1 million for the year ended December 31, 2002 compared to \$1.8 million for the year ended December 31, 2001. Research and development expenses were primarily related to the Robinul line extension development project.

Interest expense increased to \$2.8 million for the year ended December 31, 2002. This increase was a result of the amortization of deferred financing costs and other interest expenses associated with the credit facility obtained on March 5, 2002 to finance the acquisition of Sular. We expensed \$1.4 million (\$0.9 million net of taxes) of remaining debt fees related to the retirement of our term loan on April 24, 2002 that were recorded as an extraordinary item. We repaid all indebtedness outstanding under the credit facility in the second quarter of 2002 and terminated the credit facility in July 2002.

Interest income was \$0.5 million for the year ended December 31, 2002 compared to \$1.9 million for the year ended December 31, 2001. The decrease in interest income was primarily the result of the reduced amount of cash invested as we used the cash proceeds from our 2001 offering for the Prenate, Furadantin, and Sular acquisitions. Most of the cash proceeds from our 2002 offering were used to repay indebtedness outstanding under the credit facility obtained to finance the Sular acquisition in 2002.

Income taxes were provided for at a rate of 39% for the year ended December 31, 2002 and December 31, 2001, respectively.

#### *Years Ended December 31, 2001 and December 31, 2000*

Net revenues increased \$32.6 million, or 89%, over the year ended December 31, 2000, to \$69.3 million for the year ended December 31, 2001. The increase in sales for the year ended December 31, 2001 was primarily due to increased unit sales of our key products Tanafed Suspension, Robinul, Nitrolingual Pumpspray and Ponstel. According to IMS Health's National Prescription Audit Plus™ data, total prescriptions of Tanafed Suspension, Robinul and Robinul Forte and Ponstel increased 42%, 52% and 47%, respectively. While we do not report independent market data on prescriptions of Nitrolingual Pumpspray because we believe such data does not capture prescriptions from some of the non-retail channels, unit sales of Nitrolingual Pumpspray also increased substantially.

Our operating results for the year ended December 31, 2001 include net sales of Prenate Advance and Prenate GT since August 2001. The year ended December 31, 2001 does not include any net sales of Furadantin or Sular. Prior to our acquisitions of the Prenate line, Furadantin and Sular, the Prenate line had U.S. net sales of \$11.0 million for the period January 1, 2001 through August 20, 2001. Furadantin had U.S. net sales of \$4.4 million in calendar year 2001 and Sular had U.S. net sales of \$45.9 million in calendar year 2001. We began to sell Nitrolingual Pumpspray in February 2000 and Ponstel in April 2000.

Cost of revenues increased \$4.9 million, or 90%, to \$10.4 million for the year ended December 31, 2001 compared to \$5.4 million for the year ended December 31, 2000. Gross margin for each of the years ended December 31, 2001 and December 31, 2000 was 85%. Gross margin for the year ended 2001 does not include the impact of Furadantin and Sular.



Selling, general and administrative expense increased \$14.5 million, or 59%, to \$38.7 for the year ended December 31, 2001. As a percentage of net revenues, selling, general and administrative expenses were 56% in 2001 and 66% in 2000. Selling related expense increased in 2001 due to higher commission, royalty and product sampling expense as a result of increased sales and higher advertising, promotion, consulting and market research reporting costs associated with the launch of Prenate GT in September 2001. Selling expense also increased in 2001 due to additional commissions under our co-promotion agreements with PDI and Otsuka for Prenate GT and Nitrolingual Pumpspray, respectively.

General and administrative expense increased for the year ended December 31, 2001 due to additions to our management team and support personnel, and higher insurance costs due to increased insurance coverage. Also included in the 2001 expense were one-time charges of approximately \$0.3 million for severance to a departing officer as well as approximately \$0.3 million of lease abandonment costs incurred in connection with our move to a new facility.

Depreciation and amortization expense increased \$1.6 million, or 150%, to \$2.7 million for the year ended December 31, 2001. This increase resulted from higher amortization expense related to the acquisition of Furadantin on December 21, 2001, the Prenate line on August 20, 2001, Ponstel on April 14, 2000, Cognex on June 22, 2000 and increased depreciation expense for furniture, computer equipment and leasehold improvements at our corporate headquarters.

Research and development expense increased \$0.04 million, to \$1.8 million for the year ended December 31, 2001 compared to \$1.8 million for the year ended December 31, 2000. Interest expense was \$0.0 million for the year ended December 31, 2001 compared to \$0.3 million for the year ended December 31, 2000.

Interest income was \$1.9 million for the year ended December 31, 2001 compared to \$0.3 million for the year ended December 31, 2000. The increase was the result of interest earned on the proceeds of our follow-on offering that we completed in May 2001.

Income taxes were provided for at a rate of 39.0% in 2001 compared to 39.8% in 2000. The decrease is primarily due to state income tax structuring initiatives.

### **Liquidity and Capital Resources**

Our liquidity requirements arise from debt service, working capital requirements, product development activities and funding of acquisitions. We have met these cash requirements through cash from operations, borrowings for product acquisitions and the issuance of common stock.

Our cash and cash equivalents were \$47.4 million at December 31, 2002, as compared to \$53.5 million at December 31, 2001. Net cash provided by operating activities for the year ended December 31, 2002 was \$27.3 million. This primarily resulted from increased net income plus increased non-cash expenses and increased accounts payable and accrued expenses, partially offset by increases in inventories, accounts receivable, samples, other prepaid expenses and other assets. In 2002 our tax liability was reduced by \$0.9 million due to the exercise of non-qualified stock options by employees. Our purchase of inventory impacts our liquidity. During 2003, we expect to invest cash in the purchase of inventory and expect we will also experience growth in our accounts receivable. We believe that our cash on hand, cash we expect to generate from our operations and availability under our revolving credit facility will be sufficient to fund these working capital requirements, at least for the next twelve months. However, in the event that we make significant acquisitions in the future, we may need to raise additional funds through additional borrowings or the issuance of debt or equity securities. While some of our supply agreements contain minimum purchase requirements, we believe our requirements for inventory should exceed the minimum purchase agreements in 2003. Research and development expense are expected to be between \$1.5 million and \$2.5 million in 2003 due to continued development work on our proposed Robinul line extension and

other line extensions for our currently marketed products. These expenses are discretionary and will be funded by existing cash and cash generated from operations.

Net cash used in investing activities for the year ended December 31, 2002 was \$185.2 million, compared to \$69.4 million for the year ended December 31, 2001. Net cash used in investing activities in 2002 resulted primarily from the Company's March 2002 purchase of Sular from AstraZeneca and Bayer for \$184.3 million. In addition, we purchased \$1.3 million of property and equipment in 2002. Our business strategy includes the acquisition or licensing of pharmaceutical products that we believe represent attractive growth opportunities for us in the future. While we are not currently a party to any such agreements, we regularly evaluate acquisition opportunities. Subject to our liquidity and capital resources at any particular time, we may incur commitments in the future to acquire or license pharmaceutical products.

Net cash provided by financing activities for the year ended December 31, 2002 was \$151.8 million, compared to \$84.6 million for the year ended December 31, 2001. The increase in 2002 was primarily the result of our follow-on offering and the exercise of stock options by employees that together provided net proceeds of \$155.0 million. This amount was reduced by capitalized financing costs of \$3.1 million we incurred under a senior secured credit facility we obtained on March 5, 2002. This facility consisted of a \$127 million term loan and a \$25 million revolving loan which we used to fund the purchase of Sular and some of our working capital requirements. We borrowed \$127 million under the term loan facility and \$10 million under the revolving loan facility. We completed a follow-on offering of our common stock on April 24, 2002. In the offering, we sold 7,475,000 shares of common stock for net proceeds of \$153.1 million. Proceeds from the offering were used to repay all of the debt incurred under our senior secured credit facility. We voluntarily terminated this credit facility without penalty in July 2002.

On February 11, 2003, we entered into a Credit Agreement for a \$20 million senior secured revolving credit facility with various lenders and LaSalle Bank National Association, as Administrative Agent. Subject to the satisfaction of certain borrowing base requirements, we may from time-to-time borrow monies under the revolving facility for working capital requirements and general corporate purposes. Borrowings are secured by substantially all of our assets. Borrowings bear interest at our option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin. The applicable margin will vary dependent upon our leverage ratio in effect from time-to-time. As of February 28, 2003, we have no borrowings outstanding under this facility. The revolving facility matures on February 11, 2006. Fees payable under the revolving facility include a one-time commitment fee of 0.685% of the stated amount of the facility, an unused commitment fee based on funds committed but not borrowed under the revolving facility at rates which vary dependent upon our leverage ratio in effect from time-to-time and letter of credit fees equal to 0.25% per annum of the face amount of letters of credit issued and outstanding under the revolving facility. The revolving facility may be prepaid from time-to-time or terminated at our discretion without penalty. The revolving loan contains various restrictive covenants, including covenants relative to maintaining financial ratios and earnings levels, limitations on acquisitions, dispositions, mergers and capital expenditures, limitations on incurring additional indebtedness and a prohibition on payment of dividends and certain issuances of our capital stock.

#### **Contractual Obligations**

In December 2001, we entered into a lease agreement for a new facility. In April 2002, we moved into this facility. This new facility is leased under a non-cancelable operating lease that expires in May 2009. The lease for the previous facility was terminated in June 2002 and we have no further obligations related to this lease. The total rent expense was approximately \$0.2 million, \$0.5 million, and \$0.4 million for the years ended December 31, 2000, 2001, and 2002 respectively. The rent expense for 2001 included a charge of approximately \$0.3 million for the remaining lease obligation under our non-cancelable lease at that time.

We lease vehicles for certain employees under non-cancelable lease agreements expiring in 2003. The total vehicle lease expense under the lease agreements for the years ended December 31, 2000, 2001 and 2002 was \$1.3 million, \$1.9 million and \$2.3 million, respectively.

### **Inflation**

We have experienced only moderate price increases under our agreements with third-party manufacturers as a result of raw material and labor price increases. We have generally passed these price increases along to our customers.

### **Seasonality**

Although our business is generally non-seasonal, sales of certain products, such as cough and cold products, increase between October and March due to the cold and flu season. We expect the impact of seasonality to decrease as we acquire or obtain licenses for products that treat chronic conditions. However, we anticipate that the seasonality may continue to affect sales for the foreseeable future.

### **Critical Accounting Policies**

We view our critical accounting policies to be those policies which are very important to the portrayal of our financial condition and results of operations, and require management's most difficult, complex or subjective judgments. The circumstances that make these judgments difficult or complex relate to the need for management to make estimates about the effect of matters that are inherently uncertain. We believe our critical accounting policies are as follows:

- *Allowance for doubtful accounts.* We are required to estimate the level of accounts receivable recorded on our balance sheet which will ultimately not be paid. Among other things, this assessment requires analysis of the financial strength of our customers, which can be highly subjective, particularly in the recent difficult general economic environment. Our policy is to estimate bad debt expense based on prior experience supplemented by a periodic customer specific review when needed. In 2002, we reduced the allowance for doubtful accounts by approximately \$0.4 million and recorded the change as a reduction in selling, general and administrative expenses. We will continue to record bad debt expense based on prior experience supplemented by a periodic customer specific review. If we over or under estimate the level of accounts receivable that will not be paid, there may be a material impact to our financial statements.
- *Sales deductions.* We provide volume rebates, contractual price reductions with drug wholesalers and insurance companies, and certain other sales related deductions on a regular basis. The exact level of these deductions is not always immediately known and thus we must record an estimate at the time of sale. Our estimates are based on historical experience with similar programs, and since we have a relatively small customer base, customer specific historical experience is often useful in determining the estimated level of deductions expected to be refunded to our customers when sales incentives are offered. If we over or under estimate the level of sales deductions, there may be a material impact to our financial statements.
- *Product returns.* In the pharmaceutical industry, customers are normally granted the right to return product for a refund if the product has not been used prior to its expiration date, which is typically two to three years from the date of manufacture. Beginning January 1, 2002, our return policy was revised to allow product returns for products within an eighteen-month window from six months prior to the expiration date and up to twelve months after the expiration date. Previously, our return policy was for a twelve-month window. We changed our return policy to conform to industry standard practices. This change to our policy did not have a material impact on the financial statements. We believe that we have sufficient data to estimate future returns over the revised time period at the time of sale. Management is required to estimate the level of sales which will

ultimately be returned pursuant to our return policy, and record a related reserve at the time of sale. These amounts are deducted from our gross sales to determine our net revenues. Our estimates take into consideration historical returns of a given product, product specific information provided by our customers and information obtained from independent sources regarding the levels of inventory being held by our customers, as well as overall purchasing patterns by our customers. Management periodically reviews the reserves established for returns and adjusts them based on actual experience. If we over or under estimate the level of sales which will ultimately be returned, there may be a material impact to our financial statements.

- *Liabilities assumed with the acquisition of product rights.* In connection with the acquisition of product rights, we assume certain liabilities for returns of product shipped by the seller prior to the acquisition date. At the acquisition date, we estimate the amount of the assumed liabilities based on actual sales return data from the seller and include that amount in the allocation of the total purchase price. We review the estimated liability on an annual basis. If we over or under estimate liabilities assumed, there may be a material impact to our financial statements.
- *Intangible assets.* When we acquire the rights to manufacture and sell a product, we record the aggregate purchase price, along with the value of the product related liabilities we assume, as intangible assets. We use the assistance of valuation experts to help us allocate the purchase price to the fair value of the various intangible assets we have acquired. Then, we must estimate the economic useful life of each of these intangible assets in order to amortize their cost as an expense in our statement of operations over the estimated economic useful life of the related asset. The factors that drive the actual economic useful life of a pharmaceutical product are inherently uncertain, and include patent protection, physician loyalty and prescribing patterns, competition by products prescribed for similar indications, future introductions of competing products not yet FDA approved, the impact of promotional efforts and many other issues. We use all of these factors in initially estimating the economic useful lives of our products, and we also continuously monitor these factors for indications of appropriate revisions. See also "Recent Accounting Pronouncements" where we discuss the adoption of Statement of Financial Accounting Standard ("SFAS") No. 142 in 2002.

