

KING PHARMACEUTICALS INC

Form 10-K

March 15, 2004

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2003

OR

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

Commission File Number 0-24425

King Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Tennessee
(State or other jurisdiction of
incorporation or organization)

54-1684963
(I.R.S. Employer
Identification No.)

501 Fifth Street
Bristol, Tennessee
(Address of Principal Executive Offices)

37620
(Zip Code)

Registrant's telephone number, including area code: **(423) 989-8000**

Securities registered under Section 12(b) of the Exchange Act:

(Title of each class)

(Name of each exchange on which registered)

Common Stock

New York Stock Exchange

Securities registered under Section 12(g) of the Exchange Act:

None

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

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). x

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity as of June 30, 2003 was \$3,143,503,811. The number of shares of Common Stock, no par value, outstanding at March 9, 2004 was 241,354,416.

Documents Incorporated by Reference: None

PART I

Item 1. *Description of Business*

King Pharmaceuticals, Inc. was incorporated in the State of Tennessee in 1993. Our wholly owned subsidiaries are Monarch Pharmaceuticals, Inc.; Jones Pharma Incorporated; King Pharmaceuticals Research and Development, Inc.; Meridian Medical Technologies, Inc.; Parkedale Pharmaceuticals, Inc.; King Pharmaceuticals of Nevada, Inc.; and Monarch Pharmaceuticals Ireland Limited.

Our principal executive offices are located at 501 Fifth Street, Bristol, Tennessee 37620. Our telephone number is (423) 989-8000 and our facsimile number is (423) 274-8677. Our website is www.kingpharm.com. We have, since November 15, 2002, made available through our website our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and any amendments as soon as reasonably practical. These filings are also available to the public over the Internet at the website of the Securities and Exchange Commission, which we refer to as the SEC, at <http://www.sec.gov>. You may also read and copy any document that we file at the SEC's Public Reference Room located at 450 Fifth Street, NW, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room.

King is a vertically integrated pharmaceutical company that develops, manufactures, markets and sells branded prescription pharmaceutical products. By vertically integrated, we mean that we have the capabilities of a major pharmaceutical company, including

sales and marketing,

research and development,

manufacturing,

packaging,

distribution,

quality control and assurance, and

regulatory affairs.

Through a national sales force consisting of approximately 1,300 approved positions, and through marketing alliances, we market our branded pharmaceutical products to general/family practitioners, internal medicine physicians, cardiologists, endocrinologists, psychiatrists, neurologists, obstetricians/gynecologists, and hospitals across the United States and in Puerto Rico.

Our business strategy includes the development of new branded prescription pharmaceutical products, including new chemical entities, as well as the acquisition of compounds already in development, that provide us with strategic pipeline product opportunities.

Our business strategy also includes acquiring currently marketed branded pharmaceutical products and increasing their sales through focused marketing and promotion and product life cycle management. By product life cycle management, we mean the extension of the economic life of a product, including seeking and gaining all necessary related governmental approvals, by such means as:

securing U.S. Food and Drug Administration, which we refer to as FDA, approved new label indications;

developing and producing different strengths;

producing different package sizes;

developing new dosages; and

developing new product formulations.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

We acquire branded products primarily from larger pharmaceutical companies. These companies sell products for various reasons including limiting their operating expenses or eliminating duplicate products.

We also seek attractive company acquisitions which add products or products in development, technologies or sales and marketing capabilities to our key therapeutic areas or that otherwise complement our operations.

Unlike many of our competitors, we have a broad therapeutic focus that provides us with opportunities to develop or acquire a wide variety of products or late stage compounds. In addition, we have well known products in all of our therapeutic categories that generate high prescription volumes. Our branded pharmaceutical products can be divided primarily into the following therapeutic areas:

cardiovascular (including Altace®, Corzide®, Procanbid® and Thalitone®),

endocrinology/women's health (including Levoxyl®, Cytomel®, Triostat®, Prefest®, Menest®, Delestrogen® and Nordette®),

neuroscience (including Sonata® and Skelaxin®),

critical care (including Thrombin-JMI®, Brevital® and Synercid®),

anti-infectives (including Bicillin®, Cortisporin®, Neosporin® and Coly-Mycin M®) and

respiratory (including Intal® and Tilade®).

Additionally, we manufacture pharmaceutical products under contracts with a variety of pharmaceutical and biotechnology companies. We have not accepted or renewed manufacturing contracts for third parties where we perceived insignificant volumes or revenues.

The following summarizes net revenues by operating segment (in thousands).

	For the Years Ended December 31,		
	2001	2002	2003
Branded pharmaceuticals(1)	\$ 793,543	\$ 1,032,831	\$ 1,300,948
Meridian Medical Technologies			124,157
Royalties	46,774	58,375	68,365
Contract manufacturing	29,680	35,936	27,290
Other	2,265	1,193	628
Total	\$ 872,262	\$ 1,128,335	\$ 1,521,388

(1) The branded pharmaceuticals segment net revenues for 2002 reflect

a \$22,113 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001,

a \$12,399 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and

an \$11,970 charge arising from changes in accounting estimates related to Medicaid and other governmental pricing programs.

The branded pharmaceuticals segment net revenues for 2003 reflect an \$18,000 charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$900 charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997. For further information, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 17

to our audited consolidated financial statements.

Key Historical Milestones

We acquired from Glaxo Wellcome, Inc., predecessor to SmithKline Beecham Corporation, a subsidiary of GlaxoSmithKline plc, for \$54.0 million, including \$3.1 million of assumed liabilities, all rights to the Cortisporin® product line in March 1997, the Viroptic® product line in May 1997, and six additional branded products, including Septra®, and exclusive licenses, free of royalty obligations, for the prescription formulations of Neosporin® and Polysporin® in November 1997.

In February 1998, we acquired from Warner-Lambert Company (predecessor to Pfizer, Inc.), 15 branded pharmaceutical products, our facility located in Rochester, Michigan and some manufacturing contracts with third parties for \$127.9 million, including \$2.9 million of assumed liabilities.

In December 1998, we acquired from Hoechst Marion Roussel, Inc. (predecessor to Aventis Pharmaceuticals, Inc.), for \$362.5 million, the United States and Puerto Rico rights to Altace® and two other small branded pharmaceutical products. Altace® is an Angiotensin Converting Enzyme inhibitor, which we refer to as an ACE inhibitor. We are currently manufacturing a portion of the finished dosage and packaging Altace® in our facility in Bristol, Tennessee. Aventis also remains a supplier of the active ingredient ramipril, and a portion of the finished dosage of Altace®. On October 4, 2000, the FDA approved new indications for Altace® requested under a supplemental New Drug Application, which we refer to as an sNDA. In addition to the treatment of hypertension, this approval permits the promotion of Altace® to reduce the risk of stroke, myocardial infarction (heart attack) and death from cardiovascular causes in patients 55 and over either with a history of coronary artery disease, stroke or peripheral vascular disease or with diabetes and one other cardiovascular risk factor (hypertension, elevated total cholesterol levels, low HDL levels, cigarette smoking or documented microalbuminuria). Altace® is also indicated in stable patients who have demonstrated clinical signs of congestive heart failure after sustaining acute myocardial infarction. Altace® is marketed by our subsidiary Monarch and by Wyeth pursuant to the Co-Promotion Agreement we entered into in June 2000, described below.

In August 1999, we acquired the antibiotic Lorabid® in the United States and Puerto Rico from Eli Lilly and Company for \$91.7 million, including acquisition costs plus potential sales performance milestones. As of December 31, 2003, we have not made any milestone payments. We have a supply agreement with Eli Lilly under which we remain obligated to purchase minimum levels of inventory of Lorabid® through September 1, 2005. During the fourth quarter of 2002, we decided to divest our rights to Lorabid® and reviewed the related intangible assets for impairment. Based on changes in prescription trends, we believe the minimum purchase commitments under the supply agreement are greater than inventory quantities which we will be able to sell to our customers. For details regarding charges related to the liability associated with the amount of the purchase commitments in excess of expected demand and our review for impairment of the Lorabid® intangible assets, as updated for management's cash flow expectations for Lorabid®, please see the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 8 to our audited consolidated financial statements.

On February 25, 2000, we acquired Medco Research, Inc. in an all stock transaction accounted for as a pooling of interests valued at approximately \$366.0 million. We exchanged approximately 14.4 million shares of King common stock for all of the outstanding shares of Medco. Each share of Medco was exchanged for 1.3514 shares (post subsequent stock splits) of King common stock. In addition, outstanding Medco stock options were converted at the same exchange ratio to purchase approximately 1.4 million shares (post subsequent stock splits) of King common stock. Medco is now one of our wholly owned subsidiaries and, effective November 1, 2000, was renamed King Pharmaceuticals Research and Development, Inc. Through King Research and Development, we are engaged in the research and development of chemical compounds, including new chemical entities, which provide us with strategic pipeline opportunities that may lead to the commercialization of new branded prescription pharmaceutical products. Additionally, we engage in product life cycle management to develop new indications and line extensions for existing and acquired products and to improve the quality and efficiency of our manufacturing processes.

On June 23, 2000, we entered into a marketing alliance with Wyeth to market Altace® in the United States and Puerto Rico. We refer to this agreement as the Co-Promotion Agreement. Subject to the terms of the Co-Promotion Agreement, we pay Wyeth a quarterly fee based on a percentage of net sales in exchange for its marketing efforts. Wyeth purchased \$75.0 million of our common stock and paid us \$25.0 million in cash upon execution of the Co-Promotion Agreement. Wyeth paid us an additional \$50.0 million in November 2000 as a result of the FDA's final approval on October 4, 2000 of new indications for Altace®.

On August 31, 2000, we acquired Jones Pharma Incorporated in an all stock transaction accounted for as a pooling of interests valued at approximately \$2.4 billion. We exchanged approximately 98.4 million shares (post subsequent stock splits) of King common stock for all of the outstanding shares of Jones. Each share of Jones was exchanged for 1.5 shares (post subsequent stock splits) of King common stock. In addition, outstanding Jones stock options were converted at the same exchange ratio to purchase approximately 5.4 million shares (post subsequent stock splits) of King common stock. Jones is now one of our wholly owned subsidiaries.

On January 8, 2001, we entered into a license agreement with Novavax, Inc. to promote, market, distribute and sell Estrasorb®, Androsorb® and some other women's health products which may be developed by Novavax. Under the terms of this agreement, as amended by our subsequent agreements with Novavax on June 29, 2001, we have an exclusive license with Novavax to promote, market, distribute and sell, following approval, these products worldwide, except for the United States and Puerto Rico, where, under a separate agreement, we will co-market them with Novavax. During the term of the license, we will pay Novavax a reasonable royalty on net sales of these products in all territories except the United States and Puerto Rico. Novavax will pay us an amount equal to approximately 50% of gross profit derived from the sale of these products in the United States and Puerto Rico. We will share equally with Novavax approved marketing expenses related to the promotion of these products in the United States and Puerto Rico. Estrasorb® is a topical emulsion estrogen therapy which employs Novavax's proprietary micellar nanoparticle technology designed to deliver 17-beta estradiol, a naturally occurring hormone, through the skin when applied in a lotion-like form. The New Drug Application, which we refer to as an NDA, for Estrasorb® was approved by the FDA on October 9, 2003. Novavax, working together with our company, plans to launch the sales and marketing of Estrasorb™ in the United States during the first half of 2004. Androsorb® is a topical testosterone replacement therapy for testosterone deficient women.

On May 25, 2001, the FDA approved our NDA for Levoxyl®, our levothyroxine sodium drug product for the treatment of hypothyroidism. We filed the NDA as a result of the FDA's August 14, 1997 announcement in the Federal Register (62 FR 43535) that orally administered levothyroxine sodium drug products are new drugs. The notice stated that manufacturers who wish to continue to market these products must submit applications as required by the Food, Drug and Cosmetic Act, which we refer to as the FDC Act, by August 14, 2000. On April 26, 2000, the FDA issued a second Federal Register notice extending the deadline for filing these applications until August 14, 2001.

On August 8, 2001, we acquired certain rights to three branded pharmaceutical products and a license to a fourth product from Bristol-Myers Squibb Company for \$285.0 million plus approximately \$1.5 million of expenses. The product rights acquired include Bristol-Myers Squibb's rights in the United States to Corzide®, Delestrogen® and Florinef®. We also acquired a fully paid license to Corgard® in the United States. Corzide®, a combination beta-blocker and thiazide diuretic, is indicated for the management of hypertension. Corgard®, a beta-blocker, is indicated also for the management of hypertension, as well as long-term management of patients with angina pectoris. Delestrogen® is an injectable estrogen replacement therapy. Florinef® is a partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome. For information regarding charges related to Florinef®, please see the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 8 to our audited consolidated financial statements.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

On December 13, 2001, the FDA approved our NDA for Tigan® 300mg capsules. Tigan® is indicated for the treatment of post-operative nausea and vomiting and for nausea associated with gastroenteritis.

On May 29, 2002, we acquired all rights to Prefest®, a branded pharmaceutical product, from Ortho-McNeil Pharmaceutical, Inc., a Johnson & Johnson subsidiary, for \$108.0 million, plus approximately \$3.3 million of expenses. During February 2003, we paid Ortho-McNeil an additional \$7.0 million upon receipt of the FDA's approval to change the name of the product to Prefest® from Ortho-Prefest®. Prefest® is a differentiated combination hormone replacement therapy with an intermittent progestin administration, together with a continuous administration of estrogen.

On December 30, 2002, we licensed or acquired the rights to three branded pharmaceutical products from Aventis for the initial cash payment of \$197.5 million, plus \$4.3 million of expenses. The products involved include rights in the United States, Puerto Rico, and Canada to Intal® and Tilade®, inhaled anti-inflammatory agents for the management of asthma. We also obtained worldwide rights, excluding Japan, to Synercid®, an injectable antibiotic indicated for treatment of vancomycin-resistant enterococcus faecium and treatment of some complicated skin and skin structure infections. In addition to the initial cash payment, we paid \$10.3 million in December 2003 as a milestone payment due to the continued recognition of Synercid® as an effective treatment for vancomycin-resistant enterococcus faecium. As additional consideration for Synercid®, we have agreed to remaining potential milestone payments to Aventis totaling \$64.8 million.

On January 8, 2003, we acquired Meridian Medical Technologies, Inc. for \$253.9 million in cash paid to its shareholders in exchange for their shares of Meridian common stock. Meridian pioneered the development, and is the leading manufacturer, of auto-injectors for the self-administration of injectable drugs. An auto-injector is a pre-filled, pen-like device that allows a patient or caregiver to automatically inject a precise drug dosage quickly, easily, safely and reliably. Meridian's commercial pharmaceutical products primarily include EpiPen®, an auto-injector filled with epinephrine for the emergency treatment of anaphylaxis resulting from severe or allergic reactions to insect stings or bites, foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis. Meridian manufactures EpiPen® under a supply agreement with Dey L.P., which markets the product. Other pharmaceutical products that are primarily sold to the U.S. Department of Defense, which we refer to as the DoD, under an Industrial Base Maintenance Contract include Atropen® and ComboPen®, nerve agent antidotes; the Antidote Treatment Nerve Agent Auto-injector, a nerve gas antidote utilizing Meridian's patented dual chambered auto-injector and injection process; and auto-injectors filled with diazepam for treatment of seizures and morphine for pain management.