In assessing the recoverability of our intangible assets, we must make assumptions regarding estimated future cash flows and other factors. If the estimated undiscounted future cash flows do not exceed the carrying value of the intangible assets we must determine the fair value of the intangible assets. If the fair value of the intangible assets is less than its carrying value, an impairment loss will be recognized in an amount equal to the difference. We review intangible assets for impairment at least annually and whenever events or changes in circumstances, indicate that the carrying amount of an asset may not be recoverable. Such events or circumstances may include lack of promotional sensitivity, the introduction of competitive products and changes in government regulations. If we determine that an intangible asset is impaired, a non-cash impairment charge would be recognized.

- *Inventory obsolescence.* Our products have shelf lives ranging from 18 to 36 months. We must estimate the amount of inventory recorded on our balance sheet that will not be sold prior to expiration. This estimate requires analysis of forecasted demand for our products, our promotional focus, amounts of our products currently held by our customers and the impact on our products of competing products. If we over or under estimate the amount of inventory that will not be sold prior to expiration, there may be a material impact to our financial statements.

#### **Recent Accounting Pronouncements**

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard ("SFAS") No. 141 "Business Combinations". SFAS No. 141 eliminates the pooling-of-interest

method of accounting for business combinations. SFAS No. 141 is effective for any business combination completed after June 30, 2001. The adoption of SFAS No. 141 on January 1, 2002 did not have a material impact on our financial condition or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets". Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized. Separate intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives. SFAS No. 142 also establishes a new method of testing goodwill and other intangible assets for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would reduce the fair value of that goodwill or other intangible asset below its carrying value. The Company did not have any goodwill or indefinite lived intangible assets at December 31, 2002 or December 31, 2001. The amortization provisions of SFAS No. 142 apply to goodwill and other intangible assets acquired after June 30, 2001. The adoption of SFAS No. 142 on January 1, 2002 did not have a material impact on our financial condition or results of operations.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets." SFAS No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and is effective for financial periods after January 1, 2002. The adoption of SFAS No. 144 on January 1, 2002 did not have a material impact on our financial condition or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Revision of FAS Nos. 4, 44 and 64, Amendment of FASB 13 and Technical Corrections." SFAS No. 145 rescinds, amends or makes various technical corrections to certain existing authoritative pronouncements and is effective for fiscal years beginning after May 2002 for the rescission of FAS No. 4 and FAS No. 13, and all other provisions are effective for financial statements issued on or after May 15, 2002. Early adoption is encouraged. We do not believe the adoption of SFAS No. 145 will have a material impact on our financial condition or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002 with early adoption encouraged. We are evaluating the impact the adoption of SFAS No. 146 will have on our financial condition or results of operations.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123." SFAS No. 148 amends SFAS 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent disclosure in both annual and interim financial statements. The transition guidance and disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing financial statements for interim periods beginning after December 15, 2002. We do not expect the adoption of SFAS No. 148 will have a material impact on our financial condition or results of operations.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

Our operating results and cash flows are subject to fluctuations from changes in foreign currency exchange rates and interest rates. Our purchases of Nitrolingual Pumpspray under our agreement with Pohl-Boskamp and our purchases of Sular product inventory from Bayer are made in Euros. We eliminate risks from foreign currency fluctuations after the time of shipment of product by entering into forward contracts for these purchases of inventory at the time of product shipments. In addition, sales of Cognex

are recognized in the foreign currencies of the respective European countries in which it is sold. While the effect of foreign currency translations has not been material to our results of operations to date, currency translations on export sales or import purchases could be adversely affected in the future by the relationship of the U.S. dollar with foreign currencies.

In connection with borrowings incurred under the senior secured revolving credit facility arranged by LaSalle Bank, N.A., we should experience market risk with respect to changes in the general level of the interest rates and its effect upon our interest expense. Borrowings under this facility bear interest at variable rates. Because such rates are variable, an increase in interest rates will result in additional interest expense and a reduction in interest rates will result in reduced interest expense. Accordingly, our present exposure to interest rate fluctuations is primarily dependent on rate changes that may occur while borrowings under the senior secured credit facility are outstanding. As of February 28, 2003 there was no debt outstanding under this facility.

### FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plan," "intends," "estimates," "could," "should," "would," "continue," "seeks," "pro forma" or "anticipates," or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions "Description of Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this Annual Report.

Such statements include, but are not limited to the following: (i) our ability to acquire or license products, (ii) our ability to develop new formulations, use new delivery methods and seek regulatory approval for new indications of existing drugs, (iii) our ability to acquire other businesses, (iv) our ability to grow, (v) our ability to increase sales by promoting our products to physicians, (vi) our ability to develop proprietary products and line extensions, (vii) our belief that Sular is promotion sensitive, (viii) our belief that the 60-dose bottle of Nitrolingual Pumpspray will benefit patients who have mild angina and whose episodes are occasional, (ix) the expected launch date for the 60-dose bottle of Nitrolingual Pumpspray, (x) our ability to develop a line extension to Robinul for excessive salivation and our ability to receive FDA approval for it, (xi) our ability to contract with third parties to formulate, develop and manufacture materials for clinical trials and to perform scale-up work, (xii) our ability to locate and engage a development partner to assist us with our migraine project, (xiii) the expected impact of seasonality as we acquire or license products, (xiv) timely supply to us of Ponstel by Pfizer during the first quarter of 2003, (xv) timely supply to us of Ponstel by our new contract manufacturer, (xvi) the ability of our new manufacturer for Cognex to timely supply us with Cognex, (xvii) our ability to obtain regulatory approval for our migraine development, (xviii) the expected cost of development for our products under development, (xix) that patents may provide us with competitive advantages, (xx) our ability to obtain patent protection, (xxi) our ability to reverse Sular prescription declines, (xxii) our ability to manage the trade inventory level of Sular, (xxiii) our ability to obtain FDA approval of our Tanafed products by 2005, if required, (xxiv) our ability to compensate for revenue declines in non-promoted products by acquiring new products and increasing sales of existing actively promoted products, (xxv) our belief that the 60-dose bottle of Nitrolingual Pumpspray will provide an excellent companion product to the 200-dose bottle,

(xxvi) our ability to implement a successful reorganization plan, (xxvii) our belief that we have enough inventory of Ponstel to continue selling it through the third quarter of 2003 and that there exists enough raw material to sell it for two years, (xxviii) the ability of our new manufacturer for Furadantin to become qualified to manufacture the product by May 2003, (xxix) our ability to defend and enforce intellectual property rights, (xxx) our ability to reduce our shipments of Sular and reduce the levels of trade inventory in the first quarter of 2003, (xxxi) that our cash on hand, cash we expect to generate from our operations and availability under our revolving credit facility will be sufficient to fund our working capital requirements for at least the next twelve months, (xxxii) expected research and development expenses in 2003, (xxxiii) the effect of critical accounting policies on our results of operations and liquidity and (xxxiv) the impact of recent accounting pronouncements on our financial condition or results of operations.

These forward-looking statements involve uncertainties and other factors, including those described in the "Risk Factors" section and elsewhere in this Annual Report. We do not undertake to update prescription or market data or our forward-looking statements to reflect future events or circumstances.

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

The information required by this item is set forth at the pages indicated in Item 15(a) below.

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

Please see the information reported in the Current Report on Form 8-K filed with the Securities and Exchange Commission May 31, 2002, the information reported in the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on June 11, 2002 and the information reported in the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 12, 2002.

**PART III**

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

Our directors and executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Mahendra G. Shah, Ph.D.(1) . . . . .	58	Chairman of the Board, Chief Executive Officer and President
Darrell Borne . . . . .	41	Chief Financial Officer, Secretary and Treasurer
Jack Spencer . . . . .	53	Vice President of Sales
Andrew D. Shales . . . . .	42	Vice President of Marketing
Jerry N. Ellis(2)(3) . . . . .	65	Director
John N. Kapoor, Ph.D . . . . .	59	Director
Pierre Lapalme(2)(4) . . . . .	62	Director
Jon S. Saxe(2)(3)(4) . . . . .	66	Director
Patrick J. Zenner(3)(4) . . . . .	56	Director

- (1) Member of Stock Option Subcommittee.
- (2) Member of the Audit Committee.
- (3) Member of Corporate Governance Committee.
- (4) Member of the Compensation Committee.

Mahendra G. Shah, Ph.D. is the Chairman of the Board, Chief Executive Officer and President. Dr. Shah has been a director since 1993, and his present term as director will expire at the annual meeting of stockholders to be held in 2004. Dr. Shah became Chief Executive Officer in October 1999 and President in January 2002. From 1991 to 2000, he was a Vice President of EJ Financial Enterprises, Inc., which manages a fund that invests in healthcare companies. EJ Financial Enterprises, Inc. is the managing general partner of Kapoor-Pharma Investments, L.P., our largest stockholder. From 1996 to 2000 he has been the President of Protomed Pharmaceuticals, Inc., which is a privately-held drug development company. From 1987 to 1991, he was the senior director of new business development with Fujisawa USA, Inc. Prior to that, he worked in various scientific and management positions with Schering-Plough and Bristol-Myers Squibb Company. He serves on the board of Structural Bioinformatics Inc. and Introgen Therapeutics. He was previously Chairman of Inpharmakon Corporation. Dr. Shah received a Ph.D. degree in Industrial Pharmacy from St. John's University.

Darrell Borne was appointed Chief Financial Officer in December 2002 and Treasurer and Secretary in January 2003. From 2000 to 2002, Mr. Borne worked for Elastic Networks Inc., where he most recently served as Chief Financial Officer. Mr. Borne also worked from 1996 to 2000 for Rollins, Inc., where he most recently served as Vice President of Finance. Mr. Borne has previously held financial management positions at Rockdale Hospital, Mobil Corporation and Advanced Technology, Inc. He holds a BA in Accounting and an MBA from Marymount University.

Jack Spencer was appointed Vice President of Sales in December 2002. From 2000 to 2002 Mr. Spencer served as an independent consultant for start up companies. From 1996 to 2000, Mr. Spencer was a business director for Pfizer/Parke Davis Pharmaceutical Company. From 1992 to 1996, Mr. Spencer was Vice President and National Sales Director for Novo Nordisk Pharmaceuticals, Inc., Area Sales Director from 1990 to 1992, and a Regional Sales Manager from 1989 to 1990. From 1986 to 1989, Mr. Spencer was a Division Manager for E.R. Squibb & Sons and from 1979 to 1986 was a sales



representative. Mr. Spencer graduated from Marshall University in Huntington, West Virginia with a B.A. degree in Education.

Andrew D. Shales was appointed as Vice President of Marketing in May 2001. From 1997 to May 2001, Mr. Shales held various marketing managerial positions at UCB Pharma, Inc., a global, research-based pharmaceutical company headquartered in Brussels, Belgium. From 1996 to 1997, Mr. Shales directed the marketing of products in the cardiovascular and obesity markets while working at Medeva Pharmaceutical, Inc. Mr. Shales started his career at Solvay Pharmaceuticals, Inc. as a sales representative and also worked as a Market Research Analyst and Product Manager. Mr. Shales graduated from King's College in Wilkes-Barre, Pennsylvania with a B.A. degree in Psychology.

Jerry N. Ellis was elected a director in November 2000. His term as director will expire at the annual meeting of stockholders to be held in 2003. Mr. Ellis has over thirty years of auditing and accounting experience. From 1994 to 2000, Mr. Ellis was a consultant to Arthur Andersen LLP for services focusing on international auditing, audit committee practices, business risk management and training. From 1973 to 1994, he was a partner at Arthur Andersen in their Dallas, Madrid and Chicago offices. From 1962 to 1973, Mr. Ellis was an auditor at Arthur Andersen. Mr. Ellis is a director of Akorn, Inc. and an Adjunct Professor of Advanced Auditing at the University of Iowa. Mr. Ellis is a Certified Public Accountant and received B.B.A. and M.B.A. degrees from the University of Iowa.

John N. Kapoor, Ph.D. has been one of our directors since 1996, and his present term as director will expire at the annual meeting of stockholders to be held in 2003. Dr. Kapoor has over twenty years of experience in the healthcare field through his ownership and management of healthcare-related businesses. In 1990, Dr. Kapoor founded Kapoor-Pharma Investments, L.P., our largest stockholder, and its managing partner, EJ Financial Enterprises, Inc., of which he is the president and sole stockholder. EJ Financial provides general funds and strategic advice to healthcare businesses. Dr. Kapoor is the Chairman of Optioncare, Inc., Akorn, Inc., Introgen Therapeutics, Inc. and Neopharm, Inc. Dr. Kapoor is a Chairman of several private companies and a director of several other private companies. Dr. Kapoor received a B.S. degree from Bombay University and a Ph.D. in Medicinal Chemistry from the State University of New York.

Dr. Kapoor was previously the Chairman and President of Lyphomed Inc. Fujisawa Pharmaceutical Co. Ltd. was a major stockholder of Lyphomed from the mid-1980s until 1990, at which time Fujisawa completed a tender offer for the remaining shares of Lyphomed, including the shares held by Dr. Kapoor. In 1992, Fujisawa filed suit in federal district court in Illinois against Dr. Kapoor alleging that between 1980 and 1986, Lyphomed filed a large number of allegedly fraudulent new drug applications with the FDA, and that Dr. Kapoor's failure to make certain disclosures to Fujisawa constituted a violation of federal securities laws and the Racketeer Influenced and Corrupt Organizations Act. Fujisawa also alleged state law claims. Dr. Kapoor countersued, and in 1999, the litigation was settled on terms mutually acceptable to the parties. The terms of the settlement are subject to a confidentiality agreement. Dr. Kapoor also controls Inpharmakon Corporation, a party to one of our development agreements. Dr. Kapoor is the trustee of the John N. Kapoor Trust, dated September 30, 1989 which is a partner in Kapoor-Pharma Investments, L.P.