On April 29, 2003, the U.S. Patent and Trademark Office, which we refer to as the PTO, issued the first patent on our FDA-approved Levoxyl®, U.S. Patent No. 6,555,581, a utility patent with composition of matter claims. We have submitted in excess of 40 applications for additional patents to the PTO relating to our novel quick-dissolving formulation of Levoxyl®.

On June 12, 2003, we acquired the primary care business of Elan Corporation, plc, and that of some of its subsidiaries, in the United States and Puerto Rico, including the rights to Sonata® and Skelaxin® and rights pertaining to potential new formulations of these products, together with Elan's United States primary care field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan's sale of Skelaxin® included related NDAs, copyrights, trademarks, patents and rights pertaining to potential new formulations of Skelaxin®. Elan's sale of Sonata® included its rights to the product, as well as certain related copyrights. We also acquired certain intellectual property, regulatory, and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, we secured an exclusive license to the intellectual property rights in this territory of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals. The total estimated purchase price of \$814.4 million includes the cost of acquisition, assumed liabilities and a portion of contingent liabilities. The purchase price also includes the transfer of inventory with a value of approximately \$40.4 million. In addition to the initial

purchase price, we paid \$25.0 million during January 2004 as a milestone payment to Elan relating to the ongoing exclusivity of Skelaxin® and we paid \$11.0 million during March 2004 as a milestone payment to Elan in connection with the development of new formulations of Sonata®. We also

will pay royalties on the current formulation of Skelaxin® from the date of closing;

will pay up to an additional \$60.0 million if Elan achieves certain milestones in connection with the development of a reformulated version of Sonata®;

will pay \$15.0 million as a milestone payment if annual net sales of a reformulated version of Sonata® exceed \$100.0 million; and

will pay for costs associated with the development of the reformulated version of Sonata®.

On June 19, 2003, we received FDA approval of our sNDA, covering pediatric and adult formulations of our nerve gas antidote AtroPen®. This is the first time that pediatric formulations of this homeland security product have been approved for use in the United States. AtroPen® utilizes our auto-injector technology.

On October 30, 2003, we announced the receipt of an approvable letter from the FDA for a new Intal® inhaler formulation utilizing hydrofluoroalkane, which we refer to as HFA, an environmentally friendly propellant. The patent related to Intal® HFA extends through September 2017.

On November 3, 2003, we announced that we have completed enrollment in the ongoing Phase IV clinical trial to determine the safety and effectiveness of Altace® in the treatment of hypertension (high blood pressure) in children. This trial, which we refer to as TOPHAT (Treatment of Pediatric Hypertension with Altace Trial), is scheduled to conclude by the end of 2004.

On December 5, 2003, we commenced the Phase III clinical trial program involving binodenoson, our next generation cardiac pharmacologic stress-imaging agent. The data from the Phase II dose ranging study indicates that binodenoson, at effective doses, is better tolerated than adenosine, the current market leader, which we previously developed.

During December 2003, we commenced the Phase I clinical trial program for T-62, a new chemical entity that we are developing as a potential treatment for neuropathic pain. The initial Phase I trial for T-62 is a single-center, randomized double-blind, placebo-controlled evaluation of the safety and pharmacokinetics of escalating single oral doses of this new chemical entity in healthy adult subjects.

On January 13, 2004, we announced the completion of dosing of the initial concentration of MRE0094 in our ongoing Phase I clinical trial program evaluating the safety of the drug in patients. MRE0094, a new chemical entity, is an adenosine A2a receptor agonist that we are developing as a potential topical treatment for chronic diabetic foot ulcers.

On January 27, 2004, the PTO issued a second utility patent pertaining to our FDA-approved product Skelaxin®. The newly issued patent extends through December 2021.

During March 2004, we terminated our contract with BearTown Pharma, Inc. to develop tetrac.

During March 2004, we commenced the Phase II clinical trial program for an extended release formulation of our Sonata® product.

Industry

The pharmaceuticals industry is a highly competitive global business composed of a variety of participants, including large and small branded pharmaceutical companies, specialty and niche-market pharmaceutical houses, biotechnology firms, large and small research and drug development organizations, and generic drug manufacturers. These participants compete for patient and physician loyalty to their products based on a number of factors, including technological innovation or novelty, clinical efficacy, safety, convenience or ease of administration and cost-effectiveness. In order to promote their products to physicians and consumers, industry participants devote considerable resources to advertising, marketing and

sales force personnel, distribution mechanisms and relationships with medical and research centers, physicians and patient advocacy and support groups.

The industry is affected by the following:

the aging of the patient population, including diseases specific to the aging process and demographic factors, including obesity, diabetes, cardiovascular disease, and patient and physician demand for products that meet chronic or unmet medical needs;

technological innovation, both in drug discovery and corporate processes;

merger and acquisition activity whereby pharmaceutical companies are acquiring one another or smaller biotechnology companies and divestitures of products deemed non-strategic ;

cost containment and downward price pressure from managed care organizations and governmental entities, both in the United States and overseas;

increased drug development and manufacturing costs for pharmaceutical producers;

the rise of generic companies and challenges to patent protection and exclusivity;

increased governmental scrutiny of the healthcare sector, including issues of patient safety, cost efficacy and reimbursement/ insurance matters; and

the cost of advertising and marketing, including direct-to-consumer advertising on television and in print.

Branded Pharmaceuticals

We market a variety of branded prescription products that primarily can be divided into the following therapeutic areas:

cardiovascular (including Altace®, Corzide®, Thalitone® and Procanbid®),

endocrinology/women s health (including Levoxyl®, Cytomel®, Triostat®, Prefest®, Menest®, Delestrogen® and Nordette®),

neuroscience (including Sonata® and Skelaxin®),

critical care (including Thrombin-JMI®, Synercid® and Brevital®),

anti-infective (including Bicillin®, Cortisporin®, Neosporin® and Coly-MycinM®), and

respiratory (including Intal® and Tilade®).

Our branded pharmaceutical products are generally in high volume therapeutic categories and are well known for their indications (for example, Altace®, Skelaxin®, Levoxyl® and Sonata®). Additionally, many of our branded products have limited or no generic competition, including patent protected products and products that are difficult to formulate. Branded pharmaceutical products represented 85.5% and 91.5% of total net revenues for each of the years ended December 31, 2003 and 2002.

Cardiovascular. Altace®, an ACE inhibitor, is our primary product within this category. In August 1999, the results of the Heart Outcomes Prevention Evaluation trial, which we refer to as the HOPE trial, were released. The HOPE trial determined that Altace® significantly reduces the rates of stroke, myocardial infarction (heart attack) and death from cardiovascular causes in a broad range of high-risk cardiovascular patients. On October 4, 2000, the FDA approved our sNDA. This approval permits the promotion of Altace® to reduce the risk of stroke, myocardial infarction (heart attack) and death from cardiovascular causes in patients 55 and over either with a history of coronary artery disease, stroke or peripheral vascular disease or with diabetes and one other cardiovascular risk factor (hypertension, elevated

total cholesterol levels, low HDL levels, cigarette smoking or documented microalbuminuria). Corzide® is a combination beta blocker and thiazide diuretic indicated for the management of hypertension. Corgard® is a beta-blocker indicated for the management of hypertension as well as long-term management of patients with angina pectoris. Procanbid® is a branded pharmaceutical product used to treat arrhythmia with a patent listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, which we refer to as the Orange Book that expires in August 2014. Thalitone® is a hypertension diuretic tablet indicated for the management of hypertension with a patent listed in the FDA's Orange Book that expires in June 2007. These products are marketed primarily to primary care physicians and cardiologists.

Endocrinology/Women's Health. We have a number of leading branded pharmaceutical products in this category including Levoxyl®, Cytomel®, Triostat®, Prefest®, Menest®, Delestrogen® and Nordette®. Levoxyl®, Cytomel® and Triostat® are indicated for the treatment of thyroid disorders. Prefest® is a combination hormone replacement therapy. Menest® and Delestrogen® are estrogen replacement therapies and Nordette® is a contraceptive. These products are marketed primarily to primary care physicians, endocrinologists and obstetricians/gynecologists.

Neuroscience. Products in this category include Sonata® and Skelaxin®. Sonata® is a nonbenzodiazepine treatment for insomnia which is promoted primarily to primary care physicians, neurologists, and psychiatrists. Skelaxin® is a muscle relaxant indicated for the relief of discomforts associated with acute, painful musculoskeletal conditions. This product is marketed primarily to primary care physicians, neurologists, orthopedic surgeons and pain specialists.

Critical Care. Products in this category are marketed primarily to hospitals. Our largest products in this category are Thrombin-JMI®, Synercid® and Brevital®. Thrombin-JMI® aids in controlling minor bleeding during surgery. Synercid® is an injectable antibiotic, primarily administered in hospitals, indicated for treatment of vancomycin-resistant enterococcus faecium and treatment of some complicated skin and skin structure infections. Brevital® is an anesthetic solution for intravenous use in adults and for rectal and intramuscular use in pediatric patients. Brevital® is marketed as a short-term and long-term anesthetic because of its rapid onset of action and quick recovery time. Brevital® is used alone and in combination with other anesthetics. Its rapid onset of action makes it a useful induction agent prior to the administration of other agents to maintain anesthesia.

Anti-infective. Our anti-infective products are marketed primarily to general/family practitioners and internal medicine physicians and are prescribed to treat uncomplicated infections of the respiratory tract, urinary tract, eyes, ears and skin. These products are generally in technologically mature product segments. Bicillin® is our largest product in the category.

Respiratory. Our respiratory products are marketed primarily to primary care physicians and respiratory specialists. Our primary products in this area include Intal® and Tilade®. Intal® and Tilade® are oral multi-dose inhalers of non-steroidal anti-inflammatory agents indicated for the preventive management of asthma.

Some of our branded prescription products are described below:

Product	Company Acquired From and Date of Acquisition	Product Description and Indication
Cardiovascular Altace®(1)	Aventis (December 1998)	A hard-shell capsule for oral administration indicated for the treatment of hypertension and reduction of the risk of stroke, myocardial infarction (heart attack) and death from cardiovascular causes in patients 55 and over either with a history of coronary artery disease, stroke or peripheral vascular disease or with diabetes and one other cardiovascular risk factor (such as elevated cholesterol levels or cigarette smoking). Altace® is also indicated in stable patients who have demonstrated clinical signs of congestive heart failure after sustaining acute myocardial infarction.
Thalitone®(2)	Horus Global HealthNet (December 1996)	A hypertension-diuretic tablet indicated for the management of hypertension, either alone or in combination with other antihypertensive drugs, and for adjunctive therapy edema associated with congestive heart failure and various forms of renal dysfunction.
Procanbid®	Pfizer (February 1998)	A procainamide extended-release tablet indicated for the treatment of documented ventricular arrhythmia, such as sustained ventricular tachycardia, that, in the judgment of a physician, are life-threatening.
Corzide®	Bristol-Myers Squibb (August 2001)	A combination beta blocker and thiazide diuretic tablet indicated for the management of hypertension.
Corgard®(3)	Bristol-Myers Squibb (August 2001)	A beta-blocker tablet, indicated for the management of hypertension as well as long term management of patients with angina pectoris.
Adrenalin®	Pfizer (February 1998)	A sterile solution made from the active principle of the adrenal medulla used to relieve respiratory distress and hypersensitivity reactions and restore cardiac rhythm in cardiac arrest due to various causes.

Product	Company Acquired From and Date of Acquisition	Product Description and Indication
Endocrinology/Women's Health		
Levoxyl®	Jones (August 2000)	Color-coded, potency marked tablets indicated for thyroid hormone replacement or supplemental therapy for hypothyroidism.
Cytomel®	Jones (August 2000)	A tablet indicated in the medical treatment of hypothyroidism. The only commercially available thyroid hormone tablet containing T(3) as a single entity.
Triostat®	Jones (August 2000)	A sterile non-pyrogenic aqueous solution for intravenous administration indicated in the treatment of myxedema coma/precoma.
Tapazole®	Jones (August 2000)	A tablet indicated in the medical treatment of hyperthyroidism.
Florinef®	Bristol-Myers Squibb (August 2001)	A partial replacement tablet therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.
Prefest®	Ortho-McNeil (May 2002)	A single tablet combination hormone replacement therapy with an intermittent progestin and continuous estrogen administration.
Nordette®	Wyeth (July 2000)	A tablet-form oral contraceptive indicated for the prevention of pregnancy.
Menest®	GlaxoSmithKline (June 1998)	A film-coated esterified estrogen tablet for the treatment of vasomotor symptoms of menopause, atrophic vaginitis, kraurosis vulvae, female hypogonadism, female castration, primary ovarian failure, breast cancer and prostatic carcinoma.
Delestrogen®	Bristol-Myers Squibb (August 2001)	An injectable estrogen replacement therapy.
Pitocin®	Pfizer (February 1998)	A sterile hormone solution used to initiate or improve uterine contractions during labor and to control bleeding or hemorrhage in the mother after childbirth.

Product	Company Acquired From and Date of Acquisition	Product Description and Indication
Anusol-HC®	Pfizer (February 1998)	A suppository and cream indicated for the relief of inflammation accompanying hemorrhoids (piles), post-irradiation proctitis, cryptitis and other inflammatory conditions of the anorectum.
Neuroscience Sonata®	Elan (June 2003)	A nonbenzodiazepine capsule treatment for insomnia.
Skelaxin®	Elan (June 2003)	A muscle relaxant tablet indicated for the relief of discomforts associated with acute, painful musculoskeletal conditions.
Critical Care Thrombin-JMI®	Jones (August 2000)	A chromatographically purified topical (bovine) thrombin solution indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible.
Synercid®	Aventis (December 2002)	An injectable antibiotic indicated for treatment of certain complicated skin and skin structure infections.
Brevital®	Jones (August 2000)	An anesthetic solution for intravenous use in adults and for rectal and intramuscular use only in pediatric patients.
Anti-Infective Bicillin®	Wyeth (July 2000)	A penicillin-based antibiotic suspension for deep muscular injection indicated for the treatment of infections due to penicillin-G-susceptible microorganisms that are susceptible to serum levels common to this particular dosage form.
Cortisporin®	GlaxoSmithKline (March 1997)	A full line of prescription antibiotic and anti-inflammatory formulations of ophthalmic ointments and suspensions, otic solutions and suspensions, and topical creams and ointments indicated for the treatment of corticosteroid-responsive dermatoses with secondary infections.

Product	Company Acquired From and Date of Acquisition	Product Description and Indication
Viroptic®	GlaxoSmithKline (May 1997)	A sterile ophthalmic solution indicated for the treatment of ocular Herpes simplex virus, idoxuridine-resistant Herpes and vidarabine-resistant Herpes. Viroptic® is also indicated for use in pediatric patients, ages six and above.
Neosporin®(4)	GlaxoSmithKline (November 1997)	A prescription strength ophthalmic ointment and solution indicated for the topical treatment of ocular infections. It is also formulated as a prescription strength genito-urinary concentrated sterile irrigant indicated for short-term use as a continuous irrigant or rinse to help prevent infections associated with the use of indwelling catheters.
Polysporin®(4)	GlaxoSmithKline (November 1997)	A prescription strength wide range antibacterial sterile ointment indicated for the topical treatment of superficial ocular infections.
Chloromycetin®	Pfizer (February 1998)	A broad spectrum antibiotic for bacterial infections that are not responsive to other antibiotics or when other antibiotics are contraindicated.
Septra®	GlaxoSmithKline (November 1997)	An antibiotic tablet, suspension and infusion indicated for the treatment of infectious diseases, including urinary tract infections, pneumonia, enteritis and ear infections in adults and children.
Coly-MycinM®	Pfizer (February 1998)	An antibiotic sterile parenteral indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacteria and a sterile aqueous suspension for the treatment of superficial bacterial infections of the external auditory canal.
Silvadene®	Aventis (December 1998)	A topical antimicrobial cream indicated as an adjunct for the prevention and treatment of wound sepsis in patients with second-and third-degree burns.
Respiratory Intal®	Aventis (December 2002)	An oral multi-dose inhaler of a non-steroidal anti-inflammatory agent for the preventive management of asthma.

Product	Company Acquired From and Date of Acquisition	Product Description and Indication
Tilade®	Aventis (December 2002)	An oral multi-dose inhaler of a non-steroidal anti-inflammatory agent for the preventive management of asthma.

- (1) We acquired licenses for the exclusive rights in the United States under various patents to the active ingredient in Altace®.
- (2) We acquired the trademark and patents for Thalitone® from Boehringer Ingelheim Pharmaceuticals, Inc.
- (3) We acquired a fully paid license to Corgard® in the United States.
- (4) We have exclusive licenses, free of royalty obligations, to manufacture and market prescription formulations of Neosporin® and Polysporin®.

Net sales of many of our branded prescription products for the year ended December 31, 2003 are set forth in the tables below.

Cardiovascular	Net sales	Respiratory	Net sales	Other	Net sales
	(in millions)		(in millions)		(in millions)
Altace®	\$527.1	Intal®	\$37.0	Aplisol®	\$ 7.5
Corzide®	15.7	Tilade®	5.0	Tigan®	5.2
Corgard®	12.5	Other	0.2	Soloxine®(3)	1.6
Procanbid®	5.2			Other	(0.3)
Adrenalin®	1.6				
Other	0.3				

Endocrinology/ Women's Health	Net sales	Anti-infectives	Net sales
	(in millions)		(in millions)
Levoxyl®	\$134.1	Synercid®	\$32.4
Cytomel®	26.0	Bicillin®	28.6
Delestrogen®	8.9	Neosporin®	8.1
Prefest®	7.2	Cortisporin®	6.1
Menest®	5.9	Coly-MycinM®	5.4
Nordette®	4.9	Silvadene®	5.1
Triostat®	3.9	Viroptic®	2.0
Anusol-HC®	3.2	Other	(1.9)
Tapazole®	2.4		
Proctocort®	1.4		
Other	(1.5)		

Neuroscience	Net sales	Critical Care	Net sales
	(in millions)		(in millions)
Skelaxin®(1)	\$179.1	Thrombin-JMI®	\$141.7
Sonata®(2)	\$ 72.5	Brevital®	3.0
		Ketalar®	1.8
		Other	1.9

- (1) Includes net sales for Skelaxin® following its acquisition on June 12, 2003.
- (2) Includes net sales for Sonata® following its acquisition on June 12, 2003.
- (3) We sold the animal health product Soloxine® to Virbac on September 8, 2003.

Net sales in the table above reflect an \$18.0 million charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$0.9 million charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997. For additional information, please see the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 17 to our audited consolidated financial statements.

Meridian Medical Technologies

Our Meridian Medical Technologies segment consists primarily of our auto-injector business. We pioneered the development, and are a manufacturer, of auto-injectors for the self-administration of injectable drugs. An auto-injector is a pre-filled, pen-like device that allows a patient or caregiver to automatically inject a precise drug dosage quickly, easily, safely and reliably. Auto-injectors are a convenient, disposable, one-time use drug delivery system designed to improve the medical and economic value of injectable drug therapies.

The commercial pharmaceutical business of our Meridian segment primarily consists of EpiPen®, an auto-injector filled with epinephrine for the emergency treatment of anaphylaxis resulting from severe or allergic reactions to insect stings or bites, foods, drugs and other allergens, as well as idiopathic or exercise induced anaphylaxis. Dey L.P. markets EpiPen® pursuant to a supply agreement that expires December 31, 2010. Under the terms of the supply agreement, we grant Dey the exclusive right and license to market, distribute and sell EpiPen® worldwide.

Our Meridian segment also has pharmaceutical products that are presently sold primarily to the DoD, under an Industrial Base Maintenance Contract. These products include AtroPen® and ComboPen® which are nerve agent antidotes. AtroPen® is an atropine-filled auto-injector and ComboPen® consists of an atropine-filled auto-injector and a pralidoxime-filled auto-injector. Other products sold to the DoD include a diazepam-filled auto-injector for the treatment of seizures and a morphine-filled auto-injector for pain management. Additionally, in January 2004, Meridian began selling a new auto-injector to the DoD called the Antidote Treatment Nerve Agent Auto-injector. This auto-injector product, also a nerve agent antidote, utilizes a dual chambered auto-injector and injection process to administer atropine and pralidoxime, which provide an improved, more efficient means of delivering these nerve agent antidotes. All U.S. Government contracts, including our Industrial Base Maintenance Contract provide that they may be terminated for the convenience of the government as well as for default. A surge capability provision allows for the coverage of defense mobilization requirements in the event of rapid military deployment. If this surge capability provision becomes operative, we may be required to devote more of our Meridian Medical Technologies segment manufacturing capacity to the production of products for the government. Our supply contracts with the DoD are subject to post-award audit and potential price determination. These audits may include a review of our performance on the contract, our pricing practices, our cost structure and our compliance with applicable laws, regulations and standards. From time to time the DoD makes claims for pricing adjustments with respect to completed contracts.

Royalties

We have successfully developed two currently marketed adenosine-based products, Adenocard® and Adenoscan®, for which we receive royalty revenues. Specifically, we are party to an agreement under which Fujisawa manufactures and markets Adenocard® and Adenoscan® in the United States and Canada in exchange for royalties. We have licensed exclusive rights to Sanofi-Synthelabo, France, to manufacture and market Adenocard® in countries other than the United States, Canada and Japan in exchange for royalties. We have licensed exclusive rights to Sanofi to manufacture and market Adenoscan® in Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom in exchange for royalties. Sanofi has received marketing approval for Adenoscan® in a number of these countries. We have licensed exclusive rights to Suntory to manufacture and market Adenocard® and Adenoscan® in Japan in exchange for royalties. We pay one-half of all royalties received from Adenocard® sales to the University

of Virginia Alumni Patents Foundation from which we acquired rights to Adenocard®. Fujisawa Healthcare, Inc. is the source of substantially all of our royalty revenues.

Royalties received by us from sales of Adenocard® and Adenoscan® outside of the United States and Canada are shared equally with Fujisawa. Fujisawa, on its own behalf and ours, obtained a license to additional intellectual property rights for intravenous adenosine in cardiac imaging and the right to use intravenous adenosine as a cardioprotectant in combination with thrombolytic therapy, balloon angioplasty and coronary bypass surgery and secured intellectual property rights to extend the exclusivity of Adenoscan® until March 2015. For additional information on our royalty agreements, please see the section below entitled Intellectual Property.

Contract Manufacturing

We utilize a portion of our excess manufacturing capacity to provide third-party contract manufacturing. We currently provide contract manufacturing for many pharmaceutical and biotechnology companies, including Pfizer, Centocor, Inc., Santen Incorporated and Hoffman-LaRoche Inc. Many of the products that we contract manufacture are difficult to manufacture and, therefore, do not attract significant competition. Contract manufacturing as a percentage of total revenues has declined from 85% in 1994 to 2% for the year ended December 31, 2003 as we have acquired and increased the sales of branded pharmaceutical products. We believe contract manufacturing provides the following benefits:

a means of absorbing overhead costs and, as such, is an efficient utilization of excess capacity; and

experience in manufacturing a broad line of formulations, which is advantageous to us in pursuing and integrating acquired products.

Sales and Marketing

We have a national sales force consisting of approximately 1,300 approved positions, which includes the primary care sales force of approximately 350 individuals acquired as part of our acquisition of Elan's primary care business. We distribute our branded pharmaceutical products primarily through wholesale pharmaceutical distributors. These products are ordinarily dispensed to the public through pharmacies by prescription. Our marketing and sales promotions for branded pharmaceutical products principally target general/family practitioners, internal medicine physicians, cardiologists, endocrinologists, neurologists, psychiatrists, obstetricians/gynecologists and hospitals through detailing and sampling to encourage physicians to prescribe more of our products. The sales force is supported and supplemented by co-promotion arrangements, telemarketing and direct mail, as well as through advertising in trade publications and representation at regional and national medical conventions. Our telemarketing and direct mailing efforts are performed primarily by using a computer sampling system which we developed to distribute samples to physicians. We identify and target physicians through data available from IMS America, Ltd. and Scott-Levin, suppliers of prescriber prescription data. We intend to seek new markets in which to promote our product lines and will continue expansion of our field sales force as product growth, product acquisitions or product approvals warrant. We seek new international markets for product lines for which we have international rights. The marketing and distribution of these products in foreign countries generally require the prior registration of the products in those countries. We generally seek to enter into distribution agreements with companies with established marketing and distribution capabilities to distribute the products in foreign countries since we do not have a distribution mechanism in place for distribution outside the United States and Puerto Rico.

Similar to other pharmaceutical companies, our principal customers are wholesale pharmaceutical distributors. The wholesale distributor network for pharmaceutical products has in recent years been subject to increasing consolidation, which has increased our, and other industry participants', customer concentration. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. For the year ended December 31, 2003, approximately 62.3% of our sales were attributable to three wholesalers: Cardinal/Bindley (26.0%), Amerisource/Bergen (15.5%) and McKesson Corporation (20.8%).

Manufacturing

Our manufacturing facilities are located in Bristol, Tennessee; Rochester, Michigan; Middleton, Wisconsin; St. Petersburg, Florida; and St. Louis, Missouri. These facilities have manufacturing, packaging, laboratory, office and warehouse space. We are licensed by the Drug Enforcement Agency, which we refer to as the DEA, a division of the Department of Justice, to procure and produce controlled substances. We manufacture certain of our own branded pharmaceutical products, as well as products owned by other pharmaceutical companies under manufacture and supply contracts.

We can produce a broad range of dosage formulations, including sterile solutions, lyophilized (freeze-dried) products, injectables, tablets and capsules, creams and ointments, suppositories and powders. We believe our manufacturing capabilities allow us to capture higher margins and pursue product line extensions more efficiently. We manufacture a portion of the finished dosage form of Altace® at our Bristol facility. However, currently many of our product lines, including Skelaxin®, Sonata®, Bicillin®, Prefest®, Delestrogen®, Corgard®, Intal®, Tilade®, Synercid® and Cortisporin® are manufactured for us by third parties. As of December 31, 2003, capacity utilization was approximately 30% at the Bristol facility, approximately 15% at the Rochester facility, approximately 100% at the Middleton facility, approximately 90% at the St. Petersburg facility and approximately 70% at the St. Louis facility. With the exception of the Middleton and St. Petersburg facilities, we believe our facilities provide us with substantial manufacturing capacity for future growth. Thrombin-JMI® is the only product we manufacture at our Middleton facility. We are currently working to expand our capacity for Thrombin-JMI®, which should be completed in approximately two years. These long-term strategies should expand our manufacturing capacity for Thrombin-JMI® upon completion. We intend to transfer, when advantageous, production of acquired branded pharmaceutical products and their product line extensions to our manufacturing facilities as soon as practicable after regulatory requirements and contract manufacturing requirements are satisfied.

In addition to manufacturing, we have fully integrated manufacturing support systems including quality assurance, quality control, regulatory compliance and logistics. These support systems enable us to maintain high standards of quality for our products and simultaneously deliver reliable services and goods to our customers on a timely basis. Companies that do not have such support systems in-house must outsource these services.

We require a supply of quality raw materials and components to manufacture and package drug products for us and for third parties with which we have contracted. Generally we have not had difficulty obtaining raw materials and components from suppliers in the past. Currently, we rely on more than 500 suppliers to deliver the necessary raw materials and components. We have no reason to believe we will be unable to procure adequate supplies of raw materials and components on a timely basis.

Research and Development

With our acquisition of Medco Research on February 25, 2000, we established the foundation for our research and development capability. Today, King Pharmaceuticals Research and Development (formerly named Medco Research) is engaged in the discovery and development of chemical compounds, including new chemical entities, which provide us with strategic pipeline opportunities for the commercialization of new branded prescription pharmaceutical products. In addition to discovering and developing new chemical compounds, we pursue means of enhancing the value of existing products through new uses and formulations that may provide additional benefits to patients and improvements in the quality and efficiency of our manufacturing processes.

We invest in research and development because we believe it is important to our long-term growth. We presently employ approximately 75 people in research and development, which include pre-clinical and toxicology experts, medical affairs personnel, statisticians and project managers.

In the conduct of our research and development, we utilize a project management model that provides us with substantial flexibility, with a goal of maximizing efficiency and minimizing internal fixed costs. Utilizing this model, we supplement our internal efforts by collaborating with independent research organizations, including educational institutions and research-based pharmaceutical and biotechnology

companies, and contracting with others for the performance of research in their facilities. We use the services of physicians, hospitals, medical schools, universities, and other research organizations worldwide to conduct clinical trials to establish the safety and effectiveness of new products. We seek investments in external research and technologies that hold the promise to complement and strengthen our own research efforts. These investments can take many forms, including in-licensing arrangements, co-development and co-marketing agreements, joint ventures, and the acquisition of products in development.

Drug development is time-consuming, expensive and risky. Only a small percentage of chemical compounds discovered by researchers prove to be both medically effective and safe enough to become an approved medicine. The process from discovery to regulatory approval typically takes 10 to 15 years or longer. Drug candidates can fail at any stage of the process, and even late-stage product candidates sometimes fail to receive regulatory approval. Potential products for which we currently have applications under review by the FDA are:

our diazepam-filled auto-injector, which is an adjunctive injectable therapy for the emergency treatment of status epilepticus and severe recurrent convulsive seizures associated with epilepsy; and

a new Intal® inhaler formulation utilizing HFA, an environmentally friendly propellant.

Our development projects involving currently marketed compounds include the following:

an extended release formulation of Sonata®, our nonbenzodiazepine treatment for insomnia;

a modified release formulation of Altace®, our ACE inhibitor; and

a new formulation of Intal®, for the long-term management of asthma, utilizing the environmentally friendly propellant HFA.