Pierre Lapalme was elected a director in April 2000. His term as director will expire at the annual meeting of the stockholders to be held in 2005. Mr. Lapalme has served as the President and Chief Executive Officer of Ethypharm Inc. (North America), a global drug delivery systems company, since 1997. He is non-executive Chairman of the Board of DiagnoCure Inc., a biopharmaceutical company specializing in the development and marketing of products aimed at the diagnosis and treatment of genito-urinary cancers. He is a director of Eximas Pharmaceuticals, a Pennsylvania based company. He is a former member of the Board of the National Pharmaceutical Council U.S.A. and of the Pharmaceutical Manufacturers Association of Canada (PMAC). From 1979 to 1990, Mr. Lapalme was Chief Executive Officer and President of Rhone-Poulenc Canada Inc. and Rhone-Poulenc Pharmaceuticals North America. He was

appointed Senior Vice President and General Manager Rhone-Poulenc Rorer North America in 1990 and served in that position until 1994. Mr. Lapalme attended the University of Western Ontario and INSEAD France.

Jon S. Saxe was elected a director in January 2000. His term as director will expire at the annual meeting of stockholders to be held in 2004. He also serves as director of Protein Labs, Inc., of which he served as President from January 1995 to May 1999. In addition, he is a director of Questcor Pharmaceuticals Inc., Incyte Genomics Inc., ID Biomedical Corporation, Insite Vision, SciClone Pharmaceuticals, Inc. and is a director of several private companies. Mr. Saxe served as President of Saxe Associates, a biotechnology consulting firm, from May 1993 to December 1994 and is currently a Principal. He served as the President, Chief Executive Officer and a director of Synergen, Inc., a biopharmaceutical company, from October 1989 to April 1993. Mr. Saxe served in various positions including Vice President of Licensing and Corporate Development and Head of the Patent Law Department for Hoffmann-LaRoche, Inc. from 1960 through 1989. Mr. Saxe received a B.S. Ch.E. degree from Carnegie-Mellon University, a J.D. degree from George Washington University School of Law and an L.L.M. degree from New York University School of Law.

Patrick J. Zenner was appointed to the board of directors in April 2002 and his term as director will expire at the annual meeting of stockholders to be held in 2005. From 1993 to 2001, Mr. Zenner served as President and Chief Executive Officer of Hoffmann-LaRoche Inc. and served on its Global Pharmaceutical Executive Committee. From 1969 to 1993, Mr. Zenner held various positions at Hoffmann-LaRoche including sales representative and Vice President and General Manager of Roche Laboratories. He is a director of Dendrite International, Praecis Pharmaceuticals Inc., Geron Corporation, Genta Inc., West Pharmaceutical Services, Arqule Inc., CaraGen Corp., and Xoma Ltd. Mr. Zenner received a B.S.B.A. from Creighton University and an M.B.A. from Farleigh Dickinson University.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our executive officers, directors and 10% stockholders to file reports regarding initial ownership and changes in ownership with the Securities and Exchange Commission and the Nasdaq Stock Market. Executive officers, directors and 10% stockholders are required by Securities and Exchange Commission regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of copies of forms filed with the Securities and Exchange Commission pursuant to Section 16(a) of the Exchange Act or written representations from reporting persons, we believe that with respect to 2002, all Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with other than the following: The Form 3 filed on February 6, 2002 reporting the initial security ownership of Michael Leone was filed late, the Form 5 filed on February 15, 2002 reporting Brent Dixon's option grant was filed late, the Form 3 filed on August 6, 2002 reporting Patrick Zenner's initial security ownership was filed late and the Form 4 filed on December 4, 2002 reporting Andrew Shales' option grant was filed late.

#### **ITEM 11. EXECUTIVE COMPENSATION**

This information is incorporated by reference from our Proxy Statement for the 2003 Annual Meeting of Stockholders under the heading "Executive Compensation."

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

This information is incorporated by reference from our Proxy Statement for the 2003 Annual Meeting of Stockholders under the heading "Security Ownership of Certain Beneficial Owners and Management."

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

This information is incorporated by reference from our Proxy Statement for the 2003 Annual Meeting of Stockholders under the heading "Certain Relationships and Related Transactions."

### **ITEM 14. CONTROLS AND PROCEDURES**

We maintain a set of disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file under the Securities Exchange Act of 1934, as amended ("Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. As of a date (the "Evaluation Date") occurring within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-15 of the Exchange Act. As of the date that the evaluation was completed, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures provide reasonable assurance that (i) information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

We are committed to a continuing process of identifying, evaluating and implementing improvements to the effectiveness of our disclosure and internal controls and procedures. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our controls and procedures will prevent all errors. 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues 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 a 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 is also 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, controls 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 any control system, misstatements due to error or violations of law may occur and not be detected.

Since the Evaluation Date, there have not been any significant changes in our internal controls or, to the knowledge of management, in other factors that could significantly affect such controls.

**PART IV**

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

(a) Documents filed as a part of this report:

(1) Financial Statements

Independent Auditors' Report .....	F-1
Report of Independent Public Accountants .....	F-2
Consolidated Balance Sheets as of December 31, 2001 and 2002 .....	F-3
Consolidated Statements of Operations for the years ended December 31, 2000, 2001 and 2002 .....	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 2001 and 2002 .....	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2000, 2001 and 2002 .....	F-6
Notes to Consolidated Financial Statements .....	F-7

(2) Financial Statement Schedule

Independent Auditors' Report .....	S-1
Independent Auditors' Report .....	S-2
Valuation and Qualifying Accounts .....	S-3

All other schedules have been omitted because of the absence of conditions under which they are required or because the required information is given in the above-listed financial statements or notes thereto

(3) The following Exhibits are filed herewith or incorporated herein by reference.

Exhibit Number	Description
3.1(1)	— Restated Certificate of Incorporation of the Registrant, as amended
3.2(2)	— Amended and Restated Bylaws of the Registrant
3.3(3)	— Certificate of Amendment of Restated Certificate of Incorporation
4.1(2)	— Form of Stock Certificate
4.2(4)	— Credit Agreement dated as of February 11, 2003 among the Registrant, Various Lenders and LaSalle Bank National Association, as Administrative Agent
4.3(5)	— Shareholder Protection Rights Agreement
4.4(2)	— Reimbursement Agreement dated April 14, 2000 between the Registrant and Kapoor Children's 1992 Trust
10.1(2)	— 1997 Non-Qualified Stock Option Plan
10.2(2)	— 2000 Stock Plan
10.3(13)	— 2002 Stock Plan
10.4(2)	— Form of Nonqualified Stock Option Agreement
10.5(1)	— Form of Employment Agreement dated as of January 21, 2002 between the Registrant and its Executive Officers.
10.6(6)	— Lease Agreement dated December 31, 2001 between the Registrant and Castle Investment Company, Inc.

Exhibit Number	Description
10.7(2+)	— Development and Supply Agreement dated March 25, 1999 between the Registrant and Penwest Pharmaceuticals Co.
10.8(2+)	— Collaboration Agreement dated October 31, 1998 between the Registrant and Inpharmakon Corporation
10.9(2+)	— Manufacturing and Supply Agreement dated April 23, 1999 between the Registrant and Mikart, Inc.
10.10(2+)	— Product Supply Agreement dated January 29, 1999 between the Registrant and American Home Products Corporation
10.11(2+)	— License Agreement dated January 29, 1999 between the Registrant and American Home Products Corporation
10.12(2+)	— Distribution Agreement dated July 22, 1999 between the Registrant and G. Pohl-Boskamp GmbH & Co.
10.13(2)	— Form of Indemnity Agreement between the Registrant and its Directors and Executive Officers
10.14(2+)	— Asset Purchase Agreement dated April 10, 2000 between the Registrant and Warner-Lambert Company
10.15(2+)	— Supply Agreement dated April 14, 2000 between the Registrant and Warner-Lambert Company
10.16(2+)	— Asset Purchase Agreement dated April 14, 2000 between the Registrant and Warner-Lambert Company
10.17(2)	— Amendment No. 1 to the Product Development and Supply Agreement, dated May 3, 2000 between the Registrant and Penwest Pharmaceuticals Co.
10.18(2)	— Amendment to the Collaboration Agreement, dated May 3, 2000 between the Registrant and Inpharmakon Corporation
10.19(8)	— Asset Purchase Agreement dated July 27, 2001 between the Registrant and Sanofi-Synthelabo, Inc.
10.20(8)	— Supply Agreement dated May 3, 2001 between Sanofi-Synthelabo, Inc. and Banner Pharmacaps Inc.
10.21(8)	— Manufacturing and Supply Agreement dated as of October 1, 1999 between Sanofi-Synthelabo, Inc. and Patheon, Inc.
10.22(9)	— Manufacturing and Supply Agreement dated January 21, 2001 between the Registrant and Mikart, Inc.
10.23(6)	— Mutual Release Agreement dated as of December 19, 2001 between the Registrant and R. Brent Dixon
10.24(6)	— Letter of Separation of Employment dated December 18, 2001 between the Registrant and R. Brent Dixon
10.25(10)	— Letter of Separation of Employment dated December 10, 2002 between the Registrant and Michael A. Leone
10.26(11)	— Asset Purchase Agreement by and between the Registrant and Dura Pharmaceuticals, Inc. dated as of December 21, 2001
10.27(11)	— Supply Agreement between the Registrant and Dura Pharmaceuticals, Inc. dated December 21, 2001
10.28(7)	— Asset Purchase Agreement between the Registrant and AstraZeneca UK Limited dated February 12, 2002
10.29(7)	— Distributorship Agreement between the Registrant and Bayer AG dated December 12, 2001
10.30(6)	— Trademark Purchase and Assignment Agreement by and between the Registrant and Bayer Aktiengesellschaft dated as of December 13, 2001

Exhibit Number	Description
10.31(6)	— First Amendment to Asset Purchase Agreement dated January 17, 2002 between the Registrant and Sanofi-Synthelabo, Inc.
10.32(7)	— Distributorship Agreement between the Registrant and Bayer AG dated December 12, 2001
10.33(6)	— Trademark Purchase and Assignment Agreement by and between the Registrant and Bayer Aktiengesellschaft dated as of December 13, 2001
10.34(6)	— First Amendment to Asset Purchase Agreement dated January 17, 2002 between the Registrant and Sanofi-Synthelabo Inc.
10.35(12)	— Exclusive License Agreement dated June 27, 2002 between the Company and Jame Fine Chemicals Inc.
10.36(1)	— Nonexclusive Sublicense Agreement dated June 27, 2002 between the Company and Jame Fine Chemicals Inc.
10.37(12)	— Exclusive Distribution Agreement dated June 27, 2002 between the Company and Unisource, Inc.
21(10)	— Subsidiaries of the Registrant
23.1(10)	— Consent of Deloitte & Touche LLP
23.2(10)	— Notice Regarding Consent of Arthur Andersen LLP
(1)	Incorporated by reference from the Registrant's Form 10-Q for the quarter ended September 30, 2002 (Commission File No. 000-30123).
(2)	Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-30764). Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-56954).
(3)	Incorporated by reference from the Registrant's Form 10-Q for the quarter ended June 30, 2002 (Commission File No. 000-30123).
(4)	Incorporated by reference from the Registrant's Form 8-K filed on February 25, 2003 (Commission File No. 000-30123).
(5)	Incorporated by reference from the Registrant's Form 10-Q for the quarter ended March 31, 2002 (Commission File No. 000-30123).
(6)	Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-83698).
(7)	Incorporated by reference from the Registrant's Form S-1 (Commission File No. 333-83698). The Registrant has requested confidential treatment for certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.
	+ Confidential treatment was granted for certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.
(8)	Incorporated by reference from the Registrant's Form 10-Q for the quarter ended September 30, 2001 (Commission File No. 000-30123). The Company has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.
(9)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 13, 2001 (Commission File No. 000-30123). The Registrant has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.
(10)	Filed herewith.
(11)	Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 7, 2002 (Commission File No. 000-30123). The Registrant has requested confidential treatment of portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

- (12) Incorporated by reference from the Registrant's Form 10-Q for the quarter ended September 30, 2002 (Commission File No. 000-30123). Confidential treatment was granted for portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.
- (13) Incorporated by reference from the Registrants Proxy Statement for its May 24, 2002 Annual Meeting.
- (b) Reports on Form 8-K.

We did not file any reports on Form 8-K during the quarter ended December 31, 2002.





## CERTIFICATIONS

I, Mahendra G. Shah, Ph.D., Chief Executive Officer of First Horizon Pharmaceutical Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of First Horizon Pharmaceutical Corporation;
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 these 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 the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

March 18, 2003

/s/ MAHENDRA G. SHAH, PH.D.

Mahendra G. Shah, Ph.D.  
Chairman, Chief Executive Officer and President

I, Darrell Borne, Chief Financial Officer of First Horizon Pharmaceutical Corporation, certify that:

1. I have reviewed this annual report on Form 10-K of First Horizon Pharmaceutical Corporation;
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 these 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 the registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

March 18, 2003

/s/ DARRELL BORNE

Darrell Borne  
Chief Financial Officer, Treasurer and Secretary

## INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Stockholders of  
First Horizon Pharmaceutical Corporation

We have audited the accompanying consolidated balance sheet of First Horizon Pharmaceutical Corporation (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2002 and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. The consolidated financial statements of the Company as of December 31, 2001 and for each of the two years then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those consolidated financial statements in their report dated February 12, 2002.

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

In our opinion, the 2002 consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2002 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Deloitte & Touche LLP

Atlanta, Georgia  
February 14, 2003

The following report of Arthur Andersen LLP ("Andersen") is a copy of the report previously issued by Andersen on February 12, 2002. The report of Andersen is included in this annual report on Form 10-K pursuant to rule 2-02(e) of regulation S-X. The Company has not been able to obtain a reissued report from Andersen. Andersen has not consented to the inclusion of its report in this annual report on Form 10-K. Because Andersen has not consented to the inclusion of its report in this annual report, it may be difficult to seek remedies against Andersen, and the ability to seek relief against Andersen may be impaired.