Other compounds in development include the following:

binodenoson, our next generation cardiac pharmacologic stress-imaging agent;

T-62, an investigational drug for the treatment of neuropathic pain; and

MRE0094, an investigational drug for the topical treatment of chronic diabetic neuropathic foot ulcers.

We are party to a Development and Commercialization Agreement with Discovery Therapeutics, Inc. (predecessor to Aderis Pharmaceuticals) dedicated to the discovery, development and commercialization of compounds that stimulate the A2a subfamily of adenosine receptors, which we call A2a-agonists. Under the terms of that agreement, Aderis granted us an exclusive license under certain U.S. and foreign patents and pending applications relating to A2a-agonists. We have exclusive rights under this license to market and sell developed compounds, either directly or through sublicense. In exchange for these rights, we agreed to pay Aderis licensing fees, development milestones and royalties on future sales of A2a-agonist products utilizing these compounds. These compounds include binodenoson and MRE0094 which we currently have under development.

Our research and development expenses were \$26.5 million in 2001, \$28.2 million in 2002 and \$44.1 million in 2003, excluding research and development in-process at the time of acquisition. In-process research and development expenses were \$12.0 million for the year ended December 31, 2002 and \$194.0 million for the year ended December 31, 2003. There were no in-process research and development expenses during 2001.

Government Regulation

Our business and our products are subject to extensive and rigorous regulation at both the federal and state levels. Nearly all of our products are subject to pre-market approval requirements. New drugs are approved under, and are subject to, the FDC Act and related regulations. Biological drugs are subject to both the FDC Act and the Public Health Service Act, which we refer to as the PHS Act, and related regulations. Biological drugs are licensed under the PHS Act.

At the federal level, we are principally regulated by the FDA as well as by the DEA, the Consumer Product Safety Commission, the Federal Trade Commission, the U.S. Department of Agriculture, the

Occupation Safety and Health Administration, and the U.S. Environmental Protection Agency, which we refer to as the EPA. The FDC Act, the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the development, testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products and those manufactured by and for third parties. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

When we acquire the right to market an existing approved pharmaceutical product, both we and the former application holder are required to submit certain information to the FDA. This information, if adequate, results in the transfer to us of marketing rights to the pharmaceutical products. We are also required to advise the FDA about any changes in certain conditions in the approved application as set forth in the FDA's regulations. Our business strategy includes acquiring branded pharmaceutical products and transferring, when advantageous, their manufacture to our manufacturing facilities as soon as practicable after regulatory requirements are satisfied. In order to transfer manufacturing of the acquired branded products, we must demonstrate, by filing information with the FDA, that we can manufacture the product in accordance with current Good Manufacturing Practices, which we refer to as cGMPs, and the specifications and conditions of the approved marketing application. For changes requiring prior approval, there can be no assurance that the FDA will grant such approval in a timely manner, if at all.

The FDA also mandates that drugs be manufactured, packaged and labeled in conformity with cGMPs. In complying with cGMP regulations, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure that the products meet applicable specifications and other requirements to ensure product safety and efficacy.

The FDA periodically inspects drug manufacturing facilities to ensure compliance with applicable cGMP requirements. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product or recall of a product. Adverse experiences with the use of products must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The federal government has extensive enforcement powers over the activities of pharmaceutical manufacturers including the authority to withdraw product approvals, commence actions to seize and prohibit the sale of unapproved or non-complying products, to halt manufacturing operations that are not in compliance with cGMPs, and to impose or seek injunctions, voluntary or involuntary recalls, and civil monetary and criminal penalties. Such a restriction or prohibition on sales or withdrawal of approval of products marketed by us could materially adversely affect our business, financial condition or results of operations.

Marketing authority for our products is subject to revocation by the applicable governmental agencies. In addition, modifications or enhancements of approved products or changes in manufacturing locations are in many circumstances subject to additional FDA approvals, which may or may not be received and which may be subject to a lengthy application process. Our manufacturing facilities are continually subject to inspection by such governmental agencies, and manufacturing operations could be interrupted or halted in any such facilities if such inspections prove unsatisfactory.

We also manufacture and sell pharmaceutical products which are controlled substances as defined in the Controlled Substances Act and related federal and state laws, which establish certain security, licensing, record keeping, reporting and personnel requirements administered by the DEA and state authorities. The DEA has a dual mission of law enforcement and regulation. The former deals with the illicit aspects of the control of abusable substances and the equipment and raw materials used in making them. The DEA shares enforcement authority with the Federal Bureau of Investigation, another division of the Department of Justice. The DEA's regulatory responsibilities are concerned with the control of licensed manufacturers, distributors and dispensers of controlled substances, the substances themselves and the equipment and raw materials used in their manufacture and packaging in order to prevent such articles

from being diverted into illicit channels of commerce. We maintain appropriate licenses and certificates with the applicable state authorities in order to engage in pharmaceutical development, manufacturing and distribution of pharmaceutical products containing controlled substances. We are licensed by the DEA to manufacture and distribute certain pharmaceutical products containing controlled substances.

The distribution of pharmaceutical products is subject to the Prescription Drug Marketing Act, which we refer to as PDMA, a part of the FDC Act, which regulates distribution activities at both the federal and state level. Under the PDMA and its implementing regulations, states are permitted to require registration of manufacturers and distributors who provide pharmaceuticals even if these manufacturers or distributors have no place of business within the state. States are also permitted to adopt regulations limiting the distribution of product samples to licensed practitioners. The PDMA also imposes extensive licensing, personnel record keeping, packaging, quantity, labeling, product handling and facility storage and security requirements intended to prevent the sale of pharmaceutical product samples or other diversions. During 2003, we implemented an automated inventory accountability system for use by our sales force.

Our Rochester facility, manufactures both drug and biological pharmaceutical products. Prior to our acquisition of this facility in February 1998, it was one of six Pfizer facilities subject to a consent decree issued by the U.S. District Court of New Jersey in August 1993. We plan to petition for relief from the consent decree with respect to the Rochester facility when appropriate.

The Rochester facility was inspected by the FDA in March 2003. During this inspection, the FDA made cGMP observations in a written report provided to us. This written report is known as an FDA Form 483 or simply as a 483. The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a pharmaceutical manufacturer receives a 483 after an inspection. While no law or regulation requires us to respond to a 483, we provided the FDA with a written response to the 483 related to the March 2003 inspection of the Parkedale facility, including action plans to address the observations. The 483 from March 2003 does not require us to delay or discontinue the production of any products made at the Rochester facility. The FDA's Team Biologics inspected the Rochester facility in August 2003 with no FDA Form 483 issued.

We cannot determine what effect changes in regulations or statutes or legal interpretation, when and if promulgated or enacted, may have on our business in the future. New laws, regulations, standards, or interpretations could, among other things, require changes to manufacturing methods, expanded or different labeling, the recall, replacement or discontinuance of certain products, additional record keeping or expanded documentation of the properties of certain products and scientific substantiation. These changes, or new legislation, could have a material adverse effect on our business, financial condition or results of operations.

Environmental Matters

Our operations are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances and the discharge of pollutants into the air and water. Environmental permits and controls are required for some of our operations and these permits are subject to modification, renewal and revocation by the issuing authorities. We believe that our facilities are in substantial compliance with our permits and environmental laws and regulations and do not believe that future compliance with current environmental law will have a material adverse effect on our business, financial condition or results of operations. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or as a result of increased manufacturing activities at any of our facilities.

Under the Comprehensive Environmental Response, Compensation, and Liability Act, which we refer to as CERCLA, the EPA can impose liability for the entire cost of cleanup of contaminated properties upon each or any of the current and former site owners, site operators or parties who sent waste to the site, regardless of fault or the legality of the original disposal activity. In addition, many states, including

Tennessee, Michigan, Wisconsin, Florida and Missouri, have statutes and regulatory authorities similar to CERCLA and to the EPA. We have entered into hazardous waste hauling agreements with licensed third parties to properly dispose of hazardous wastes. We cannot assure you that we will not be found liable under CERCLA or other applicable state statutes or regulations for the costs of undertaking a clean up at a site to which our wastes were transported.

Competition

General

We compete with other pharmaceutical companies for products and product line acquisitions. Competitors include Biovail Corporation, Forest Laboratories, Inc., Galen Holdings, plc, Shire Pharmaceuticals Group plc, Medicis Pharmaceutical Corporation, Watson Pharmaceuticals, Inc., and other companies which also acquire branded pharmaceutical products and product lines from other pharmaceutical companies. Additionally, since our products are generally established and commonly sold, they are subject to competition from products with similar qualities. Our branded pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic equivalents. The manufacturers of generic products typically do not bear the related research and development costs and consequently are able to offer such products at considerably lower prices than the branded equivalents. There are, however, a number of factors, which enable products to remain profitable once patent protection has ceased. These include the establishment of a strong brand image with the prescriber or the consumer, supported by the development of a broader range of alternative formulations than the manufacturers of generic products typically supply.

Generic Substitutes

Many of our branded pharmaceutical products have either a strong market niche or competitive position. Some of our branded pharmaceutical products face competition from generic substitutes. For a manufacturer to launch a generic substitute, it must prove to the FDA when filing an application to make a generic substitute that the branded pharmaceutical and the generic substitute have bioequivalence. It typically takes two or three years to prove bioequivalence and receive FDA approval for many generic substitutes. By focusing our efforts in part on products with patent protection, challenging bioequivalence or complex manufacturing requirements, we are better able to maintain market share and produce sustainable, high margins and cash flows.

Due to recent statutory changes, the FDA may approve generic substitutes of our branded pharmaceutical products in a shorter period of time. Previously, the FDA required that generic applicants claiming patent invalidity or non-infringement give us notice each time either an abbreviated new drug application, which we refer to as an ANDA, was submitted or amended to claim invalidity or non-infringement of newly listed patents. If we filed a patent infringement suit against the generic applicant within 45 days of receiving such notice, the FDA was barred (or stayed) from approving the ANDA for 30 months unless specific events occurred sooner. To avoid multiple 30-month stays for the same branded drug, the recent statutory changes modified the relevant provisions of the Hatch-Waxman Act (21 U.S.C. §§ 355(j)(2) and (5)) to indicate that a 30-month stay will only attach to patents that are listed in the FDA's Orange Book at the time an ANDA is originally filed. Although the ANDA filer is still required to certify against a late-listed patent, the NDA holder can still bring suit based upon infringement of that patent, but such a suit will no longer trigger an additional 30-month stay of FDA approval of the ANDA. As a result, generic substitutes of our branded pharmaceutical products could be approved sooner.

Also, recent regulatory changes significantly alter patent listing requirements in the FDA's Orange Book. Only patents listed in the FDA's Orange Book are eligible for protection by a 30-month stay. We are now required to list all patents that claim a composition of matter relating to a drug or a method of using a drug. Previously, this provision was interpreted broadly, allowing the listing of many drug patents. The FDA's new regulations prohibit listing of certain types of patents, including patents claiming certain metabolites (the active moiety that results from the body's metabolism of the drug substance), intermediates (namely, substances not present in the finished product), certain methods of use, or patents

claiming certain product packaging. As such, some patents that may issue in the future may not be eligible for listing in the FDA's Orange Book and thus not eligible for protection by a 30-month stay.

Intellectual Property

Patents, Licenses and Proprietary Rights

We consider the protection of discoveries in connection with our development activities important to our business. The patent positions of pharmaceutical companies, including ours, are uncertain and involve legal and factual questions, which can be difficult to resolve. We intend to seek patent protection in the United States and selected foreign countries where and when appropriate.

In connection with the Altace® product line, we acquired a license for the exclusive rights in the United States and Puerto Rico to various Aventis patents, including the rights to the active ingredients in Altace® having patents listed in the FDA Orange Book that expire in January 2005, October 2008 and April 2012. Our rights include the use of the active ingredients in Altace® generally in combination as human therapeutic or human diagnostic products in the United States. For a discussion of challenges to our patents by generic drug manufacturers, please see the section entitled "Risk Factors" under the heading "If we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl® and Skelaxin® or relating to our product Prefest® against generic drug manufacturers, our results of operations could be materially adversely affected." We also own U.S. patents listed in the FDA's Orange Book that expire in August 2014 for Procanbid®. Additionally, we own a U.S. patent for Thalitone®, which is listed in the FDA's Orange Book and expires in June 2007.

Skelaxin® has two method-of-use patents listed in the FDA's Orange Book, which do not expire until December 2021. For a discussion of challenges to our patents by generic drug manufacturers, please see the section entitled "Risk Factors" under the heading "If we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl®, and Skelaxin®, or relating to our product Prefest®, against generic drug manufacturers, our results of operations could be materially adversely affected."

We have filed in excess of 40 patent applications related to Levoxyl®. The first U.S. patent on Levoxyl®, U.S. Patent No. 6,555,581, a utility patent with composition of matter claims, listed in the FDA's Orange Book, was issued on April 29, 2003 and extends through February 15, 2022. The other pending patent applications generally cover, among other things, formulation methodologies and equipment, formulation technologies, biopharmaceutical characteristics, drug delivery systems and methods-of-use. If these other applications are granted, the resulting patents will potentially provide us with additional patent protection on our FDA-approved novel formulation of Levoxyl®. For a discussion of challenges to our patent by generic drug manufacturers, please see the section entitled "Risk Factors" under the heading "If we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl®, and Skelaxin®, or relating to our product Prefest®, against generic drug manufacturers, our results of operations could be materially adversely affected."

Sonata® has a composition of matter patent listed in the FDA's Orange Book that extends through June 2008.

In connection with our acquisition of the rights to Intal®, Tilade®, and Synercid® on December 30, 2002, we acquired associated intellectual property rights, including patent rights in the United States related to the HFA formulation of Intal® until September 2017, a composition of matter patent in the United States for Tilade® until October 2006 and a formulation patent in the United States for Synercid® until November 2017.

We have exclusive licenses expiring in June 2036 for the prescription formulations of Neosporin® and Polysporin® and a license expiring in February 2038 for the prescription formulation of Anusol-HC®. These licenses are subject to early termination in the event we fail to meet specified quality control standards, including cGMP regulations with respect to the products, or commit a material breach of other terms and conditions of the licenses which would have a significant adverse effect on the uses of the

licensed products retained by the licensor, which would include among other things, marketing products under these trade names outside the prescription field.

In connection with the acquisition of the rights to Prefest® on May 29, 2002, we acquired a pharmaceutical preparation patent listed in the FDA's Orange Book that expires in January 2012, as well as a second Orange Book listed patent that expires in April 2009. For a discussion of a challenge to our patents by a generic drug manufacturer, please see the section entitled "Risk Factors." If we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl® and Skelaxin® or relating to our product Prefest® against generic drug manufacturers, our results of operations could be materially adversely affected.

In connection with the acquisition of Lorabid®, we acquired, among other things, all of Eli Lilly's rights in approximately 30 patents and received a broad royalty-free non-exclusive license in the United States and Puerto Rico to 12 other patents and associated technology. We also received an exclusive sublicense to four other patents for which we must pay a royalty to Eli Lilly if certain sales thresholds are met. Lorabid® has patent protection through 2005.