To the Board of Directors and Stockholders of  
First Horizon Pharmaceutical Corporation

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

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

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

/s/ ARTHUR ANDERSEN LLP

Atlanta, Georgia  
February 12, 2002

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	December 31,	
	2001	2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 53,458	\$ 47,409
Accounts receivable, net of allowance for doubtful accounts and discounts of \$1,087 and \$767 at December 31, 2001 and December 31, 2002, respectively . . . . .	12,244	15,904
Inventories . . . . .	4,363	17,444
Samples and other prepaid expenses . . . . .	1,243	3,413
Income taxes receivable . . . . .	1,674	—
Current deferred tax assets . . . . .	323	6,647
<b>Total current assets</b> . . . . .	<b>73,305</b>	<b>90,817</b>
Property and equipment, net . . . . .	710	1,607
Other assets:		
Intangibles, net . . . . .	92,849	260,441
Deferred tax assets . . . . .	2,230	—
Other . . . . .	1,056	67
<b>Total other assets</b> . . . . .	<b>96,135</b>	<b>260,508</b>
<b>Total assets</b> . . . . .	<b>\$170,150</b>	<b>\$352,932</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Account payable . . . . .	\$ 4,540	\$ 5,316
Accrued expenses . . . . .	22,102	40,547
<b>Total current liabilities</b> . . . . .	<b>26,642</b>	<b>45,863</b>
Long-term liabilities:		
Deferred tax liabilities . . . . .	—	1,221
Other long-term liabilities . . . . .	144	165
<b>Total liabilities</b> . . . . .	<b>26,786</b>	<b>47,249</b>
<b>COMMITMENTS AND CONTINGENCIES (NOTE 10 and 12)</b>		
Stockholders' equity:		
Preferred stock, 1,000,000 shares authorized and none outstanding . . . . .	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 27,626,002 and 35,436,629 shares issued and outstanding at December 31, 2001 and December 31, 2002, respectively . . . . .	28	35
Additional paid-in capital . . . . .	131,560	287,306
Deferred compensation . . . . .	(557)	(207)
Retained earnings . . . . .	12,333	18,499
Accumulated other comprehensive income . . . . .	—	50
<b>Total stockholders' equity</b> . . . . .	<b>143,364</b>	<b>305,683</b>
<b>Total liabilities and stockholders' equity</b> . . . . .	<b>\$170,150</b>	<b>\$352,932</b>

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

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT PER SHARE DATA)**

	Year Ended December 31,		
	2000	2001	2002
Net revenues . . . . .	\$36,650	\$69,290	\$115,178
Operating costs and expenses:			
Cost of revenues . . . . .	5,436	10,354	23,967
Selling, general and administrative expense . . . . .	24,217	38,689	61,843
Depreciation and amortization . . . . .	1,091	2,724	14,471
Research and development expense . . . . .	1,784	1,819	1,096
Total operating costs and expenses . . . . .	<u>32,528</u>	<u>53,586</u>	<u>101,377</u>
Operating income . . . . .	4,122	15,704	13,801
Other (expense) income:			
Interest expense . . . . .	(324)	(4)	(2,776)
Interest income . . . . .	348	1,874	492
Other . . . . .	21	4	(7)
Total other (expense) income . . . . .	<u>45</u>	<u>1,874</u>	<u>(2,291)</u>
Income before provision for income taxes . . . . .	4,167	17,578	11,510
Provision for income taxes . . . . .	<u>(1,660)</u>	<u>(6,855)</u>	<u>(4,481)</u>
Net income before extraordinary items . . . . .	2,507	10,723	7,029
Extraordinary item, net of taxes . . . . .	—	—	(863)
Net income . . . . .	<u>\$ 2,507</u>	<u>\$10,723</u>	<u>\$ 6,166</u>
Other Comprehensive income:			
Foreign currency translation adjustment . . . . .	—	—	50
Comprehensive income . . . . .	<u>\$ 2,507</u>	<u>\$10,723</u>	<u>\$ 6,216</u>
Net income (loss) per common share:			
Income before extraordinary item . . . . .	\$ 0.15	\$ 0.44	\$ 0.21
Extraordinary item, net of taxes . . . . .	\$ —	\$ —	\$ (0.03)
Basic earnings per common share . . . . .	<u>\$ 0.15</u>	<u>\$ 0.44</u>	<u>\$ 0.19</u>
Income before extraordinary item . . . . .	\$ 0.13	\$ 0.41	\$ 0.21
Extraordinary item, net of taxes . . . . .	\$ —	\$ —	\$ (0.03)
Diluted earnings per common share . . . . .	<u>\$ 0.13</u>	<u>\$ 0.41</u>	<u>\$ 0.18</u>
Weighted average common shares outstanding:			
Basic . . . . .	<u>16,612</u>	<u>24,474</u>	<u>32,930</u>
Diluted . . . . .	<u>19,106</u>	<u>25,845</u>	<u>33,749</u>

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

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**

	Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated (Deficit) Earnings	Accumulated Other Comprehensive Income	Total
	Shares	Amount					
BALANCE, December 31, 1999 . . . . .	8,539,643	\$ 9	\$ 5,787	\$(1,284)	\$ (897)	\$—	\$ 3,615
Stock options exercised . . . . .	54,963	—	79	—	—	—	79
Net proceeds from the sale of shares . . . . .	4,378,294	4	31,183	—	—	—	31,187
Tax benefit from nonqualified stock option exercises . . . . .	—	—	415	—	—	—	415
Deferred compensation . . . . .	—	—	328	441	—	—	769
Net income . . . . .	—	—	—	—	2,507	—	2,507
BALANCE, December 31, 2000 . . . . .	12,972,900	13	37,792	(843)	1,610	—	38,572
Stock options exercised . . . . .	453,628	—	645	—	—	—	645
Net proceeds from the sale of shares . . . . .	4,604,266	5	83,679	—	—	—	83,684
Three-for-two common stock split . . . . .	9,015,397	9	(9)	—	—	—	—
Stock options exercised post stock split . . . . .	573,468	1	335	—	—	—	336
Employee stock purchase plan . . . . .	6,343	—	109	—	—	—	109
Tax benefit from nonqualified stock option exercises . . . . .	—	—	8,922	—	—	—	8,922
Deferred compensation . . . . .	—	—	87	286	—	—	373
Net income . . . . .	—	—	—	—	10,723	—	10,723
BALANCE, December 31, 2001 . . . . .	27,626,002	28	131,560	(557)	12,333	—	143,364
Stock options exercised . . . . .	332,485	—	1,689	—	—	—	1,689
Net proceeds from the sale of shares . . . . .	7,475,000	7	153,075	—	—	—	153,082
Employee stock purchase plan . . . . .	19,542	—	194	—	—	—	194
Shares repurchased and retired . . . . .	(16,400)	—	(76)	—	—	—	(76)
Tax benefit from nonqualified stock option exercises . . . . .	—	—	864	—	—	—	864
Deferred compensation . . . . .	—	—	—	350	—	—	350
Net income . . . . .	—	—	—	—	6,166	—	6,166
Other comprehensive income:							
Foreign currency translation adjustment . . . . .	—	—	—	—	—	50	50
BALANCE, December 31, 2002 . . . . .	<u>35,436,629</u>	<u>\$35</u>	<u>\$287,306</u>	<u>\$ (207)</u>	<u>\$18,499</u>	<u>\$50</u>	<u>\$305,683</u>

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

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(IN THOUSANDS)**

	Year Ended December 31,		
	2000	2001	2002
Cash flows from operating activities:			
Net income	\$ 2,507	\$ 10,723	\$ 6,166
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	1,091	2,724	14,471
Amortization of loan costs	—	—	1,678
Loss on early extinguishment of debt	—	—	1,404
Deferred income tax benefit	(241)	(1,838)	(2,873)
Non-cash compensation expense	769	373	350
Loss on disposal of property and equipment	25	—	102
Reduction in taxes payable—stock option exercises	415	8,922	864
Changes in assets and liabilities, net of acquired assets and liabilities:			
Accounts receivable	(3,810)	(5,534)	(3,660)
Inventories	(1,942)	(1,813)	(7,358)
Samples, other prepaid expenses and other assets	(788)	98	(2,180)
Income taxes receivable	—	(1,674)	1,674
Notes receivable from related party	30	—	—
Accounts payable	1,021	2,725	776
Accrued expenses and other	4,198	9,341	15,899
Net cash provided by operating activities	3,275	24,047	27,313
Cash flows from investing activities:			
Purchase of products	(16,509)	(69,179)	(183,879)
Purchase of property and equipment	(547)	(191)	(1,340)
Net cash used in investing activities	(17,056)	(69,370)	(185,219)
Cash flows from financing activities:			
Payments on revolving loan agreement, net	(800)	—	—
Capitalized financing costs incurred	—	—	(3,082)
Principal payments on long-term debt	(12,177)	(221)	(137,000)
Proceeds from long-term debt	9,500	—	137,000
Net proceeds from issuance of common stock	31,266	84,774	154,965
Repurchase of common stock	—	—	(76)
Net cash provided by financing activities	27,789	84,553	151,807
Effects of foreign currency exchange rates on cash	—	—	50
Net change in cash and cash equivalents	14,008	39,230	(6,049)
Cash and cash equivalents, beginning of period	220	14,228	53,458
Cash and cash equivalents, end of period	<u>\$ 14,228</u>	<u>\$ 53,458</u>	<u>\$ 47,409</u>

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



**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Description of Business.* First Horizon Pharmaceutical Corporation (formerly Horizon Pharmaceutical Corporation, the "Company"), a Delaware corporation, is a specialty pharmaceutical company that markets and sells brand name prescription products to primary care and select specialty physicians in the U.S. through their nationwide sales and marketing force. In addition, limited sales to European customers are made through local distributors in the region. The Company focuses on the treatment of cardiovascular, obstetrical and gynecological, pediatric and gastroenterological conditions and disorders. The Company's strategy is to acquire or license pharmaceutical products that other companies do not actively market, or that the Company believes have high sales growth potential, are promotion-sensitive and complement the Company's existing products. In addition, the Company seeks to maximize the value of their drugs by developing new patentable formulations, using new delivery methods and seeking regulatory approval for new indications of existing drugs.

*Principles of Consolidation.* The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

*Revenue Recognition.* Revenues from product sales are recognized upon shipment to customers and are shown net of sales adjustments for discounts, rebates to customers, returns and other adjustments, which are provided in the same period that the related sales are recorded.

In December 1999, the Securities and Exchange Commission issued Staff Accounting Bulletin ("SAB") No. 101, "Revenue Recognition in Financial Statements." SAB No. 101 is applicable to public companies and provides guidance on applying accounting principles generally accepted in the U.S. to revenue recognition issues in financial statements. Management believes the Company's revenue recognition criteria are consistent with the guidance provided by SAB No. 101.

*Revenue Deductions.* Rebate costs, which are recorded as a reduction of sales, include estimated amounts for volume rebate programs, contractual price reductions with wholesalers and insurance providers, and certain other sales related deductions. Provision for these estimated costs are recorded at the time of sale and are periodically adjusted to reflect actual experiences.

*Product Returns.* The Company's customers generally may return product from six months prior to the expiration date of the product until twelve months after expiration. In accordance with Statement of Financial Accounting Standards ("SFAS") No. 48, "Revenue Recognition When Right of Return Exists," a provision for these estimated returns is recorded at the time of sale based on historical returns of the product, product specific information provided by customers and information obtained from independent sources regarding the levels of inventory being held by customers, as well as overall purchasing patterns by customers. The provision is periodically adjusted to reflect actual experience. These costs are recorded as a reduction of sales. An adjustment of \$135,000 was recorded to reduce the provision for product returns in December 2002.

In connection with the acquisition of product rights, the Company also assumes certain liabilities for returns of product shipped by the seller prior to the acquisition date. At the acquisition date, the Company

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

estimates the amount of assumed liabilities based on actual sales return data from the seller. This amount is included in the purchase price allocation. The Company periodically reviews this estimated liability.

*Cost of Revenues.* Cost of revenues is comprised of purchased product costs. In 2001, the cost of revenues included \$118,000 of amortization of intangible assets associated with manufacturing and supply agreements entered into in connection with the purchase of products.

*Royalties.* The Company pays royalties on the sale of certain products. These costs are included in selling, general and administrative expenses in the accompanying statements of operations. Total royalties were \$2.1 million, \$3.4 million, and \$3.8 million for the years ending December 31, 2000, 2001 and 2002, respectively.

*Research and Development.* Research and development expenses consist primarily of costs incurred to develop formulations, engage contract research organizations to conduct clinical studies, test products under development and engage medical and regulatory consultants. The Company expenses all research and development costs as incurred. Research and development costs were \$1.8 million, \$1.8 million and \$1.1 million for the years ended December 31, 2000, 2001 and 2002, respectively.

*Cash and Cash Equivalents.* The Company considers only those investments that are highly liquid, and readily convertible to cash with an original maturity of three months or less to be cash equivalents.

*Concentration of Credit Risk.* The Company extends credit on an uncollateralized basis primarily to wholesale drug distributors and retail pharmacy chains throughout the U.S. The Company is required to estimate the level of accounts receivable which ultimately will not be paid. The Company calculates this estimate based on prior experience supplemented by a periodic customer specific review when needed. Historically, the Company has not experienced significant credit losses on its accounts. The Company's three largest customers accounted for approximately 82% and 73% of accounts receivable at December 31, 2001 and 2002, respectively.

The mix of sales of the Company's products changes as products are added. On a combined basis, products with sales greater than 10% of the Company's sales comprised approximately 66%, 66%, and 85% of total sales in 2000, 2001 and 2002, respectively.

The following table presents a summary of sales to significant customers as a percentage of the Company's total revenues:

<u>Customer</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>
McKesson Corporation . . . . .	29%	22%	23%
Cardinal Health, Inc (including Bindley Western) . . . . .	25	40	23
AmerisourceBergen Corporation . . . . .	19	20	31

The Company's international sales represent less than 3% of sales for the periods presented.

*Segment Reporting.* The Company operates in a single segment, the sale and marketing of prescription products.

*Inventories.* Inventories consist of purchased pharmaceutical products and are stated at the lower of cost or market. Cost is determined using the first-in, first-out method, and market is considered to be net

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

realizable value. Inventories consist of finished product and bulk product awaiting processing and packaging into finished product. Inventories at December 31, 2001 and 2002 consisted of (in thousands):

	<u>2001</u>	<u>2002</u>
Bulk product . . . . .	\$ 581	\$7,543
Finished product . . . . .	3,782	9,901
	4,363	17,444

*Samples.* Samples primarily consist of product samples used in the sales and marketing efforts of the Company's products. Samples are expensed upon distribution as a selling expense. Sample inventories at December 31, 2001 and 2002 were \$827,000 and \$2.3 million, respectively.

*Property and Equipment.* Property and equipment are recorded at cost, less accumulated depreciation. Major improvements, which extend the lives of existing property and equipment, are capitalized. Expenditures for maintenance and repairs are charged to expense as incurred. Upon retirement or disposal of assets, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized as other income (expense) in the statement of operations.

Depreciation is provided for on the straight-line basis over the estimated useful lives of the assets as follows:

Office equipment . . . . .	5 to 10 years
Furniture and fixtures . . . . .	5 to 10 years
Computer hardware and software . . . . .	3 to 5 years
Leasehold improvements . . . . .	based on term of lease

The components of property and equipment at December 31, 2001 and 2002 are as follows (in thousands):

	<u>2001</u>	<u>2002</u>
Office equipment . . . . .	\$ 93	\$ 95
Furniture and fixtures . . . . .	227	421
Computer hardware and software . . . . .	477	1,052
Leasehold improvements . . . . .	318	679
	1,115	2,247
Less accumulated depreciation . . . . .	(405)	(640)
Property and equipment, net . . . . .	\$ 710	\$1,607

Depreciation expense related to property and equipment for the years ended December 31, 2000, 2001 and 2002 was \$141,000, \$284,000 and \$341,000, respectively.

In the event that facts and circumstances indicate that the carrying amounts of property and equipment may be impaired, an evaluation of recoverability is performed using the estimated future undiscounted cash flows associated with the asset compared to the asset's carrying amount to determine if a write-down is required, pursuant to the provisions of SFAS No. 144 "Accounting for the Impairment or

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Disposal of Long-Lived Assets" and its related interpretations. Any impairment loss is measured as the difference between the carrying amount and the fair value of the impaired asset. The Company believes there are no impaired assets as of December 31, 2002.

*Intangible Assets.* Intangible assets, which include license rights, tradenames, managed care contracts and distribution, manufacturing and supply agreements, are stated at cost, net of accumulated amortization. These costs are capitalized and amortized on a straight-line basis over the estimated periods benefited by the asset (1 to 20 years). Amortization of such assets, excluding distribution, manufacturing and supply agreements, is included in depreciation and amortization expense in the accompanying statements of operations. Amortization expense for the years ended December 31, 2000, 2001 and 2002 totaled \$950,000, \$2.6 million and \$14.1 million, respectively. Included in the \$2.6 million of amortization expense in 2001 is \$118,000 of amortization of upfront fees paid to secure distribution, manufacturing and supply agreements in connection with two product acquisitions in 2001. This amortization expense is included in the cost of revenues. These distribution, manufacturing and supply agreements are discussed in more detail in Notes 8 and 10.

In accordance with SFAS No. 144, the Company continually reevaluates the propriety of the carrying amount of the definite lived intangibles as well as the related amortization period to determine whether current events and circumstances warrant adjustments to the carrying values and/or estimates of useful lives. This evaluation is performed using the estimated projected future undiscounted cash flows associated with the asset compared to the asset's carrying amount to determine if a write-down is required. To the extent such projections indicate that the undiscounted cash flows are not expected to be adequate to recover the carrying amounts, the assets are written down to fair value as determined by discounting future cash flows. The Company believes there are no intangible asset impairments and there were no asset write-downs as of December 31, 2002.

*Shipping and Handling.* Costs incurred related to freight-in are included in cost of revenues and costs related to freight-out are included in selling, general and administrative expense. The Company does not bill for freight.

*Income Taxes.* The Company provides for income taxes in accordance with SFAS No. 109 "Accounting for Income Taxes." SFAS No. 109 requires recognition of deferred tax assets and liabilities using currently enacted tax rates.

*Advertising Costs.* The Company charges the costs of advertising to expense as incurred. Advertising expenses were \$1.2 million, \$2.9 million and \$5.2 million for the years ended December 31, 2000, 2001 and 2002, respectively.

*Financial Instruments.* The Company's carrying value of financial instruments approximates fair value due to the short maturity of those instruments.

*Foreign Currency Exposure.* Certain of the Company's product purchases and sales are denominated in foreign currencies. Gains or losses on foreign currency transactions are included in income as incurred. The Company enters into short term forward foreign exchange contracts in relation to certain purchases of two of its products. These forward contracts are not designated as hedging instruments and as such any change in fair value while open is recognized currently in income. This gain or loss offsets the transaction gain or loss on the underlying foreign denominated payables. Foreign denominated payables, receivables and open exchange contracts as of December 31, 2001 and 2002 were insignificant.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Common Stock Split.* On August 24, 2001 the Company's Board of Directors authorized a three-for-two stock split effected in the form of a stock dividend distributed on September 24, 2001 to stockholders of record as of September 10, 2001. As a result of the stock split, the accompanying consolidated financial statements reflect an increase in the number of outstanding shares of common stock and the transfer of the par value of these additional shares from paid-in capital. All references to the number of shares (other than transactions prior to September 10, 2001 on the Consolidated Statements of Stockholders' Equity), per share amounts and any other reference to shares in the Consolidated Financial Statements and the accompanying Notes to the Consolidated Financial Statements have been adjusted to reflect the split on a retroactive basis.

*Stock Options.* At December 31, 2002, the Company had three stock-based employee compensation plans, which are described more fully in Note 6. The Company applies Accounting Principles Board Opinion ("APB") No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for all stock options issued to employees. Accordingly, the Company records compensation expense for any stock option grants with exercise prices lower than fair value, recognized ratably over the vesting period. The Company has recognized compensation expense related to stock option grants of \$769,000, \$373,000 and \$350,000 for the years ended December 31, 2000, 2001 and 2002, respectively. The 2000 compensation expense includes \$361,000 related to accelerated vesting granted to a retiring executive.

*Earnings Per Share.* As required by SFAS No. 128, "Earnings Per Share," the Company has presented basic and diluted earnings per common share amounts in the accompanying financial statements. Basic earnings per common share are calculated based on the weighted average common shares outstanding during the year. Diluted earnings per common share are calculated similarly to basic earnings per common share except that the weighted average shares outstanding are increased to include additional shares from the assumed exercise of stock options, if dilutive. The number of additional shares is calculated by assuming that outstanding stock options that are dilutive were exercised and that the proceeds from such exercises were used to acquire shares of common stock at the average market price during the period.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Below is the calculation of basic and diluted net income per common share (in thousands, except per share data):

	Year Ended December 31,		
	2000	2001	2002
Net income before extraordinary item . . . . .	\$ 2,507	\$10,723	\$ 7,029
Extraordinary item, net of taxes . . . . .	—	—	(863)
Net income . . . . .	<u>\$ 2,507</u>	<u>\$10,723</u>	<u>\$ 6,166</u>
Weighted average common shares outstanding—basic . . . . .	16,612	24,474	32,930
Dilutive effect of stock options . . . . .	2,494	1,371	819
Weighted average common shares outstanding—diluted . . . . .	<u>19,106</u>	<u>25,845</u>	<u>33,749</u>
Basic net income per share, before extraordinary item . . . . .	0.15	0.44	0.21
Extraordinary item, net of taxes . . . . .	—	—	(0.03)
Basic net income per share . . . . .	<u>\$ 0.15</u>	<u>\$ 0.44</u>	<u>\$ 0.19</u>
Diluted net income per share, before extraordinary item . . . . .	0.13	0.41	0.21
Extraordinary item, net of taxes . . . . .	—	—	(0.03)
Diluted net income per share . . . . .	<u>\$ 0.13</u>	<u>\$ 0.41</u>	<u>\$ 0.18</u>

The number of outstanding options, which are excluded from the above calculation as their impact would be anti-dilutive, are 122,850, 692,650 and 1,747,441 for the years ended December 31, 2000, 2001 and 2002, respectively.

*Other Comprehensive Income.* Assets and liabilities for non-U.S. subsidiaries are translated from local currencies to U.S. dollars using exchange rates at the end of the period. Results of operations for non-U.S. subsidiaries are translated using average exchange rates for the period. Adjustments resulting from the translation process are reported in a separate component of stockholders' equity and are not included in the determination of the results of operations.

*Supplemental Cash Flow Disclosures.* Supplemental cash flow information for the years ended December 31, 2000, 2001 and 2002 was as follows (in thousands):

	2000	2001	2002
Cash paid for taxes . . . . .	\$940	\$2,163	\$1,482
Cash paid for interest . . . . .	\$385	\$ 7	\$1,098

*New Accounting Pronouncements*

In July 2001, the FASB issued SFAS No. 141, "Business Combinations." SFAS No. 141 eliminates the pooling-of-interest method of accounting for business combinations. SFAS No. 141 is effective for any business combination completed after June 30, 2001. The adoption of SFAS No. 141 did not have a material impact on the Company's financial condition or results of operations.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

In July 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets." Under SFAS No. 142, goodwill and indefinite lived intangible assets are no longer amortized. Separate intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives. SFAS No. 142 also establishes a new method of testing goodwill and other unamortized intangible assets for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would reduce the fair value of that goodwill or other intangible asset below its carrying value. The amortization provisions of SFAS No. 142 apply to goodwill and other intangible assets acquired after June 30, 2001. The adoption of SFAS No. 142 did not have a material impact on the Company's financial condition or results of operations. The Company currently has no goodwill or indefinite lived intangible assets.

In August 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long Lived Assets." SFAS No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and was effective for financial periods after January 1, 2002. The adoption of SFAS No. 144 on January 1, 2002 did not have a material impact on the Company's financial condition or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Revision of FAS Nos. 4, 44, and 64, Amendment of FASB 13 and Technical Corrections." SFAS No. 145 rescinds, amends, or makes various technical corrections to certain existing authoritative pronouncements and is effective for fiscal years beginning after May 31, 2002 for the rescission of FAS No. 4 and FAS No. 13, and all other provisions are effective for financial statements issued on or after May 15, 2002. Early adoption is encouraged. The Company does not believe the adoption of SFAS No. 145 will have a material impact on the Company's financial condition or results of operations, except as disclosed in Note 9.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities." SFAS No. 146 requires recording costs associated with exit or disposal activities at their fair values when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early adoption encouraged. The Company is currently evaluating the impact the adoption of SFAS No. 146 will have on the Company's financial condition or results of operations.

In November 2002, the FASB issued FASB Interpretation ("FIN") No. 45, "Guarantor's Accounting and Disclosure Retirements for Guarantees, including Indirect Guarantees of Indebtedness of Other." FIN 45 elaborates on disclosures to be made by a guarantor in its financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of the guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and measurement provisions of FIN No. 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements in FIN No. 45 are effective for all financial statements of periods ending after December 15, 2002. For the year ended December 31, 2002, the Company was not a guarantor on any debt instruments and had no debt outstanding at the end of the period.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123." SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

requirements of SFAS No. 123 to require more prominent disclosure in both annual and interim financial statements. The transition guidance and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing financial statements for interim periods beginning after December 15, 2002. The Company did not adopt the fair value method of valuing stock options, however, the adoption of the disclosure provisions of SFAS No. 148 did not have a material impact on the Company's financial condition or results of operations.

**2. CREDIT FACILITY**

At December 31, 2001, the Company had an existing revolving loan agreement. There were no borrowings under this revolving loan agreement at December 31, 2001. The availability under the agreement was \$2.5 million and was subject to a 0.25% fee on the unused portion. In March 2002, this revolving loan agreement was terminated as a condition of and in connection with the Company entering into a new credit facility arranged by Deutsche Bank Alex. Brown.

In March 2002, the Company entered into a six-month \$152 million senior secured credit facility with a syndicate of banks arranged through Deutsche Bank Alex. Brown. The facility consisted of a \$127 million term loan and a \$25 million revolving loan. For the Sular acquisition, as discussed in Note 8, the Company borrowed \$127 million of the term loan and \$10 million of the revolving loan. Borrowings under the term loan accrued interest at the Company's option of the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin and matured six months from the closing date of the Sular transaction. As a condition of this facility, the Company's existing revolving loan agreement was terminated. In April 2002, both the term loan and the revolving loan were repaid in full with the proceeds from the Company's follow-on offering, as discussed in Note 5. In July, 2002, the Company terminated the credit facility. For the year ended December 31, 2002, total interest paid under this credit facility was \$1.1 million.

**3. LONG-TERM DEBT**

The Company had no other debt at December 31, 2001 or December 31, 2002.

**4. ACCRUED EXPENSES**

Accrued expenses consist of the following (in thousands):

	<u>2001</u>	<u>2002</u>
Employee compensation and benefits .....	\$ 3,325	\$ 2,125
Product returns .....	3,374	12,216
Sales deductions .....	5,637	10,671
Accrued royalties .....	1,042	892
Assumed liabilities—product acquisitions .....	5,593	3,665
Income taxes payable .....	—	4,266
Other .....	3,131	6,712
	<u>\$22,102</u>	<u>\$40,547</u>



**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. STOCKHOLDERS' EQUITY**

In May 2000, the Company completed its initial public offering and issued 5,700,000 shares of common stock at a price of \$5.33 per share. In June 2000, the Company's underwriters exercised their over-allotment option and an additional 855,000 shares of common stock were issued at a price of \$5.33 per share. These offerings generated proceeds, net of offering expenses, of \$31.1 million, which the Company used to repay debt, finance product acquisitions, and for general corporate purposes.