We have filed with the PTO an application for a patent covering our new Tigan® technology, including our FDA-approved Tigan® 300mg capsules. The pending patent application is drawn to, among other things, formulations, dosages, dosage forms, biopharmaceutical characteristics, methods-of-production, methods-of-use and methods-of-instruction. If the application is granted, the resulting patent will potentially provide us with patent protection for our FDA-approved Tigan® 300mg capsules for 20 years from the filing date of the application.

In connection with the acquisition of Meridian on January 8, 2003, we acquired the intellectual property rights associated with Meridian's dual-chambered auto-injector and injection process, which has a patent that expires in April 2010.

We receive royalties on sales of Adenoscan® and Adenocard®, two products that we successfully developed. Adenoscan® has patent coverage that extends to March 2015, Adenocard® has patent coverage that extends through June 2004.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation to develop and sustain our competitive position. There can be no assurance that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets or disclose the technology or that we can adequately protect our trade secrets.

Trademarks

We sell our branded products under a variety of trademarks. We believe that we have valid proprietary interests in all currently used trademarks, including those for our principal branded pharmaceutical products registered in the United States.

Backlog

As of February 26, 2004, we had no material backlog.

Employees

As of February 26, 2004, we employed 2,997 full-time and 6 part-time persons. Approximately 230 employees of the Rochester facility are covered by a collective bargaining agreement with the Paper, Allied Industrial, Chemical & Energy Workers, International Union (PACE), Local No. 60178, which expires on February 28, 2006. Approximately 320 employees of the St. Louis facility are covered by a collective bargaining agreement with the International Brotherhood of Teamsters, Chaffeurs, Warehousemen and Helpers of America Union, Local No. 688, which expires February 28, 2005. We believe our employee relations are good.

RISK FACTORS

Before you purchase our securities, you should carefully consider the risks described below and the other information contained in this report, including our audited consolidated financial statements and related notes. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the adverse events described in this Risk Factors section or other sections of this report actually occurs, our business, results of operations and financial condition could be materially adversely affected, the trading price, if any, of our securities could decline and you might lose all or part of your investment.

Risks Related to our Business

Investigations by the SEC and Office of Inspector General of the Department of Health and Human Services, other possible governmental investigations, and securities and ERISA litigation could have a material adverse effect on our business.

As previously reported, in March 2003 the SEC initiated a formal investigation of King. We received SEC subpoenas relating to, among other topics, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and the Audit Committee's internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, we received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®.

In connection with our determination that we have underpaid amounts due to Medicaid and other governmental pricing programs, we have continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Public Health Service. We expect that these discussions will include a detailed review by the appropriate agencies of our calculations of our underpayments, and it is possible that this review could result in material changes. The SEC, the Office of Inspector General, the Department of Justice, the Department of Veterans Affairs, the Public Health Service, the Centers for Medicare and Medicaid Services and other governmental agencies that might be investigating or might commence an investigation of us could impose, based on a claim of a violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time. For additional information, please see the section entitled

Risk Factors under the heading If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business and the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations under the heading Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of our securities against us, our directors, former directors, executive officers, former executive officers, a subsidiary, and a former director of the subsidiary in the United States District Court for the Eastern District of Tennessee, alleging violations of the Securities Act of 1933 and/or the Securities Exchange Act of 1934. These 22 complaints have been consolidated in the United States District Court for the Eastern District of Tennessee. In addition, holders of our securities filed two class action complaints alleging violations of the Securities Act of 1933 in Tennessee state court. We removed these two cases to the United States District Court for the Eastern

District of Tennessee, where these two cases were consolidated with the other class actions. Plaintiffs in these actions unsuccessfully moved to remand these two cases back to Tennessee state court. These two actions therefore remain part of the consolidated action. The district court has appointed lead plaintiffs in the consolidated action, and those lead plaintiffs filed a consolidated amended complaint on October 21, 2003 alleging that we, through some of our executive officers, former executive officers, directors and former directors, made false or misleading statements concerning our business, financial condition and results of operations during periods beginning February 16, 1999 and continuing until March 10, 2003. Plaintiffs in the consolidated action have also named the underwriters of our November 2001 public offering as defendants. We and other defendants have filed motions to dismiss the consolidated amended complaint, and those motions are currently pending.

Seven purported shareholder derivative complaints have also been filed in federal and state courts in Tennessee alleging a breach of fiduciary duty, among other things, by some of our officers and directors. The derivative cases in state court were consolidated and are currently stayed. The stay will remain in place at least until the motions to dismiss the consolidated federal class securities action are decided. The derivative cases in federal court are stayed until there is a decision on the merits in the state court derivative suits. Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act, which we refer to as ERISA. As amended, the complaint alleges that we and certain of our executive officers, former executive officers, directors, former directors and an employee violated fiduciary duties that were allegedly owed our 401(k) Retirement Savings Plan's participants and beneficiaries under ERISA. The allegations underlying each of these additional lawsuits are similar in many respects to those in the class action litigation described above. We filed a motion to dismiss the ERISA action on March 5, 2004; this motion to dismiss is currently pending.

We intend to defend all of these lawsuits vigorously but are unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

If any governmental sanctions are imposed, or if we were not to prevail in the pending litigation, neither of which we can predict or reasonably estimate at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the governmental investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending us in the pending litigation has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees.

If sales of our major products or royalty payments to us decrease, our results of operations could be materially adversely affected.

Altace®, Skelaxin®, Thrombin-JMI®, Levoxyl®, Sonata® and royalty revenues for the year ended December 31, 2003 accounted for 34.6%, 11.8%, 9.3%, 8.8%, 4.8% and 4.5% of our total revenues, respectively, or 73.8% in total. We believe that these sources of revenue may constitute a significant portion of our revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of any of these products or products for which we receive royalty payments could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl® and Skelaxin®, or relating to our product Prefest®, against generic drug manufacturers, our results of operations could be materially adversely affected.

Cobalt Pharmaceuticals, Inc., a generic drug manufacturer located in Mississauga, Ontario, Canada, has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA's Orange Book: United States Patent Nos. 4,587,258, the 258 patent, and 5,061,722, the 722 patent, two composition of matter patents related to Altace®, and United States Patent No. 5,403,856, the 856 patent, a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the

Hatch-Waxman Act, any generic manufacturer may file an ANDA with a certification, known as a Paragraph IV certification, challenging the validity or infringement of a patent listed in the FDA's Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the '722 patent, and we filed suit on March 14, 2003 to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt's ANDA for 30 months from no earlier than February 5, 2003. Should the court find in favor of a Cobalt summary judgment motion on the '722 patent, however, we would not receive the full benefit of that 30 month stay. Subsequent to filing our original complaint, we amended our complaint to add an allegation of infringement of the '856 patent. In its answer to the amended complaint, Cobalt denied infringement and alleged that the '856 patent is invalid. Pursuant to FDA regulations, however, Cobalt is not required to certify against the '856 patent. We intend to vigorously enforce our rights under the '722 and '856 patents. Regardless of the outcome of the lawsuit involving the '722 and '856 patents, however, Cobalt has not challenged the validity of the '258 patent and, therefore, cannot market a generic version of Altace® prior to the expiration of that patent in January 2005.

Eon Labs, Inc., CorePharma, LLC and Mutual Pharmaceutical Co., Inc. have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. United States Patent Nos. 6,407,128, the '128 patent, and 6,683,102, the '102 patent, two method-of-use patents relating to Skelaxin®, are listed in the FDA's Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the '128 patent. Mutual has filed a Paragraph IV certification alleging noninfringement and invalidity of the '102 patent. We filed separate suits against Eon Labs on January 2, 2003 and CorePharma on March 7, 2003 and are currently assessing our right to bring suit against Mutual. Pursuant to the Hatch-Waxman Act, the filing of the suits against Core and Eon provides us with an automatic stay of FDA approval of Eon's ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of Core's ANDA for 30 months from no earlier than January 24, 2003. We intend to vigorously enforce our rights under the '128 and '102 patents to the full extent of the law. On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA's Orange Book for the '128 patent may be deleted from the ANDA applicants' product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA's previous position on this issue. We are currently assessing our administrative and legal options and may request the FDA to reinstate its previous policy on this issue and reject any ANDAs that delete such use from their product labeling. If we are unable to persuade the FDA to reinstate its previous policy, however, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

Mylan Pharmaceuticals, Inc. and KV Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. United States Patent No. 6,555,581, the '581 patent, a utility patent with formulation claims relating to Levoxyl®, was issued to us on April 29, 2003. The '581 patent is listed in the FDA's Orange Book and does not expire until February 15, 2022. No earlier than April 30, 2003, we received notice of Mylan's Paragraph IV certification, which alleges noninfringement of the '581 patent. We filed suit against Mylan on June 13, 2003 in the Eastern District of Pennsylvania and on June 16, 2003 in the Northern District of West Virginia; these suits have been consolidated in the Northern District of West Virginia and trial is currently scheduled for June 2005. Pursuant to the Hatch-Waxman Act, the filing of the suits against Mylan provides us with an automatic stay of FDA approval of Mylan's ANDA for 30 months from no earlier than April 30, 2003. On June 24, 2003, we received notice of KV's Paragraph IV certification, which alleges noninfringement and invalidity of the '581 patent. We filed suit against KV on August 7, 2003 and trial is currently scheduled to begin December 6, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suit against KV provides us with an automatic stay of FDA approval of KV's ANDA for 30 months from no earlier than June 24, 2003. We intend to vigorously enforce our rights under the '581 patent to the full extent of the law.

Barr Laboratories Inc. has filed an ANDA, which included a Paragraph IV certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995, the 995 patent, a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573, the 573 patent, a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the FDA's Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 15, 2003, we received notice of Barr's Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. On November 26, 2003, we filed suit against Barr in the Southern District of New York for infringement of the 995 and 573 patents. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Barr's ANDA for 30 months from no earlier than October 15, 2003. We intend to vigorously enforce our rights under both patents.

Although we have an obligation to indemnify our officers and directors, we may not have sufficient insurance coverage available for this purpose and may be forced to pay these indemnification costs directly and we may not be able to maintain existing levels of coverage, which could make it difficult to attract or retain qualified directors and officers.

Our charter and bylaws require that we indemnify our directors and officers to the fullest extent provided by applicable Tennessee law. Although we have purchased liability insurance for our directors and officers to fund such obligations, if our insurance carrier should deny coverage, or if the indemnification costs exceed the insurance coverage, we would be forced to bear some or all of these indemnification costs directly, which could be substantial and may have an adverse effect on our business, financial condition, results of operations and cash flows. If the cost of this insurance continues to increase significantly, or if this insurance becomes unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers, which could make it difficult to attract or retain qualified directors and officers.

We may not achieve our intended benefits from the Co-Promotion Agreement with Wyeth for the promotion of Altace®.

We entered into the Co-Promotion Agreement with Wyeth for Altace® partially because we believed a larger pharmaceutical company with more sales representatives and, in our opinion, with substantial experience in the promotion of pharmaceutical products to physicians would significantly increase the sales revenue potential of Altace®. By effectively co-marketing the new indications for Altace® that were approved by the FDA on October 4, 2000, we intend to increase the demand for the product. In the agreement, both of us have incentives to maximize the sales of Altace® and to optimize the marketing of the product by coordinating our promotional activities.

It is possible that we or Wyeth or both of us will not be successful in effectively promoting Altace® or in optimizing its sales. The content of agreed-upon promotional messages for Altace® may not sufficiently convey the merits of Altace® and may not be successful in convincing physicians to prescribe Altace® instead of other ACE inhibitors or competing therapies. The targets for sales force staffing, the number and frequency of details to physicians and the physicians who are called upon may be inadequate to realize our expectations for revenues from Altace®. If disputes arise between Wyeth and us relating to our respective obligations under the Co-Promotion Agreement and these disputes are resolved against us, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Neither we nor Wyeth may be able to overcome the perception by physicians of a class effect, which we discuss below. Further, developments in technologies, the introduction of other products or new therapies may make it more attractive for Wyeth to concentrate on the promotion of a product or products other than Altace® or to lessen their emphasis on the marketing of Altace®. Our strategic decisions in dealing with managed health care organizations may not prove to be correct and we could consequently lose sales in this market to competing ACE inhibitor products or alternative therapies. If any of these

situations occurred, they could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If our Bristol facility and the Aventis (USA) facility do not remain FDA-approved manufacturing and packaging sites for Altace® or if there is an interruption in the supply of raw material for Altace® or of the finished product, the distribution, marketing and subsequent sales of the product could be adversely affected.

Our Bristol facility is an FDA-approved manufacturing and packaging site for Altace®. Aventis (USA) in Kansas City, Missouri, is our alternative or back-up FDA-approved manufacturing and packaging site for Altace®. Aventis Pharma Deutschland GmbH (Germany) is our single supplier of ramipril, the active ingredient in Altace®. Because the manufacture of ramipril is a patented process, we cannot secure the raw material from another source. We have entered into a long-term supply agreement with Aventis (Germany) for ramipril and we believe that it adequately protects our supply of raw material, but there can be no guarantee that there will be no interruptions or delays in the supply of the raw material. Any interruptions or delays in manufacturing or receiving the finished product or raw material used for the future production of Altace® or the failure to maintain our Bristol facility and the Aventis (USA) facility as FDA-approved manufacturing and packaging sites for Altace® could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Sales of Altace® may be affected by the perception of a class effect, and Altace® and our other products may be subject to various sources of competition from alternate therapies.

Although the FDA has approved indications for Altace® that are unique among ACE inhibitors, we may be unable to meet investors expectations regarding sales of Altace® due to a perceived class effect or the inability to market Altace®'s differentiating uses and indications effectively.

All prescription drugs currently marketed by pharmaceutical companies may be grouped into existing drug classes, but the criteria for inclusion vary from class to class. For some classes, specific biochemical properties may be the defining characteristic. For example, Altace® (ramipril) is a member of a class of products known as ACE inhibitors because ramipril is one of several chemicals that inhibit the production of enzymes that convert angiotensin, which could otherwise lead to hypertension.

When one drug from a class is demonstrated to have a particularly beneficial or previously undemonstrated effect (e.g., the benefit of Altace® as shown by the HOPE trial), marketers of other drugs in the same class (for example, other ACE inhibitors) will represent that their products offer the same benefit simply by virtue of membership in the same drug class. Consequently, other companies with ACE inhibitors that compete with Altace® will represent that their products are equivalent to Altace®. By doing so, these companies will represent that their products offer the same efficacious results demonstrated by the HOPE trial. Regulatory agencies do not decide whether products within a class are quantitatively equivalent in terms of efficacy or safety. Because comparative data among products in the same drug class are rare, marketing forces often dictate a physician's decision to use one ACE inhibitor over another. We may not be able to overcome other companies' representations that their ACE inhibitors will offer the same benefits as Altace® as demonstrated by the HOPE trial. As a result, sales of Altace® may suffer from the perception of a class effect.