During 2000, the Company issued 12,441 shares of common stock under its employee stock purchase plan.

In December 2000, the Company entered into a separation agreement with a retiring executive, whereby the executive will receive severance and other benefits. In addition, the vesting portion of his stock options was accelerated, generating compensation expense of \$361,000.

In May 2001, the Company completed a follow-on offering of 6,900,000 shares of common stock at a price of \$12.87 per share. The Company received net proceeds of \$83.6 million from the offering after deducting offering expenses. The proceeds were used to finance product acquisitions and for general corporate purposes.

During 2001, the Company issued 12,742 shares of common stock under its employee stock purchase plan.

In April 2002, the Company completed a follow-on offering of 7,475,000 shares of common stock at a price of \$21.75 per share. The Company received net proceeds of \$152.6 million after the exercise of the over allotment option and after deducting offering expenses. Proceeds from the offering were used to repay debt incurred under the Company's credit facility and the balance of the proceeds will be used for other general corporate purposes.

In May 2002, the Company and shareholders amended the Certificate of Incorporation to increase the number of authorized shares of common stock to 100,000,000.

In July 2002, the Company announced a share buyback program. This program allows for the repurchase of up to \$8 million in common stock until July 2003. Through December 31, 2002 the Company repurchased 16,400 shares that have been retired.

In July 2002, the Company announced the adoption of a shareholder rights plan. The terms of the plan provide for a dividend of one right to purchase a fraction of a share of a newly created class of preferred stock for each share of common stock outstanding as of the close of business on July 26, 2002, payable on August 9, 2002. The rights expire on July 26, 2012 and may only be exercised if certain conditions are met.

During 2002, the Company issued 19,542 shares of common stock under its employee stock purchase plan.

Under the Company's Restated Certificate of Incorporation the Board of Directors has the authority, without further action by the stockholders, to issue up to 1,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, without any further vote or action by the stockholders. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. STOCKHOLDERS' EQUITY (Continued)**

payments upon liquidation. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company, which could have a depressive effect on the market price of the common stock. The Company has no present plan to issue any shares of preferred stock. As of December 31, 2001 and December 31, 2002 there were no shares of preferred stock outstanding.

**6. STOCK OPTIONS**

Pursuant to the Company's 1997 Non-Qualified Stock Option Plan (the "1997 Plan"), the Board of Directors approved the issuance of options to purchase shares of common stock of the Company to various employees. Under the plan, 6,000,000 shares of common stock were reserved for issuance. Vesting periods range from immediate to four years, and options granted generally expire seven years from the date of grant. All options also include accelerated vesting provisions in the event of a change in control, as defined in the plan. In 2000, the Company terminated the 1997 Plan and no additional grants of stock options will be made under the 1997 Plan. At December 31, 2002, 900,199 options remained issued and outstanding under the 1997 Plan.

On February 14, 2000, the Board of Directors and stockholders approved the 2000 Stock Plan (the "2000 Plan"). This plan provides for the granting of incentive stock options, nonqualified stock options, stock awards or stock bonuses, and sales of stock. The 2000 Plan provides for the grants of these options and other awards to officers, directors, full- and part-time employees, advisors and consultants. Only employees may receive incentive stock options. The Company has reserved 3,000,000 shares of common stock for issuance under the 2000 Plan. The Company's compensation committee administers the 2000 Plan and has the sole authority to determine the meaning and application of the terms of the plan and all grant agreements, the persons to whom option or stock grants are made, the nature and amount of option or stock grants, the price to be paid upon exercise of each option, the period within which options may be exercised, the restrictions on stock awards, and the other terms and conditions of awards. All options granted under the 2000 Plan include accelerated vesting provisions in the event of a change in control, as defined in the plan. The 2000 Plan will terminate in February 2010. In May 2002, the 2000 plan was terminated and no additional options will be granted or awarded under this plan. At December 31, 2002, 2,023,595 options remained issued and outstanding under the 2000 plan.

On May 24, 2002, the Board of Directors and stockholders approved the 2002 Stock Plan (the "2002 Plan"). This plan provides for the granting of incentive stock options, nonqualified stock options, stock awards or stock bonuses, and sales of stock. The 2002 Plan provides for the grants of these options and other awards to officers, directors, full and part-time employees, advisors and consultants. Only full-time employees may receive incentive stock options. The aggregate number of shares available under the 2002 plan shall be seven percent of the outstanding shares of common stock on the last day of the preceding fiscal year less any options already granted under the 2002 plan. The Company's compensation committee administers the 2002 Plan and has the sole authority to determine the meaning and application of the terms of the plan and all grant agreements, the persons to whom option or stock grants are made, the nature and amount of option or stock grants, the price to be paid upon exercise of each option, the period within which options may be exercised, the restrictions on stock awards, and the other terms and conditions of awards. All options granted under the 2002 Plan include accelerated vesting provisions in the event of a change in control, as defined in the plan. The 2002 Plan will terminate in May 2012. At December 31, 2002, 287,000 options were issued and outstanding under the 2002 plan. For fiscal year 2003, there are 2,193,564 options available for issue under the 2002 plan.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. STOCK OPTIONS (Continued)**

The Company has granted stock options to officers, directors, and employees as follows:

	Number of Shares Subject to Option	Weighted Average Exercise Price
Outstanding at December 31, 1999 .....	2,628,750	1.00
Granted .....	579,600	7.26
Canceled .....	(78,900)	4.98
Exercised .....	(82,444)	0.96
Outstanding at December 31, 2000 .....	3,047,006	2.09
Granted .....	1,505,674	19.36
Canceled .....	(314,694)	7.53
Exercised .....	(1,253,910)	0.79
Outstanding at December 31, 2001 .....	2,984,076	10.78
Granted .....	758,350	16.82
Canceled .....	(199,147)	15.05
Exercised .....	(332,485)	13.43
Outstanding at December 31, 2002 .....	3,210,794	\$12.34

The following table sets forth the range of exercise prices, number of shares, weighted average exercise price, and remaining contractual lives by similar price and grant date at December 31, 2002.

Range of Exercise Price	Outstanding			Exercisable	
	Outstanding at December 31, 2002	Weighted Average Remaining Life	Weighted Average Price	Exercisable at December 2002	Weighted Average Price
\$ 0.33-\$ 3.87 .....	977,825	3.61 years	\$ 1.54	753,312	\$ 1.37
4.43- 7.13 .....	485,250	5.38 years	5.57	113,797	5.79
12.00- 14.96 .....	466,888	5.10 years	14.44	80,290	13.64
15.17- 20.00 .....	218,974	5.38 years	17.38	52,564	17.26
20.28- 29.22 .....	1,061,857	6.07 years	23.69	163,204	23.99
Total .....	3,210,794			1,163,167	

Upon the exercise of outstanding options, the Company became entitled to a tax effected benefit of \$8.9 million and \$864,000 in 2001 and 2002, respectively, which is equal to the number of options multiplied by the difference between the market price of the options as of the date of exercise and the exercise price for the options, adjusted for the impact of tax rates. The impact of the benefit has been credited to additional paid-in capital.

The Company applies Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for all stock options issued to employees. Accordingly, the Company records compensation expense for any stock option grants with exercise prices lower than fair value, recognized ratably over the vesting period. The Company has recognized compensation expense related to stock option grants of \$769,000, \$373,000 and \$350,000 in 2000, 2001 and 2002,

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. STOCK OPTIONS (Continued)**

respectively. The 2000 compensation expense includes \$361 related to accelerated vesting granted to a retiring executive.

All options granted in 2000, 2001 and 2002 have been granted at exercise prices equal to fair market value at the date of grant.

Had compensation costs for the Company's options been determined using the Black Scholes option-pricing models prescribed by SFAS No. 123, "Accounting for Stock Based Compensation," the Company's pro forma net income per common share would have been reported as follows (in thousands, except per share amounts):

	<u>2000</u>	<u>2001</u>	<u>2002</u>
Net income:			
As reported . . . . .	\$ 2,507	\$10,723	\$ 6,166
Deduct: Total stock-based employee compensation expense determined under fair value based for all awards, net of related tax effects . . . . .	<u>(247)</u>	<u>(949)</u>	<u>(2,582)</u>
Pro forma . . . . .	2,260	9,774	3,584
Net income per common share—basic:			
As reported . . . . .	0.15	0.44	0.19
Pro forma . . . . .	0.14	0.40	0.11
Net income per common share—diluted:			
As reported . . . . .	0.13	0.41	0.18
Pro forma . . . . .	0.12	0.38	0.11

The weighted average fair value of options granted during 2000, 2001 and 2002 is estimated at \$4.88, \$11.98 and \$16.82 per share, respectively. The value of options is estimated on the date of the grant using the following weighted average assumptions:

	<u>2000</u>	<u>2001</u>	<u>2002</u>
Risk-free interest rate . . . . .	6.45%	4.10%	4.36%
Expected dividend yield . . . . .	—	—	—
Expected lives . . . . .	4 years	4 years	4 years
Expected volatility . . . . .	42.0%	59.0%	105.9%

The Company adopted an employee stock purchase plan on February 14, 2000 that is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code. The Company has reserved 750,000 shares of common stock for the stock purchase plan. In order to participate in the stock purchase plan, employees must meet eligibility requirements, including length of employment. Participating employees will be able to direct the Company to make payroll deductions of up to 7.0% of their compensation during an offering period for the purchase of shares of the Company's common stock. Each offering period is six months. The stock purchase plan provides participating employees with the right, subject to specific limitations, to purchase the Company's common stock at a price equal to 85.0% of the lesser of the fair market value of the Company's common stock on the first or last day of the offering period. The Board of Directors has the authority to amend, suspend or discontinue the stock purchase plan as long as the change will not adversely affect participants without their consent.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**6. STOCK OPTIONS (Continued)**

and as long as the Company receives the stockholder approval required by law. The stock purchase plan will terminate on December 31, 2010.

**7. INCOME TAXES**

The income tax provision (benefit) for 2000, 2001 and 2002 consisted of the following (in thousands):

	<u>2000</u>	<u>2001</u>	<u>2002</u>
Current .....	\$2,021	\$ 8,693	\$ 7,354
Deferred .....	(361)	(1,838)	(2,873)
	<u>\$1,660</u>	<u>\$ 6,855</u>	<u>\$ 4,481</u>

A reconciliation of the statutory rate to the effective rate as recognized in the statements of operations is as follows:

	<u>2000</u>	<u>2001</u>	<u>2002</u>
Federal statutory rate .....	34.0%	34.0%	34.0%
State income tax, net of federal benefit .....	3.8	3.9	2.3
Non-deductible expenses and other .....	<u>2.0</u>	<u>1.1</u>	<u>2.6</u>
	<u>39.8%</u>	<u>39.0%</u>	<u>38.9%</u>

Deferred tax assets and liabilities reflect the impact of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts recognized for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2001 and 2002 are as follows (in thousands):

	<u>2001</u>	<u>2002</u>
Deferred tax assets:		
Accrued returns .....	\$1,299	\$4,413
Accrued liabilities and reserves .....	675	731
Deferred compensation .....	542	583
Accrued commission .....	377	286
Other assets .....	<u>50</u>	<u>1,295</u>
	<u>\$2,943</u>	<u>\$7,308</u>
Deferred tax liabilities:		
Intangibles .....	\$ 356	\$1,818
Other liabilities .....	<u>34</u>	<u>64</u>
	<u>390</u>	<u>1,882</u>
Net deferred tax assets .....	<u>\$2,553</u>	<u>\$5,426</u>

For any deferred tax assets where the Company determines that it is more likely than not that a deferred tax asset would not be recovered, the Company would record a valuation allowance. For the years ended December 31, 2001 and 2002, there were no valuation allowances recorded.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND INTANGIBLE ASSETS**

On January 29, 1999, the Company acquired exclusive rights in the U. S. to Robinul and Robinul Forte tablets from American Home Products Corporation ("AHP") for \$4.0 million in cash with an additional \$1.8 million financed by the seller. Pursuant to the acquisition, the Company also assumed liabilities of \$193,000 for returns of products shipped by the seller prior to the acquisition date. The Company has recorded the total purchase price for this acquisition including the liabilities assumed to the licensing rights within intangible assets in its financial statements. The licensing rights are being amortized over an estimated economic life of 20 years. The Company agreed to pay royalties on net sales as long as the Company sells the product.

In December 2002, the Company reviewed the estimated assumed liability for sales returns for the Robinul and Robinul Forte products. This review is performed by the Company on a periodic basis and is done for all acquisitions. From this review, the Company determined that the established reserves for Robinul and Robinul Forte were in excess of the currently expected returns. As a result of the revised estimate, the Company reduced the liability and increased net revenues by \$64,000 in December 2002.

On April 14, 2000, the Company acquired exclusive rights from Warner-Lambert Company to distribute, market, and sell the drug Ponstel in the U.S. for \$9.5 million in cash and a \$3.5 million promissory note to the seller. The Company also assumed liabilities of \$1.1 million for certain returns of products shipped by the seller prior to the acquisition date, and returned after October 20, 2000. The Company financed \$9.5 million of the transaction under a bridge loan agreement. Both the bridge loan and promissory note were paid in full upon the receipt of proceeds from the Company's initial public offering in June 2000. The acquisition agreement includes the purchase of the license rights and certain trademarks. The value allocated to tradename and license rights is being amortized over their estimated useful lives of 20 years. In addition, the Company agreed to purchase the entire outstanding inventory of Ponstel for approximately \$100,000.

On June 22, 2000, the Company acquired exclusive rights from Warner-Lambert Company to market, distribute and sell the drug Cognex and a new unapproved version of Cognex called Cognex CR, in the U.S. and other countries for \$3.5 million in cash. The Company must also pay up to \$1.5 million in additional purchase price if the Company obtains FDA approval to market Cognex CR. The Company also assumed liabilities of \$799,000 for returns of products shipped by Warner-Lambert prior to the acquisition date, and returned after June 22, 2001. The purchase price was allocated among the fair values of intangible assets (primarily tradename and licensing rights) and liabilities assumed and is being amortized over 20 years. In March 2001, the Company reviewed the estimated assumed liability for sales returns for Cognex. From this review, the Company determined that the established reserves for Cognex were less than what was needed to cover future anticipated returns of Cognex. As a result of this revised estimate, assumed liabilities for Cognex increased by \$2.7 million.

In September 2002, the Company reviewed the estimated assumed liability for sales returns for the Ponstel and Cognex products. This review is performed by the Company on a periodic basis and is done for all acquisitions. From this review, the Company determined that the established reserves for Ponstel and Cognex were in excess of the currently expected returns. As a result of the revised estimate, the Company reduced the liability and increased net revenues by \$2.6 million in September 2002.

On August 20, 2001, the Company acquired from Sanofi-Synthelabo Inc. ("Sanofi") the Prenate line of prescription prenatal vitamins (the "Prenate Acquisition"). The purchase price was \$51.9 million in cash and the assumption of liabilities of \$900,000 for returns of product shipped by Sanofi prior to the acquisition date, and returned after February 20, 2002 and for estimated contractual price reductions with

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND INTANGIBLE ASSETS (Continued)**

wholesalers and insurance providers. The agreement includes the purchase of the Prenate license rights, certain tradenames and managed care contracts and a supply agreement. The purchase price was allocated among the fair values of the intangible assets acquired and the liabilities assumed and is being amortized over a period of 3 to 20 years. The managed care contracts are being amortized over a period of 5 years and the supply agreement is being amortized over a period of 3 years. All other intangibles are being amortized over 20 years. The weighted average amortization period is 17 years. In addition, the Company purchased the outstanding inventory of Prenate for approximately \$50,000. The purchase price allocation as of December 31, 2001 is as follows (in thousands):

License rights .....	\$44,926
Tradenames .....	5,500
Managed care contracts .....	1,430
Supply agreement .....	940
Total .....	<u>52,796</u>
Accumulated amortization .....	<u>(1,151)</u>
Intangibles, net .....	<u>\$51,645</u>

For the year ended December 31, 2001, aggregate amortization expense related to the Prenate Acquisition was \$1.2 million related to the period from the purchase date to year-end.

On December 21, 2001, the Company acquired from Dura Pharmaceuticals Inc., an affiliate of Elan Pharmaceuticals PLC ("Elan"), the U.S. rights to Furadantin, a prescription drug used for the treatment of urinary tract infections in children, for approximately \$16 million in cash plus the assumption of liabilities of \$324,000 for the return of product shipped by Elan prior to the acquisition date returned after December 31, 2002. The purchase price was allocated among the fair value of the intangible assets acquired and liabilities assumed and is being amortized over a weighted average amortization period of 17 years. The purchase agreement includes all assets related to Furadantin, including the new drug application ("NDA") and the trademark. The license rights and tradename are being amortized over 20 years. Additionally, the Company purchased the outstanding inventory of Furadantin for \$252,000. The Company has also entered into a transitional supply agreement with Elan Pharmaceuticals whereby they will supply the Company with Furadantin until May 2003. The supply agreement is being amortized over its useful life of 17 months. The preliminary purchase price allocation was as follows (in thousands):

License rights .....	\$15,804
Tradename .....	320
Supply agreement .....	200
Total .....	<u>16,324</u>
Accumulated amortization .....	<u>(29)</u>
Intangibles, net .....	<u>\$16,295</u>

For the year ended December 31, 2001, aggregate amortization expense related to the Furadantin acquisition was \$29,000 related to the period from the purchase date to year-end.

The unaudited pro forma summary below presents certain financial information as if the Prenate and Furadantin acquisitions had occurred as of January 1, 2000. These pro forma results have been prepared

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND INTANGIBLE ASSETS (Continued)**

for comparative purposes and do not purport to be indicative of what would have occurred had the acquisitions been made on the first day of the respective years of acquisition. Additionally, these pro forma results are not indicative of future results (in thousands, except per share data):

	For the Year Ended	
	2000	2001
Net revenues .....	\$58,298	\$84,645
Net income .....	\$ 4,007	\$11,743
Diluted net income per share .....	\$ 0.21	\$ 0.45

On March 6, 2002, the Company acquired from AstraZeneca UK Limited certain U.S. rights relating to the antihypertensive prescription medication Sular. The Company also entered into a long-term manufacturing, supply, and distribution agreement with Sular's current manufacturer, Bayer AG. The aggregate purchase price paid was \$184.3 million in cash, including \$624,000 in acquisition costs, plus the assumption of liabilities of \$1.9 million related to the return of product shipped prior to the acquisition date. In addition, the Company must pay up to \$30 million in additional purchase price after closing, based on the achievement of certain performance milestones during a specified period of time. The agreements include the purchase of the Sular license rights, certain tradenames and managed care contracts and a distribution agreement. The purchase price also included \$5.7 million of product inventory. The purchase price was allocated among the fair values of the intangible and tangible assets acquired and the liabilities assumed and is being amortized over a period of 5 to 20 years. The weighted average amortization period is 19 years. The results of Sular are included in the consolidated statements of operations from March 6, 2002. The preliminary purchase price allocation was as follows (in thousands):

License rights .....	\$160,721
Distribution agreement .....	10,350
Managed Care contracts .....	6,870
Tradename .....	2,560
Total intangibles .....	180,501
Inventory .....	5,724
Total assets .....	186,225
Liabilities assumed .....	(1,895)
Total acquisition .....	\$184,330

For the year ended December 31, 2002, aggregate amortization expense related to the Sular acquisition was \$8.6 million related to the period from the purchase date to year-end.

The unaudited pro forma summary below presents certain financial information as if the Sular acquisition had occurred as of January 1, 2002. These pro forma results have been prepared for comparative purposes and do not purport to be indicative of what would have occurred had the acquisition



**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. ACQUISITIONS AND INTANGIBLE ASSETS (Continued)**

been made on January 1, 2002. Additionally, these pro forma results are not indicative of future results (in thousands, except per share data):

	<b>For the Year Ended 2002</b>
Net revenues .....	<u>\$121,545</u>
Net income .....	<u>\$ 8,951</u>
Diluted net income per share .....	<u>\$ 0.27</u>

The purchase price allocation of Sular is preliminary and subject to revision, with any such revision to be finalized upon the ultimate resolution of the value of certain liabilities assumed, yet no later than the one year anniversary of the purchase date. The Company does not expect any such revisions will have a material impact on the Company's financial position or results of operations.

In December 2002, the Company reviewed the estimated assumed liability for sales returns for the Sular product. This review is performed by the Company on a periodic basis and is done for all acquisitions. From this review, the Company determined that the established reserves for Sular were less than what was needed to cover future anticipated returns of Sular. As a result of this revised estimate, assumed liabilities for Sular increased by \$671,000.

The following table reflects the components of all intangible assets as of December 31, 2002 (in thousands):

	<b>Gross Amount</b>	<b>Accumulated Amortization</b>	<b>Net Amount</b>	<b>Average Life</b>
Licensing rights .....	\$244,415	\$(14,138)	\$230,277	20 years
Tradenames .....	11,060	(631)	10,429	20 years
Contracts .....	8,300	(1,490)	6,810	5 years
Supply/Distribution Agreements .....	11,490	(1,403)	10,087	1 to 10 years
Other intangibles .....	<u>3,082</u>	<u>(244)</u>	<u>2,838</u>	20 years
Total .....	<u>\$278,347</u>	<u>\$(17,906)</u>	<u>\$260,441</u>	<u>19 years</u>

For the year ended December 31, 2002, amortization expense related to intangible assets was \$14.2 million. Amortization is calculated on a straight-line basis over the estimated useful life of the intangible asset. Estimated annual amortization expense for each of the 5 succeeding fiscal years is as follows (in thousands):

Year ending December 31,	
2003 .....	\$16,043
2004 .....	15,870
2005 .....	15,670
2006 .....	15,567
2007 .....	14,354

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**9. EXTRAORDINARY ITEM**

In order to finance the Sular acquisition, the Company obtained a \$152 million senior secured credit facility. The Company incurred \$3.1 million of deferred financing costs associated with this credit facility. These deferred financing costs were being amortized over the anticipated facility repayment period. On April 24, 2002, the credit facility was repaid with the proceeds from the follow-on offering. The Company recognized an extraordinary loss of \$863,000 net of income tax benefit of \$540,000 related to the early retirement of debt. The Company will assess the classification of this loss under SFAS No. 145 in the second fiscal quarter of 2003. Under the provisions of SFAS No. 145, this extraordinary loss may be reclassified into other (expense)/income section of the consolidated statement of operations.

**10. LICENSE AGREEMENTS AND PRODUCT RIGHTS**

On January 1, 1996, the Company obtained exclusive distribution rights from Unisource, Inc. for Tanafed in North America through December 31, 2003 with an option for an additional 7 years. The agreement requires the Company to purchase all of their requirements for Tanafed from Unisource, including at least certain minimum quantities of Tanafed in each year of the agreement. In December 1998, the Company obtained exclusive distribution and supply rights from Unisource, Inc. for Tanafed DM in North America through December 2005, subject to an automatic 7 year renewal. The agreement requires the Company to purchase all of its requirements for Tanafed DM from Unisource, subject to certain minimum purchase requirements. The Company entered into a patent and license agreement with Jame Fine Chemicals, Inc., the raw materials supplier for Tanafed in January 2000. The agreement grants the Company a semi-exclusive license to use, sell and distribute finished products containing an active ingredient used in Tanafed. Pursuant to the agreement, the Company must pay a royalty on sales of Tanafed. The license continues through the life of the licensed patent, which expires in 2014.

On June 27, 2002, the Company entered into a new agreement with Jame Fine Chemicals, Inc for a 10 year exclusive license to make, have made, use, distribute, market, promote, advertise and sell pharmaceutical formulations containing the ingredients dextromethorphan tannate and/or dexchlorpheniramine tannate. The Company's two new Tanafed products, Tanafed DP and Tanafed DMX contain all or some of these ingredients. The agreement became effective in August 2002. The Company paid a license fee of \$508,000. The Company is also committed to fund a maximum royalty of \$2.5 million in installments through March 2005. This royalty is refundable under certain circumstances. A nonrefundable royalty will commence in January 2005. The Company will amortize the license fee over the life of the agreement.

In June 2002, we entered into an exclusive distribution agreement with Unisource granting us exclusive rights to sell Tanafed DP and Tanafed DMX in North America and for Unisource to supply Tanafed DP and Tanafed DMX to us through June 2007, subject to an automatic three year renewal. The agreement requires us to purchase all of our Tanafed DP and Tanafed DMX requirements from Unisource and subjects us to minimum purchase requirements. We must pay Unisource for the manufacture and supply of Tanafed DP and Tanafed DMX based upon fixed unit costs.

On October 31, 1998, the Company entered into an agreement with Inpharmakon Corporation in which the Company acquired rights to the proprietary information for a migraine product for which the Company plans to conduct clinical studies and submit a new drug application. The agreement expires on October 31, 2008, but the Company may renew it indefinitely after expiration. If the Company does not obtain regulatory approval of the drug within a specified time after filing for such approval and thereafter commence and continue to aggressively market and sell the product, Inpharmakon may terminate the

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. LICENSE AGREEMENTS AND PRODUCT RIGHTS (Continued)**

agreement. In the event that Inpharmakon terminates the agreement for failure to achieve these milestones, Inpharmakon may purchase rights to develop the drug. The Company must also pay up to an aggregate of \$950,000 in non-refundable fees to Inpharmakon at various developmental milestones through and including regulatory approval of the product, and, in the event of commercial sales of the product, the Company must pay royalties at rates which management believes are within industry customary ranges. If the Company elects to sell the business opportunity to a third party, the Company must share the proceeds of the sale with Inpharmakon. On May 3, 2000, the Company amended the terms of the agreement with Inpharmakon. Under the amended terms, the Company paid Inpharmakon \$200,000 on June 15, 2000. In addition, a \$200,000 milestone payment was paid to Inpharmakon in December 2001. No payments were made to Inpharmakon in 2002.

In January 1999, the Company acquired exclusive rights in the U.S. to Robinul and Robinul Forte tablets from American Home Products Corporation. The Company must pay royalties on net sales under its license agreement with American Home Products. The Company entered agreements with Mikart, dated April 23, 1999 and January 21, 2001, for Mikart to become qualified under applicable regulations to manufacture and supply the Company's requirements for Robinul. Mikart became qualified by the FDA to manufacture Robinul on December 3, 2001 and began supplying the Robinul products to the Company in December 2001. Under these agreements, Mikart will manufacture the products for 5 years from the time Mikart became a qualified manufacturer plus renewal terms of one year until either party elects not to renew. The agreement with Mikart requires that the Company purchase certain designated minimum quantities.

In January 2002, the Company entered into a license agreement with Wyeth-Ayerst Canada Inc. and Whitehall-Robins Inc. under which the Company acquired rights to have the product manufactured, and to market and sell Robinul and Robinul Forte in Canada. The Company will pay Wyeth-Ayerst Canada a royalty on net sales of Robinul in Canada.