Currently, no generic form of Altace® is available, although Cobalt Pharmaceuticals has filed a Paragraph IV certification pertaining to Altace® which we have described above. That is, there is no product that has the same active ingredient, ramipril, as Altace®. Although no generic substitute for Altace® has been approved by the FDA, there are other ACE inhibitors whose patents have expired or will expire in the next few years and there are generic forms of other ACE inhibitors. Also, there are different therapeutic agents that may be used to treat certain conditions treated by Altace®. For example, the group of products known as angiotensin II receptor blockers, which we refer to as an ARB, beta-blockers, calcium channel blockers and diuretics, may be prescribed to treat certain conditions that Altace® is used to treat. New ACE inhibitors or other anti-hypertensive therapies, increased sales of generic forms of other ACE inhibitors or of other therapeutic agents that compete with Altace® may adversely affect the sales of

Altace®. In these events, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Our Co-Promotion Agreement for Altace® with Wyeth could be terminated before we realize all of the benefits of the agreement, it could be assigned to another company by Wyeth or Wyeth could market a competing product.

Our exclusive Co-Promotion Agreement for Altace® with Wyeth could, under some circumstances, be terminated before we realize all of the benefits of the agreement. If the Co-Promotion Agreement is terminated for any reason, we may not realize increased sales which we believe may result from the expanded promotion of Altace®. If we must unwind our marketing alliance efforts, there may be a material adverse effect on the sales of Altace®.

If another company were to acquire, directly or indirectly, over 50% of the combined voting power of Wyeth's voting securities or more than half of its total assets, then Wyeth could assign its rights and obligations under the Altace® Co-Promotion Agreement to a successor without our prior consent. However, a successor would be required to first assume in writing the obligations of Wyeth under the Co-Promotion Agreement before the rights of Wyeth were assigned to it. Another party might not market Altace® as effectively or efficiently as Wyeth did. Also, a company that acquires Wyeth might not place as much emphasis on the Co-Promotion Agreement, might expend fewer marketing resources, such as fewer sales representatives, than Wyeth did, or might have less experience or expertise in marketing pharmaceutical products to physicians. In any of these cases, there may be a material adverse effect on the sales of Altace®.

When feasible, Wyeth must give us six months' written notice of its intent to sell, market or distribute any product competitive with Altace®. Under the Co-Promotion Agreement, a product competes with Altace® if it is an ACE inhibitor, an ARB, or an ACE inhibitor or ARB in combination with other cardiovascular agents in a single product. However, an ARB alone or in combination with other cardiovascular agents competes with Altace® only if the level of promotional effort used by Wyeth for the ARB is greater than 50% of that applied to Altace®. A product would not compete with Altace® if in the last 12 months it had net sales of less than \$100.0 million or 15% of net sales of Altace®, whichever was higher. Also, a product would not compete with Altace® under the Co-Promotion Agreement if the product were acquired by Wyeth through a merger with or acquisition by a third party and the product were no longer actively promoted by Wyeth or its successor through detailing the product to physicians.

Once we have been notified in writing of Wyeth's intent to market, sell or distribute a competing product, then Wyeth has 90 days to inform us as to whether it intends to divest its interest in the competing product. If Wyeth elects to divest the competing product, it must try to identify a purchaser and to enter into a definitive agreement with the purchaser as soon as practicable. If Wyeth elects not to divest the competing product or fails to divest the product within one year of providing notice to us of its plan to divest the competing product, then both of us must attempt to establish acceptable terms under which we would co-promote the competing product for the remaining term of our Altace® Co-Promotion Agreement. Alternatively, Wyeth and we could agree upon another commercial relationship, such as royalties payable to us for the sale of the competing product, or we could agree to adjust the promotion fee we pay to Wyeth for the co-promotion of Altace®. If Wyeth and we are unable to establish acceptable terms under any of these options, then we have the option at our sole discretion to reacquire all the marketing rights to Altace® and terminate the Co-Promotion Agreement upon 180 days prior written notice to Wyeth. In the event we decided to reacquire all the marketing rights to Altace® we would be obligated to pay Wyeth an amount of cash equal to twice the net sales of Altace® in the United States for the 12 month period preceding the reacquisition. The foregoing could have a material effect on our business, financial condition, results of operations and cash flows.

Our sales of Levoxyl® could be affected by future actions of the FDA, the possible development and approval of a generic substitute for Levoxyl® and our ability to maintain effective patent protection for Levoxyl®.

On August 14, 1997, the FDA announced in the Federal Register (62 FR 43535) that orally administered levothyroxine sodium drug products are new drugs. The notice stated that manufacturers who wish to continue to market these products must submit applications as required by the FDC Act by August 14, 2000. On April 26, 2000, the FDA issued a second Federal Register notice extending the deadline for filing these applications until August 14, 2001.

On May 25, 2001, the FDA approved our NDA for Levoxyl®, our levothyroxine sodium drug product. Other manufacturers of levothyroxine sodium drug products have received FDA approval of NDAs for their levothyroxine sodium products. The FDA has announced that after August 14, 2001, it will not accept NDAs for levothyroxine sodium drug products. However, the FDA has stated it will continue to review applications which were submitted by August 14, 2001. Other manufacturers who wish to submit an application for an equivalent product after August 14, 2001 must submit an ANDA seeking approval of a generic substitute for a levothyroxine sodium product with an approved NDA. A manufacturer could submit an ANDA demonstrating in vivo bioequivalence (in other words, the two products produce identical effects on the body) to Levoxyl®. If the FDA were to determine that another levothyroxine sodium product is bioequivalent to Levoxyl®, generic substitution for Levoxyl® may become possible which could result in a decrease in sales of our product Levoxyl® and have a material adverse effect upon our results of operations and cash flows.

During 2001 and 2002, we filed with the PTO in excess of 40 applications for U.S. patents concerning our FDA-approved product Levoxyl®. The first U.S. patent on Levoxyl®, the 581 patent, a utility patent with composition of matter claims, listed in the FDA's Orange Book, was issued on April 29, 2003 and extends through February 15, 2022. We cannot assure you that any or all of the other patent applications currently under review will issue.

As noted above, Mylan and KV have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. The 581 patent, a utility patent with formulation claims relating to Levoxyl®, was issued to us on April 29, 2003. No earlier than April 30, 2003, we received notice of Mylan's Paragraph IV certification, which alleges noninfringement of the 581 patent. On June 24, 2003, we received notice of KV's Paragraph IV certification, which alleges noninfringement and invalidity of the 581 patent. We have filed separate suits against Mylan and KV and intend to vigorously enforce our rights under the 581 patent to the full extent of the law. If we are not successful in enforcing our patents, our business, financial condition, results of operations and cash flows could be materially adversely affected.

On March 26, 2002, Jerome Stevens filed a Petition for Stay of Action (assigned Docket No. 02P1035) with the FDA seeking redress from the FDA for the public disclosure on the FDA's website of alleged trade secrets relating to the manufacturing process for Jerome Stevens orally-administered levothyroxine sodium drug product Unithroid. While Jerome Stevens does not specifically request that the FDA stay any action with respect to our levothyroxine sodium drug product Levoxyl®, Jerome Stevens does request, among other broad remedies, that the FDA immediately and indefinitely stay . . . all grants of drug pre-market authority that used, relied on, or were based on Jerome confidential and trade secret manufacturing information We have filed a Comment on Jerome Stevens' Petition with the FDA, stating that the NDA for Levoxyl® was filed with the FDA before the disclosure of Jerome Stevens' alleged trade secrets, and that the approval of the Levoxyl® NDA is unrelated to such disclosure. Based on these facts, we do not believe that Jerome Stevens' Petition applies to Levoxyl®. However, if the FDA were to determine that there is a valid legal basis for suspension or withdrawal of substantial FDA approval of the Levoxyl® NDA, it could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We filed a Citizen's Petition with the FDA on March 28, 2003 requesting that the FDA refrain from approving or accepting for filing any ANDA or supplemental ANDA for levothyroxine sodium drug products until adequate standards for establishing bioequivalence for levothyroxine sodium drug products

are adopted in accordance with FDA procedures. A manufacturer of another major levothyroxine sodium product and professional endocrinology societies have submitted similar and/or related comments to the FDA. If the FDA approves an ANDA for a generic equivalent of Levoxyl® under the current standards, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Sales of certain of our women's health products have been and may continue to be negatively affected by the perception of an increase in certain health risks associated with the use of combination hormone therapies and oral estrogen therapies.

From time to time studies on various aspects of pharmaceutical products, therapies or classes of drugs are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study. For example, an ongoing clinical trial entitled the Women's Health Initiative is being conducted by the National Institutes of Health. Data from that trial released in July 2002 indicated that an increase in certain health risks may result from the long-term use of a competitor's combination hormone therapy for women. News of this data and the perception it has created have negatively affected the entire combination hormone replacement therapy and oral estrogen replacement therapy markets generally, which include our products Prefest®, Menest® and Delestrogen® and may affect our future marketing efforts for Estrasorb™. We cannot assure you that sales of our currently marketed products will not continue to be negatively affected by the perception created by the data released to date or any additional data that may be released in the future. If sales of these products continue to be negatively affected by the perception created by data associated with the Women's Health Initiative, there may be a material adverse effect on our business, financial condition, results of operations and cash flows including a write-off of intangible assets associated with these products.

We are required annually, or on an interim basis as needed, to review the carrying value of our intangible assets and goodwill for impairment. If events such as generic competition or inability to manufacture or obtain sufficient supply of product occur that cause the sales of our products to decline, the intangible asset value of any declining product could become impaired.

As of December 31, 2003, we had \$1.9 billion of net intangible assets and goodwill. Intangible assets primarily include the net book value of various product rights, trademarks, patents and other intangible rights. If future sales of a product decline significantly, it could result in an impairment of the declining product's net book value, resulting in a non-cash impairment charge. For example, during the fourth quarter of 2002, we decided to divest our rights to Lorabid®, resulting in an impairment charge of \$66.8 million. Additionally, the FDA approved for sale generic substitutes for our product Florinef® in March 2002 and in January 2003. During the first quarter of 2003, we recorded an intangible asset impairment charge of \$111.0 million related to this product due to revised sales projections for Florinef® triggered by the entry of a second generic product into the market. Prescriptions for our women's health products, including Nordette® and Prefest®, have continued to decline over the past year due to the perception created by data associated with the Women's Health Initiative mentioned above and the entry of a second generic for Nordette®. During the second quarter of 2003 a generic substitute for our product Cortisporin® ophthalmic suspension entered the market. Prescriptions for Tapazole® have continued to decline since the entry of a generic substitute in August 2000. At December 31, 2003, the Florinef®, Nordette®, Prefest®, Cortisporin®, and Tapazole® product rights have net intangible assets associated with them of \$22.6 million, \$96.0 million, \$108.5 million, \$18.3 million, and \$18.2 million, respectively. Management currently believes that these assets are not presently impaired based on estimated undiscounted future cash flows; however, if revenue declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with these product rights. For a discussion of these issues related to Florinef®, Cortisporin®, Tapazole® and the Rochester facility, please see the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations under the heading Other Developments. Any impairment of the net book value of any product or combination

of products, depending on the size of the product or products, could result in a material adverse effect on our business, financial condition, results of operations and cash flows.

If we cannot implement our strategy to grow our business through increased sales and acquisitions, our competitive position in the pharmaceutical industry may suffer.

Our current strategy is focused on increasing sales of our existing products and enhancing our competitive standing through acquisitions of products in development and FDA-approved products, including through acquisitions of other companies, that complement our business and enable us to promote and sell new products through existing marketing and distribution channels. Moreover, since we engage in limited proprietary research activity with respect to the development of new chemical entities, we rely heavily on purchasing products in development from other companies and FDA-approved products.

Other companies, some of which have substantially greater financial, marketing and sales resources than we do, compete with us for the acquisition of products in development, FDA-approved products or companies. We may not be able to acquire rights to additional products in development, FDA-approved products, or companies on acceptable terms, if at all, or be able to obtain future financing for acquisitions on acceptable terms, if at all. The inability to effect acquisitions of additional branded products in development and FDA-approved products could limit the overall growth of our business. Furthermore, even if we obtain rights to a pharmaceutical product or acquire a company, we may not be able to generate sales sufficient to create a profit or otherwise avoid a loss.

If we cannot integrate the business of companies or products we acquire, our business may suffer.

We recently completed several acquisitions including Intal®, Tilade® and Synercid® from Aventis in December 2002 and Meridian in January 2003. Additionally, we acquired a primary care business in the United States and Puerto Rico from Elan on June 12, 2003, which includes the products Sonata® and Skelaxin® and a dedicated primary care field sales force consisting of approximately 350 individuals. The integration of these acquisitions into our business requires significant management attention and may require the further expansion of our existing sales force or newly-acquired sales force. In order to manage our acquisitions effectively, we must maintain adequate operational, financial and management information systems and motivate and effectively manage an increasing number of employees. Our acquisitions have significantly expanded our product offerings, operations and number of employees. Our future success will also depend in part on our ability to retain or hire qualified employees to operate our expanding facilities efficiently in accordance with applicable regulatory standards. If we cannot integrate our acquisitions successfully, these changes and acquisitions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we are not able to develop or license new products, our business may suffer.

We are engaged in the development and licensing of new products. For example, we are

engaged in the development of a modified-release formulation of Sonata®;

in exclusive license agreements with Novavax to promote, market, distribute and sell Androsorb™, once approved, a topical testosterone replacement therapy for testosterone deficient women, and other women's health products;

engaged in the development of binodenoson, a myocardial pharmacologic stress imaging agent; T-62, an investigational drug for the treatment of neuropathic pain; and MRE0094, an investigational drug for the topical treatment of chronic diabetic foot ulcers;

engaged in the development of a new inhaler for Intal® using the alternative propellant HFA and a diazepam-filled auto-injector, each of which is under FDA review; and

in a licensing agreement with SkyePharma to develop and commercialize a modified-release formulation of Altace® utilizing SkyePharma's patented oral drug delivery technology Geomatrix®.

We compete with other pharmaceutical companies, including large pharmaceutical companies with financial resources and capabilities substantially greater than ours, in the development and licensing of new products. We cannot assure you that we will be able to

engage in product life cycle management to develop new indications and line extensions for existing and acquired products;

successfully develop, license or successfully commercialize new products on a timely basis or at all;

develop or license new products already in development in a cost effective manner; or

obtain FDA approvals necessary to successfully implement the strategies described above.

If we are not successful in the development or licensing of new products already in development, including the failure to obtain any necessary FDA approval, our business, financial condition, and results of operations could be materially adversely affected.

Further, other companies may license or develop products or may acquire technologies for the development of products that are the same as or similar to the products we have in development or that we license. Because there is rapid technological change in the industry and because many other companies may have more financial resources than we do, other companies may

develop or license their products more rapidly than we can,

complete any applicable regulatory approval process sooner than we can,

market or license their products before we can market or license our products, or

offer their newly developed or licensed products at prices lower than our prices,

and thereby have a negative impact on the sales of our newly developed or licensed products. Technological developments or the FDA's approval of new products or of new therapeutic indications for existing products may make our existing products or those products we are licensing or developing obsolete or may make them more difficult to market successfully, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We do not have proprietary protection for most of our branded pharmaceutical products, and our sales could suffer from competition by generic substitutes.

Although most of our revenue is generated by products not subject to competition from generic products, there is no proprietary protection for most of our branded pharmaceutical products, and generic substitutes for many of these products are sold by other pharmaceutical companies. Even our products that currently have no generic substitute could face generic competition if generics are developed by other companies and approved by the FDA. For example, Florinef® is subject to competition from two generics, one approved by the FDA in March 2002 and the other approved in January 2003. We are also aware that an ANDA for Cortisporin® ophthalmic suspension which was previously inactive has been reactivated by the FDA with a new sponsor. We understand the sponsor entered the market as of April 14, 2003 with a generic equivalent for Cortisporin® ophthalmic suspension. The entry of the generic has negatively affected our market share for this product. Accordingly, our business, financial condition, results of operations and cash flows could be materially adversely affected. In addition, governmental and other pressure to reduce pharmaceutical costs may result in physicians prescribing products for which there are generic substitutes. Also, our branded products for which there is no generic form available may face competition from different therapeutic agents used for the same indications for which our branded products are used. Increased competition from the sale of generic pharmaceutical products or from different therapeutic agents used for the same indications for which our branded products are used may cause a decrease in

revenue from our branded products and could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Due to recent statutory changes, the FDA may approve generic substitutes of branded pharmaceutical products in a shorter period of time. Previously, the FDA required that generic applicants claiming patent invalidity or non-infringement give us notice each time either an ANDA was submitted or amended to claim invalidity or non-infringement of newly listed patents. If we filed a patent infringement suit against the generic applicant within 45 days of receiving such notice, the FDA was barred from approving the ANDA for 30 months unless specific events occurred sooner. To avoid multiple 30-month stays for the same branded drug, the recent statutory changes modified the relevant provisions of the Hatch-Waxman Act (21 U.S.C. §§ 355(j)(2) and (5)) to indicate that a 30-month stay will only attach to patents that are listed in the FDA's Orange Book at the time an ANDA is filed. Although the ANDA filer is still required to certify against a late-listed patent, the NDA holder can still bring suit based upon infringement of that patent. Such a suit will no longer trigger an additional 30-month stay of FDA approval of the ANDA. As a result, generic substitutes of our branded pharmaceutical products could be approved sooner.

Also, recent regulatory changes significantly alter patent listing requirements in the FDA's Orange Book. Only patents listed in the FDA's Orange Book are eligible for protection by a 30-month stay. We are now required to list all patents that claim a composition of matter relating to a drug or a method of using a drug. Previously, this provision was interpreted broadly, allowing the listing of many drug patents. The FDA's new regulations prohibit listing of certain types of patents, including patents claiming certain metabolites (the active moiety that results from the body's metabolism of the drug substance), intermediates (namely, substances not present in the finished product), certain methods of use, or patents claiming certain product packaging. As such, some patents that may issue in the future may not be eligible for listing in the FDA's Orange Book and thus not eligible for protection by a 30-month stay.

If we cannot sell our products in amounts greater than our minimum purchase requirements under some of our supply agreements or sell our products in accordance with our forecasts, our results of operations and cash flows may be adversely affected.

Some of our supply agreements, including those related to Altace®, require us to purchase certain minimum levels of active ingredients or finished goods, subject to some terms and conditions of various supply agreements. If sales of our products do not increase at the currently anticipated rates, if we are unable to maintain market exclusivity for our products, if our product life cycle management is not successful, if we fail to sell our products in accordance with the forecasts we develop as required by our supply agreements or if we do not terminate supply agreements at optimal times for us, we may incur losses in connection with the purchase commitments under the supply agreement. In the event we incur losses in connection with the purchase commitments under the supply agreements, there may be a material adverse effect upon our results of operations and cash flows.

Additionally we purchase raw materials and some of our finished goods based on our forecast for sales of our products. We also manufacture many of our finished goods on these forecasts. If we do not meet expected forecasts for sales, we could purchase inventory quantities in excess of expected demand. This purchase of excess inventory could have a material adverse effect on our results of operations and cash flows.

Any significant delays or difficulties in the manufacture of or supply of materials for our products may reduce our profit margins and revenues, limit the sales of our products, or harm our products' reputations.

We manufacture many of our products in facilities we own and operate. These products include Altace®, Levoxyl® and Thrombin-JMI®, which together represent approximately 52.8% of our revenues for the year ended December 31, 2003. Many of our production processes are complex and require specialized and expensive equipment. Any unforeseen delays or interruptions in our manufacturing operations may reduce our profit margins and revenues. If we are unable to resume manufacturing, after interruption, we

may not be able to distribute our products as planned. Furthermore, growing demand for our products could exceed our ability to supply the demand. If such situations occur, it may be necessary for us to seek alternative manufacturers which could adversely impact our ability to produce and distribute our products. We cannot assure you that we would be able to utilize third-party manufacturers for our products in a timely manner or at all. In addition, our manufacturing output may decline as a result of power outages, supply shortages, accidents, natural disasters or other disruptions of the manufacturing process. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

A portion or all of many of our product lines, including Altace®, Skelaxin®, Sonata®, Bicillin®, Prefest®, Intal®, Tilade®, Synercid® and Cortisporin®, are currently manufactured by third parties. Estrasorb™ will be manufactured for us by Novavax. Our dependence upon third parties for the manufacture of our products may adversely impact our profit margins or may result in unforeseen delays or other problems beyond our control. For example, if any of these third parties are not in compliance with applicable regulations, the manufacture of our products could be adversely affected. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to distribute our products as planned. If we encounter delays or difficulties with contract manufacturers in producing or packaging our products, the distribution, marketing and subsequent sales of these products would be adversely affected, and we may have to seek alternative sources of supply or abandon or sell product lines on unsatisfactory terms. We might not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. We also cannot assure you that the manufacturers we utilize will be able to provide us with sufficient quantities of our products or that the products supplied to us will meet our specifications.

Our supply agreement for Bicillin® with Wyeth expires on July 7, 2004. There are limitations on the number of units over and above current estimated demand for this product we can order under our supply agreement with Wyeth. Furthermore, the expiration dating on this product is limited to 24 months. We do not anticipate extending our supply agreement for Bicillin® with Wyeth. Instead, we have begun the process of transferring the manufacture of Bicillin® to our Rochester facility. If we are unable to transfer this product to our Rochester facility in accordance with our plan, our gross margins on the product may be reduced and/or demand for Bicillin® may eventually exceed our ability to supply the product. If we are unable to adequately supply continued demand for Bicillin®, net sales of the product may be significantly reduced, the market for the product may be permanently diminished and the carrying value of our Bicillin® assets could become impaired, any of which could have a material adverse affect on our business, financial condition, results of operations, and cash flows. For the year ended December 31, 2003, net sales of Bicillin® were \$28.6 million representing 1.9% of total revenues.

We require a supply of quality raw materials and components to manufacture and package pharmaceutical products for us and for third parties with which we have contracted. Currently, we rely on over 500 suppliers to deliver the necessary raw materials and components. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and components on a timely basis. However, if we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to distribute our products as planned.

The occurrence of any of these events could result in significant backorders for our products which could have a material adverse effect on our business, financial condition, results of operations and cash flows and could adversely affect our market share for the products and the reputation of our products.

If third-party developers of some of our new product candidates and reformulated products fail to devote sufficient time and resources to our concerns, or if their performance is substandard or otherwise fails to comply with the terms of their agreements with us, the introduction of new or reformulated products may not be successful.

We develop products and product line extensions through research and development and through contractual relationships with third parties that develop new products, including new product formulations,

on our behalf. Our reliance on third parties for the development of some of our products exposes us to risks which could cause delays in the development of new products or reformulated products or could cause other problems beyond our control. These third-party developers

may not be successful in developing the products or product line extensions for us;

may face financial or business related difficulties which could make it difficult or impossible for them to continue business operations; or

may otherwise breach or terminate their agreements with us.

If any of these events occur and we are unable to successfully develop these products and new product formulations by other means, our business, financial condition, results of operations and cash flows could be materially and adversely affected.

Our Rochester facility has been the subject of FDA concerns. If we cannot adequately address the FDA's concerns, we may be unable to operate the Rochester facility and, accordingly, our business may suffer.

Our Rochester facility manufactures both drug and biological pharmaceutical products. The Rochester facility was one of six Pfizer facilities subject to a consent decree issued by the U.S. District Court of New Jersey in August 1993 as a result of FDA concerns about compliance issues within Pfizer facilities in the period before the decree was entered. The Rochester facility continues to be subject to the consent decree.

The Rochester facility was inspected by the FDA in February/ March 2003 and by an FDA Team Biologics inspector in August 2003. When an FDA inspector completes an authorized inspection of a manufacturing facility, the inspector typically provides the owner/operator of the facility with a written report listing the inspector's observations of objectionable conditions and practices. This written report is known as an FDA Form 483 or simply as a 483. The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a pharmaceutical manufacturer receives a 483 after an inspection and our Rochester facility received a 483 following the March 2003 inspection. While no law or regulation requires us to respond to a 483, we have submitted a written response detailing our plan of action with respect to each of the observations made on the 483 and our commitment to correct any objectionable practice or condition. The risk to us of a 483, if left uncorrected, could include, among other things, the imposition of civil monetary penalties, the commencement of actions to seize or prohibit the sale of unapproved or non-complying products, or the cessation of manufacturing operations at the Rochester facility that are not in compliance with cGMPs. While we believe the receipt of the 483 will not have a material adverse effect on our business, financial condition, results of operations and cash flows, we cannot assure you that future inspections may not result in adverse regulatory actions which could have a material adverse effect on our business, financial condition, results of operations and cash flows. Our Rochester facility did not receive a 483 following the August 2003 inspection.

We are near maximum capacity at our Middleton facility which will limit our ability to increase production of Thrombin-JMI®.

We are currently working on long-term strategies to expand our production capacity for Thrombin-JMI® which should potentially be completed in approximately two years. These long-term strategies may further expand our manufacturing capacity for Thrombin-JMI® upon completion. We cannot assure you that our plans to expand our production capacity for Thrombin-JMI® will be successful and/or timely. If we cannot successfully and timely expand our production capacity for Thrombin-JMI®, our ability to increase production of Thrombin-JMI® will be limited, thereby limiting our unit sales growth for this product.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property, our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our products or products and technologies we develop or license. In addition, our competitors may develop products, including generic products, similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our sales. Some of our major branded pharmaceutical products have proprietary patent protection, including Altace® with composition of matter patents that do not expire until January 2005 and October 2008, and a method-of-use patent that does not expire until April 2012. All of these patents are listed in the FDA's Orange Book. A challenge to these patents can be subject to expensive litigation. As we mentioned earlier, Cobalt has filed an ANDA seeking permission from the FDA to market a generic version of Altace® prior to the expiration of the 722 patent, but not before January 2005, the expiration date of the 258 patent. Additionally, as mentioned above, Mylan and KV have each filed ANDAs seeking permission from the FDA to market a generic version of Levoxyl® prior to the expiration of the 581 patent. As noted above, each of Eon Labs, CorePharma and Mutual has filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® prior to the expiration of the 128 and 102 patents. Finally, as noted above, Barr has filed an ANDA with the FDA seeking permission to market a generic version of Prefest® prior to the expiration of the 995 patent and the 573 patent.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation in order to maintain our competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other intellectual property, our business, financial condition, results of operations and cash flows could be materially adversely affected.

If the implementation of our new information technology system is not successful, our business could be disrupted.

In November 2000, we began the process of implementing a new information technology system which became operational at our Bristol facilities in July 2003. This system is supporting many of our business functions, including manufacturing, warehousing, distribution, logistics, sales reporting, accounting, inventory, quality control, budgeting and other company functions. In connection with its implementation, we have incurred related costs of approximately \$30.5 million. In the event we do not successfully convert our other sites in a timely manner from their existing information systems to the new one or in the event the new system does not operate as expected at these other locations, our business could be disrupted. This disruption or additional costs, if required, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Wholesaler and distributor buying patterns and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our profitability.

Our results of operations, including, in particular, product sales revenue, may vary from quarter to quarter due to many factors. Wholesalers and distributors represent a substantial portion of our sales. Buying patterns of our wholesalers and distributors may vary from time to time. In the event wholesalers and distributors with whom we do business determine to limit their purchases of our inventory, sales of our products could be adversely affected. For example, in advance of an anticipated price increase, many of our customers may order pharmaceutical products in larger than normal quantities. The ordering of excess quantities in any quarter could cause sales of some of our branded pharmaceutical products to be lower in subsequent quarters than they would have been otherwise. As part of our ongoing efforts to facilitate improved management of wholesale channel inventory levels of our branded pharmaceutical products, we

are actively engaged in negotiations with our wholesale customers to establish inventory management agreements. While we cannot assure you that we will successfully negotiate mutually beneficial inventory management agreements, we believe that sales of some of our key products during the first half of 2004, particularly Altace®, may be dramatically lower than prescription demand would indicate. Other factors include expenditures related to the acquisition, sale and promotion of pharmaceutical products, a changing customer base, the availability and cost of raw materials, interruptions in supply by third-party manufacturers, new products introduced by us or our competitors, the mix of products we sell, sales and marketing expenditures, product recalls, competitive pricing pressures and general economic and industry conditions that may affect customer demand. We cannot assure you that we will be successful in maintaining or improving our profitability or avoiding losses in any future period.

If the stock price of Novavax declines, our investment in Novavax convertible notes could result in additional special charges related to a valuation allowance for these notes. Upon implementation of Financial Accounting Standards Board Interpretation No. 46, we may be required to consolidate the financial results of Novavax, Inc.

During the period from December 2000 through June 2002, we provided \$40.0 million in financing to Novavax in the form of notes receivable convertible to common stock of Novavax. The loan is impaired as defined under Statement of Financial Accounting Standards No. 114, Accounting by Creditors for Impairment of a Loan. We established a valuation allowance in the second quarter of 2002 which was adjusted in subsequent quarters during 2002 and 2003. As of December 31, 2003, the valuation allowance for the Novavax convertible notes equaled \$17.3 million. We will adjust the amount of the valuation allowance in future periods until the loan is no longer considered to be impaired. We may incur additional charges related to our investment in the convertible notes. Accordingly, these charges may adversely impact our earnings. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities, which we refer to as FIN 46.

We hold notes receivable convertible to common stock of Novavax with a face value of \$40.0 million at December 31, 2003. We also have an exclusive worldwide license to promote, market, distribute and sell Estrasorb™ and Androsorb™, products owned by Novavax, following approval, except in the United States and Puerto Rico, where we will co-market the products with Novavax. Once approved, we will pay Novavax a royalty based on a percentage of net sales of the products outside of the United States and Puerto Rico. Novavax will pay us a co-promotion fee equal to approximately 50% of net sales less cost of revenues of the products within the United States and Puerto Rico. The NDA for Estrasorb™ was approved by the FDA during October 2003. As of December 31, 2003, we owned approximately 0.9% of Novavax common stock.