On March 25, 1999, the Company acquired the rights from Penwest Pharmaceuticals Co. ("Penwest") to use Penwest's TIMERx controlled-release technology to develop FHCP 01 pursuant to a product development agreement. In November 2002, the Company entered into an amended and restated product development agreement with Penwest. Under the Penwest agreements, the Company has the right to manufacture, use and sell the developed migraine product in North America for a period extending 15 years from the date a new drug application is issued for the product, as well as license certain Penwest patents. Under these agreement, the Company is required to pay Penwest up to an aggregate of approximately \$2.6 million of non-refundable fees upon achieving specified milestones through the first anniversary of the first commercial sale of the product following the regulatory approval and royalties upon any sales of the migraine product at rates the Company believes are within industry customary ranges. Penwest was able to terminate the product development agreement in the event the Company failed to timely achieve designated performance milestones within prescribed time periods including the completion of clinical trials by April 2002, applying for FDA approval of the product within six months after completing clinical trials and commercially launching the product within two months after obtaining FDA approval. Penwest was also able to terminate the product development agreement if the Company failed to either sell specified minimum quantities of the product each year after approval of the product or pay the applicable royalty to Penwest as if the Company had sold such minimum quantity. The Company did not complete clinical trials of the migraine product by April 2002, however, in November 2002, the Company entered into an amended and restated product development agreement with Penwest under which Penwest

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. LICENSE AGREEMENTS AND PRODUCT RIGHTS (Continued)**

agreed to waive this provision. To date, the Company has paid Penwest \$427,000, which is included in research and development expense in the accompanying statements of operations.

In July 1999, the Company entered into an agreement with Pohl-Boskamp for the exclusive rights to distribute, market and sell Nitrolingual Pumpspray beginning on February 1, 2000 in the U.S. for 5 years plus an additional 5 year renewal period subject to establishing mutually acceptable minimum purchase requirements. Under the agreement, Pohl-Boskamp supplies the Company with their requirements of product at prices that decrease as volume purchased in each year increases. The Company must purchase designated minimum quantities in each year of the agreement and pay a royalty on net sales of the product. Aventis had exclusive rights through January 2000 to a version of the product containing CFC named Nitrolingual spray. To promote earlier adoption of Nitrolingual Pumpspray, the Company obtained exclusive rights from Aventis to market this CFC product in the U.S. as of November 22, 1999.

In April 2000, the Company acquired exclusive rights from Pfizer to market, distribute and sell Ponstel in the U.S.. The total purchase price was \$13.0 million. In April 2000, the Company also entered into a supply agreement with Pfizer under which Pfizer was to supply the Company with designated quantities of Ponstel through the expiration of the supply agreement, which occurred on March 31, 2001. Pfizer only delivered a portion of the quantity of Ponstel required by the supply agreement during its term. Pfizer has continued to supply Ponstel to the Company under the same terms. The Company pays Pfizer an agreed upon price for the supply of Ponstel.

In December 2000, the Company signed an agreement with West-ward Pharmaceuticals to manufacture Ponstel after West-ward obtains FDA approval to manufacture the product. The Company anticipates that this will occur by the third quarter of 2003. This agreement expires in April 2005 subject to automatic annual renewals. The Company must purchase all of its requirements for Ponstel from West-ward and is subject to minimum purchase requirements. The Company must pay West-ward a price for Ponstel based on a multiple of West-ward's direct cost of goods sold in the manufacture and supply of the product. In addition, the Company must pay West-ward milestone payments, as long as no generics have been introduced, upon certain anniversary dates of FDA approval of the manufacture of Ponstel by West-ward. We have filed a site transfer application with the FDA in order to obtain such approval.

For the Cognex product, the Company negotiated a supply agreement with a Warner-Lambert affiliate to continue to manufacture and supply Cognex and the active ingredient in Cognex for 2 years subject to a one-year renewal. The Company will pay Warner-Lambert's affiliate a production fee for its manufacture of Cognex and the active ingredient. The supply agreement contains designated quantities of Cognex and its active ingredient that Warner-Lambert's affiliate will supply and that the Company must purchase.

In addition, the Company entered into a transition services agreement with Warner-Lambert under which Warner-Lambert provided transitional administrative services to the Company until December 31, 2000 in connection with the sale of Cognex in European countries.

For the Prenate product line, under the terms of the asset purchase agreement, the Company was assigned a contract between Sanofi and Patheon Inc. to manufacture the product line. The term of the agreement is for 5 years from October 1, 1999 subject to automatic one-year renewals. The Company also assumed a supply and packaging agreement with Banner Pharmacaps Inc. ("Banner") and Sanofi for the supply and packaging of the products. The agreement with Banner is for a term of 5 years subject to two-year renewals. Under the terms of the supply agreement with Banner, the Company will pay Banner a

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. LICENSE AGREEMENTS AND PRODUCT RIGHTS (Continued)**

royalty on net sales above a certain amount of net sales. The Sanofi packaging agreement is for a term of 3 years subject to a 3 year renewal.

Each of the Company's third-party manufacturing agreements requires that the Company purchase all of their product requirements from the manufacturers that are a party to those agreements.

The Company uses third-party manufacturers for the production of its products for development and commercial purposes. Given the general under-utilization of resources, the availability of excess capacity for manufacturing in the marketplace, and the lower cost of outsourcing, the Company intends to continue to outsource manufacturing for the near-term.

The Company relies on third-party suppliers to produce its products. The supplier for two products and the suppliers for components of two other products hold patents relating to their respective products. Due to the patent restrictions, the supply of these three products, whose sales comprised 50.1% and 56.3% of the Company's sales in 2001 and 2002, respectively, are exclusively available through these suppliers.

**11. RETIREMENT PLAN**

In 1996, the Company began a qualified defined contribution 401(k) plan, which provides benefits to substantially all employees. The annual contribution, if any, to the trust is at the discretion of the Board of Directors of the Company. Employer contributions to the plan for the years ended December 31, 2000, 2001 and 2002 were \$52,000, \$184,000 and \$332,000, respectively.

**12. COMMITMENTS AND CONTINGENCIES**

In December 2001, the Company entered into a lease agreement for a new facility. In April 2002, the Company moved into this facility. This new facility is leased under a non-cancelable operating lease that expires in May 2009. The lease for the previous facility was terminated in June 2002 and the Company has no further obligations related to this lease. The total rent expense for the Company was \$199,000, \$531,000 and \$429,000 for the years ended December 31, 2000, 2001, and 2002 respectively. The rent expense for 2001 included a charge of \$304,000 for the remaining lease obligation under the Company's non-cancelable lease at that time.

The Company leases vehicles for certain employees under non-cancelable lease agreements expiring in 2004. The total vehicle lease expense under the lease agreements for the years ended December 31, 2000, 2001 and 2002 was \$1.3 million, \$1.9 million and \$2.3 million, respectively.

The total minimum future commitments under leases for years succeeding December 31, 2002 is as follows (in thousands):

Period ending December 31,	
2003 .....	\$2,320
2004 .....	1,290
2005 .....	643
2006 .....	662
2007 .....	670
Thereafter .....	915
Total .....	<u>\$6,500</u>

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. COMMITMENTS AND CONTINGENCIES (Continued)**

The Company has employment contracts with certain executives, which provide for certain levels of severance in the event of termination without cause or for certain change of control events, as defined.

A putative class action lawsuit was filed in the U.S. District Court for the Northern District of Georgia on August 22, 2002 (and two subsequent lawsuits have been filed based upon substantially the same allegations) against the Company, members of its Board of Directors, certain officers and representatives of the underwriters for the public offering completed on April 24, 2002. The complaints generally allege that the Company issued a series of materially false and misleading statements to the market in connection with the public offering on April 24, 2002 relating to the sales of Tanafed Suspension and Prenate GT. Due to the inherent uncertainties involved in litigation, the Company is unable to predict the outcome of this litigation, however, an adverse result could have a material adverse effect on the financial position and results of operations.

The Company is also involved with other various routine legal proceedings incident to the ordinary course of business. None of these proceedings are expected to have a material adverse effect on the consolidated financial statements.

**13. RELATED-PARTY TRANSACTIONS**

The Company purchases repackaging services from Diversified Healthcare Services, a related party. For the years ended December 31, 2000, 2001 and 2002, the amounts paid for repackaging were approximately \$136,000, \$5,000 and \$47,000, respectively.

The Company pays royalties to a related party for particular products sold. For the years ended December 31, 2000, 2001, and 2002, the amounts paid for royalties were approximately \$213,000, \$140,000 and \$93,000, respectively.

During 1998, the Company entered into a collaboration agreement with Inpharmakon Corporation, an affiliate of an officer and director of the Company, under which Inpharmakon will assist the Company in developing their FHPC 01 product. This agreement was amended in May 2000 as discussed in Note 10. The Company paid \$201,000, \$200,000 and \$0 to Inpharmakon in 2000, 2001 and 2002, respectively. These payments were expensed as a development expense.

**FIRST HORIZON PHARMACEUTICAL CORPORATION**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**14. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following table sets forth summary quarterly financial information for the years ended December 31, 2001 and 2002 (in thousands):

<u>2001 by Quarter</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Net revenues .....	\$12,453	\$12,979	\$18,510	\$25,348
Gross profit .....	10,682	11,272	15,681	21,301
Operating income .....	1,767	3,060	4,479	6,398
Net income .....	1,227	2,268	3,159	4,069
Earnings per share:				
Basic .....	\$ 0.06	\$ 0.09	\$ 0.12	\$ 0.15
Diluted .....	\$ 0.06	\$ 0.09	\$ 0.11	\$ 0.14
<u>2002 by Quarter</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Net revenues .....	\$27,120	\$26,006	\$27,106	\$34,946
Gross profit .....	22,824	21,305	19,681	27,400
Operating income .....	6,162	127	224	7,288
Net income (loss) .....	3,037	(1,526)	138	4,517
Earnings per share:				
Basic .....	\$ 0.11	\$ (0.05)	\$ 0.00	\$ 0.13
Diluted .....	\$ 0.11	\$ (0.05)	\$ 0.00	\$ 0.13

Quarterly amounts do not add to annual amounts due to the effect of rounding on a quarterly basis.

**15. SUBSEQUENT EVENTS**

On February 11, 2003, the Company entered into a Credit Agreement for a \$20 million senior secured revolving credit facility with various lenders and LaSalle Bank National Association, as Administrative Agent. Borrowings may be used for working capital requirements and general corporate purposes. Borrowings are secured by substantially all of our assets. Borrowings bear interest at our option at the base rate in effect from time to time plus an applicable margin or the Eurodollar rate, plus an applicable margin. The applicable margin will vary dependent upon our leverage ratio in effect from time to time. The revolving facility matures on February 11, 2006. The revolving loan contains various restrictive covenants, including covenants relative to maintaining financial ratios and earnings levels, limitations on acquisitions, dispositions, mergers and capital expenditures, limitations on incurring additional indebtedness and a prohibition on payment of dividends and certain issuances of our capital stock.

(This page has been left blank intentionally.)



**INDEPENDENT AUDITORS' REPORT**

To the Board of Directors and Stockholders of  
First Horizon Pharmaceutical Corporation

We have audited the accompanying consolidated financial statements of First Horizon Pharmaceutical Corporation (a Delaware corporation) and subsidiaries (the "Company") as of and for the year ended December 31, 2002 and have issued our report thereon dated February 14, 2003; such report is included elsewhere in this Form 10-K. Our audit also included the 2002 financial statement schedules of the Company, listed in Item 15. These financial statement schedules are the responsibility of the Company's management. Our responsibility is to express an opinion based on our audit. The consolidated financial statements of the Company as of December 31, 2001 and 2000 and for the years then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on the 2001 and 2000 consolidated financial statements in their report dated February 12, 2002. Those auditors also audited the 2001 and 2000 financial statement schedules listed in Item 15, and their report dated February 12, 2002 expressed an unqualified opinion on those financial statement schedules.

In our opinion, such 2002 financial statement schedules, when considered in relation to the basic 2002 consolidated financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ Deloitte & Touche LLP

Atlanta, Georgia  
February 14, 2003

The following report of Arthur Andersen LLP ("Andersen") is a copy of the report previously issued by Andersen on February 12, 2002. The report of Andersen is included in this annual report on Form 10-K pursuant to rule 2-02(e) of regulation S-X. The Company has not been able to obtain a reissued report from Andersen. Andersen has not consented to the inclusion of its report in this annual report on Form 10-K. Because Andersen has not consented to the inclusion of its report in this annual report, it may be difficult to seek remedies against Andersen, and the ability to seek relief against Andersen may be impaired.

#### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Board of Directors and Stockholders  
of First Horizon Pharmaceutical Corporation

We have audited in accordance with auditing standards generally accepted in the United States, the consolidated financial statements of First Horizon Pharmaceutical Corporation (a Delaware Corporation) and subsidiary included in this Annual Report and have issued our report thereon dated February 12, 2002. Our audit was made for the purpose of forming an opinion on the basic financial statements taken as a whole. The accompanying schedule of Valuation and Qualifying Accounts is the responsibility of the Company's management and is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, fairly states in all material respects the financial data required to be set forth therein in relation to the basic financial statements taken as a whole.

/s/ ARTHUR ANDERSEN LLP

Atlanta, Georgia  
February 12, 2002

**SCHEDULE II**

**FIRST HORIZON PHARMACEUTICAL CORPORATION**

**VALUATION AND QUALIFYING ACCOUNTS**

**YEARS ENDED DECEMBER 31, 2000, 2001 AND 2002**

**(IN THOUSANDS)**

<u>Classification</u>	<u>Balance of Beginning of Year</u>	<u>Charged to Costs and Expenses</u>	<u>Deductions</u>	<u>Balance End of Year</u>
2000 Allowance for doubtful accounts and discounts .....	\$ 56	\$ 375	\$ (147)	\$ 284
Allowance for product returns .....	272	737	(184)	825
Allowance for sales deductions .....	851	4,015	(3,052)	1,814
2001 Allowance for doubtful accounts and discounts .....	284	1,064	(261)	1,087
Allowance for product returns .....	825	3,167	(618)	3,374
Allowance for sales deductions .....	1,814	10,174	(6,351)	5,637
2002 Allowance for doubtful accounts and discounts .....	1,087	1,185	(1,505)	767
Allowance for product returns .....	3,374	16,047	(7,205)	12,216
Allowance for product rebates .....	3,866	12,269	(7,765)	8,370
Allowance for sales deductions .....	1,771	10,415	(9,885)	2,301