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46, Consolidation of Variable Interest Entities. FIN 46 requires a variable interest entity to be consolidated by a company if that company is required to absorb a majority of the variable interest entity's expected losses or entitled to receive a majority of the entity's residual returns or both. We are in the process of assessing what impact this pronouncement will have on our consolidated financial statements. Based on our analysis of the impact of FIN 46, we believe that it is reasonably possible that Novavax could be a variable interest entity and our interest in Novavax may require us to consolidate Novavax in the first quarter of 2004. At September 30, 2003, Novavax reported total assets of \$61.6 million, total liabilities of \$48.7 million, revenues for the nine months ended September 30, 2003 of \$7.7 million, and a net loss of \$14.2 million for the nine months ended September 30, 2003. The consolidation of Novavax could have a material effect on components of our reported consolidated financial condition and components of reported consolidated results of operations.

Our wholly owned subsidiary, Jones Pharma Incorporated, is a defendant in litigation which is currently being handled by its insurance carriers. Should this coverage be inadequate or subsequently denied or were we to lose some of these lawsuits, our results of operations could be adversely affected.

Our wholly owned subsidiary, Jones Pharma Incorporated, is a defendant in 926 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine, which is usually referred to as fen/phen. In 1996, Jones acted as a distributor of Obenix®, a branded phentermine product. Jones also distributed a generic phentermine product. We believe that Jones phentermine products have been identified in less than 100 of the foregoing cases. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs. They seek compensatory and punitive damages as well as medical care and court-supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to, product liability, strict liability, negligence, breach of warranties and misrepresentation. These suits are filed in various jurisdictions throughout the United States, and in each of these suits Jones is one of many defendants, including manufacturers and other distributors of these drugs. Jones denies any liability incident to the distribution of its phentermine product and intends to pursue all defenses available to it. Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. In the event that insurance coverage is inadequate to satisfy any resulting liability, Jones will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

Sales of Thrombin-JMI® may be affected by the perception of risks associated with some of the raw materials used in its manufacture; if we are unable to successfully develop purification procedures at our facilities that are in accordance with the FDA's expectations for biological products generally, the FDA could limit our ability to manufacture biological products at those facilities.

The source material for our product Thrombin-JMI® comes from bovine plasma and lung tissue which has been certified by the United States Department of Agriculture for use in the manufacture of pharmaceutical products. Bovine-sourced materials, particularly those from outside the United States, may be of some concern because of potential transmission of bovine spongiform encephalopathy, or BSE. However, we have taken precautions to minimize the risks of contamination from BSE in our source materials. Our principal precaution is the use of bovine materials only from FDA-approved sources in the United States. Accordingly, all source animals used in our production of Thrombin-JMI® are of United States origin. Additionally, source animals used in production of Thrombin-JMI® are generally less than 18 months of age. (BSE has not been identified in animals less than 30 months of age).

We have two approved vendors as sources of supply of the bovine raw materials but currently receive these materials from a single vendor. Any interruption or delay in the supply of these materials could adversely affect the sales of Thrombin-JMI®. In addition to other actions taken by us and our vendor to minimize the risk of BSE, we are developing steps to further purify the material of other potential contaminants. We will continue surveillance of the source and believe that the risk of BSE contamination in the source materials for Thrombin-JMI® is very low. While we believe that our procedures and those of our vendor for the supply, testing and handling of the bovine material comply with all federal, state, and local regulations, we cannot eliminate the risk of contamination or injury from these materials. There are high levels of global public concern about BSE. Physicians could determine not to administer Thrombin-JMI® because of the perceived risk which could adversely affect our sales of the product. Any injuries resulting from BSE contamination could expose us to extensive liability. Also there is currently no alternative to the bovine-sourced materials for Thrombin-JMI®. If public concern for the risk of BSE-infection in the United States should increase, the manufacture and sale of Thrombin-JMI® and our business, financial condition, results of operations and cash flows could be materially and adversely affected.

The FDA expects manufacturers of biological products to have validated processes capable of removing extraneous viral contaminants to a high level of assurance. As a result, many manufacturers of biologics are currently engaged in developing procedures to remove potential extraneous viral contaminants from their products. We are in the process of developing appropriate processing steps to achieve maximum

assurance for the removal of potential extraneous viral contaminants from Thrombin-JMI®, which does not include BSE because it is not a viral contaminant. If we are not successful in gaining FDA approval for these processes, our ability to manufacture Thrombin-JMI® may be adversely affected. We cannot assure you that we will be successful in these efforts. Failure to obtain the FDA's approval for these procedures could have a material adverse effect on our business, financial condition, results of operations and cash flows.

On November 15, 2006, we may be required to repurchase our 2 3/4% Convertible Debentures due November 15, 2021.

We issued 2 3/4% Convertible Debentures due November 15, 2021 in February 2002 in an aggregate amount of \$345.0 million. The price at which the debentures are convertible into common stock is \$50.16, subject to adjustments spelled out in the documents governing the debentures. If the price of our stock has not reached that amount by November 15, 2006, we may be required to repurchase all or a portion of the debentures representing the \$345.0 million on November 15, 2006 if some or all of the holders of the debentures request that we repurchase their debentures. We cannot assure you that a significant repurchase requirement at that time would not have a material adverse effect on our business, financial condition, results of operations or cash flows.

A failure by Dey L.P. to successfully market the EpiPen® auto-injector or an increase in competition could have a material adverse effect on our results of operations.

Dey L.P. markets our EpiPen® auto-injector through a supply agreement with us that expires on December 31, 2010. Under the terms of the agreement, we grant Dey the exclusive right and license to market, distribute and sell EpiPen® worldwide. Although demand for EpiPen® continues to be strong due to increased awareness of the health risks associated with allergic reactions, we expect competition to intensify. We understand that a new competitive product manufactured by Hollister-Stier Laboratories LLC received FDA approval approximately one year ago. The new product, TwinJect® Auto-Injector (epinephrine) injection, is not a therapeutically equivalent product but has the same indications, same usage and the same route of delivery as EpiPen®. Users of EpiPen® would have to obtain a new prescription in order to substitute TwinJect®. The supply agreement with Dey includes minimum purchase requirements that are less than Dey's purchases in recent years. A failure by Dey to successfully market and distribute EpiPen® or an increase in competition could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our relationship with the U.S. Department of Defense and other government entities is subject to risks associated with doing business with the government.

All U.S. government contracts provide that they may be terminated for the convenience of the government as well as for default. The unexpected termination of one or more of our significant government contracts could result in a material adverse effect on our business, financial condition, results of operations and cash flows. A surge capability provision allows for the coverage of defense mobilization requirements in the event of rapid military deployment. If this surge capability provision becomes operative, we may be required to devote more of our Meridian Medical Technologies segment manufacturing capacity to the production of products for the government which could result in less manufacturing capacity being devoted to products in this segment with higher profit margins. Our supply contracts with the Department of Defense are subject to post-award audit and potential price determination. These audits may include a review of our performance on the contract, our pricing practices, our cost structure and our compliance with applicable laws, regulations and standards. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while costs already reimbursed must be refunded. Therefore, a post-award audit or price redetermination could result in an adjustment to our revenues. From time to time the Department of Defense makes claims for pricing adjustments with respect to completed contracts. If a government audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including

termination of contracts, forfeitures of profits, suspension of payments, fines and suspension or disqualification from doing business with the government.

Other risks involved in government sales include the unpredictability in funding for various government programs and the risks associated with changes in procurement policies and priorities. Reductions in defense budgets may result in reductions in our revenues. We also provide our nerve agent antidote auto-injectors to a number of state agencies and local communities for homeland defense against chemical agent terrorist attacks. Changes in governmental and agency procurement policies and priorities may also result in a reduction in government funding for programs involving our auto-injectors. A significant loss in government funding of these programs could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our sales depend on payment and reimbursement from third-party payors, and if they reduce or refuse payment or reimbursement, the use and sales of our products will suffer, we may not increase our market share, and our revenues and profitability will suffer.

The commercial success of some of our products is dependent, in part, on whether third-party reimbursement is available for the use of our products by hospitals, clinics, doctors and patients. Third-party payors include state and federal governments, under programs such as Medicaid and other entitlement programs, managed care organizations, private insurance plans and health maintenance organizations. Because of the growing size of the patient population covered by managed care organizations, it is important to our business that we market our products to them and to the pharmacy benefit managers that serve many of these organizations. Payment or reimbursement of only a portion of the cost of our prescription products could make our products less attractive, from a net-cost perspective, to patients, suppliers and prescribing physicians. Managed care organizations and other third-party payors try to negotiate the pricing of products to control their costs. Managed care organizations and pharmacy benefit managers typically develop formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generics are often favored. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products or therapies for treatment of particular medical conditions. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization patient population. If our products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be negatively affected, as could our overall business and financial condition.

We have expanded our contracts with managed care organizations in an effort to increase the inclusion of our products on formularies. To the extent that our products are purchased by patients through a managed care group with which we have a contract, our average selling price is lower than it would be for a non-contracted managed care group. We take reserves for the estimated amounts of rebates we will pay to managed care organizations each quarter. Any increased usage of our products through Medicaid or managed care programs will increase the amount of rebates that we owe. We cannot assure you that our products will be included on the formulary lists of managed care organizations or that adverse reimbursement issues will not have a material effect on our financial condition, results of operations or cash flows.

If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business.

As discussed in this Risk Factors section under the heading Investigations by the SEC and Office of Inspector General at the Department of Health and Human Services, other possible governmental investigations, and securities and ERISA litigation could have a material adverse effect on our business, in the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations under the heading Governmental Investigations, Medicaid Accrual Adjustment and Related

Matters, and elsewhere in this report in connection with our Audit Committee's assessment and internal review of issues raised by the SEC investigation, we estimated that we had underpaid amounts due under Medicaid and other governmental pricing programs, and recorded an adjustment of \$46.5 million to net sales and accrued expenses in the fourth quarter of 2002. This amount represented our best estimate as of July 2003 of the extent to which we had underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002. Since that time, our outside consultants have undertaken a comprehensive audit to determine the actual amount of underpayments under Medicaid during the period from 1998 to 2002. As a result of that recently completed audit, we have determined that our accrual for estimated amounts due under Medicaid and other governmental pricing programs through December 31, 2002, should be increased by \$18.0 million. In addition, based on the results of the comprehensive audit for the period from 1998 through 2002, we estimate that we underpaid amounts due Medicaid by \$0.9 million during the period from 1994 through 1997. We are currently in the process of conducting detailed audits of our compliance with the requirements of several other governmental pricing programs and there could be further adjustments to our accruals. Pending determination of the precise amount of our obligations, we have placed a total of \$65.5 million in an interest-bearing escrow account from which the requisite payments will be made.

Although the amounts described above constitute our best estimate of amounts owed in respect of Medicaid and other governmental pricing programs, our calculations are subject to review and challenge by the applicable governmental agencies. In connection with the pending governmental investigations, we have continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Public Health Service. We expect that these discussions will include a detailed review of our calculations by the appropriate agencies, and it is possible that this review could result in material changes. In addition, these agencies and other governmental agencies that might be investigating or might commence an investigation of King could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time.

We have implemented a new information technology system that is intended to significantly enhance the accuracy of our calculations for estimating amounts due under Medicaid and other governmental pricing programs; however, our processes for these calculations and the judgments involved in making these calculations will continue to involve subjective decisions and manual input, and, as a result, these calculations will remain subject to the risk of errors.

If we are unable to obtain approval of new HFA propellants for Intal® and Tilade®, our sales of these products could be adversely affected.

Under government regulations, chlorofluorocarbon compounds are being phased out because of environmental concerns. Our products Intal® and Tilade® currently use these compounds as propellants. The FDA has issued an approvable letter with respect to the NDA covering a new inhaler for Intal® using the alternative propellant hydrofluoroalkane, or HFA. The approvable letter provides that final approval of the NDA for Intal® HFA is subject to addressing certain FDA comments solely pertaining to the chemical, manufacturing, and controls section of the NDA covering the product. In the event we cannot also obtain final approval for alternative propellants for Intal® and Tilade® before the final phase-out date of chlorofluorocarbon compounds or if we are unable to maintain an adequate supply of chlorofluorocarbon compounds for the production of this product prior to this date, our ability to market this product could be materially adversely affected, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If the operations of our centralized distribution facility were interrupted, our business could be harmed.

For efficiency purposes, we rely on one centralized distribution facility in Bristol, Tennessee. An interruption in this operation could have a material adverse effect on our business, financial conditions, results of operations and cash flows.

The loss of our key personnel or an inability to attract new personnel could harm our business.

We are highly dependent on the principal members of our management staff, the loss of whose services might impede the achievement of our strategic objectives. We cannot assure you that we will be able to attract and retain key personnel in sufficient numbers, with the requisite skills or on acceptable terms necessary or advisable to support our continued growth and integration. The loss of the services of key personnel could have a material adverse effect on us, especially in light of our recent growth. We do not maintain key-person life insurance on any of our employees. In addition, we do not have employment agreements with any of our key employees.

On February 19, 2004, Jefferson J. Gregory announced his plan to retire as our Chief Executive Officer. Our Board of Directors has begun a search for a new Chief Executive Officer and Mr. Gregory intends to continue to serve in this capacity until a successor is appointed.

Our shareholder rights plan and bylaws discourage unsolicited takeover proposals and could prevent shareholders from realizing a premium on their common stock.

We have a shareholder rights plan that may have the effect of discouraging unsolicited takeover proposals. The rights issued under the shareholder rights plan would cause substantial dilution to a person or group which attempts to acquire us on terms not approved in advance by our Board of Directors. In addition, our charter and bylaws contain provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions include:

a classified Board of Directors;

the ability of our Board of Directors to designate the terms of and issue new series of preferred stock;

advance notice requirements for nominations for election to our Board of Directors; and

special voting requirements for the amendment of our charter and bylaws.

We are also subject to anti-takeover provisions under Tennessee laws, each of which could delay or prevent a change of control. Together these provisions and the rights plan may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for common stock.

Our stock price is volatile, which could result in substantial losses for investors purchasing shares.

The trading price of our common stock is likely to be volatile. The stock market in general and the market for emerging growth companies, such as King in particular, have experienced extreme volatility. Many factors contribute to this volatility, including

variations in our results of operations;

perceived risks and uncertainties concerning our business;

announcements of earnings;

developments in the governmental investigations or securities and ERISA litigation;

failure to meet or exceed our own specific projections for revenue, product sales and earnings per share;

failure to meet timelines for product development or other projections or forward-looking statements we may make to the public;

failure to meet or exceed security analysts' financial projections for our company;

comments or recommendations made by securities analysts;

general market conditions;

perceptions about market conditions in the pharmaceutical industry;

announcements of technological innovations or the results of clinical trials or studies;

changes in marketing, product pricing and sales strategies or development of new products by us or our competitors;

changes in domestic or foreign governmental regulations or regulatory approval processes; and

announcements concerning regulatory compliance and government agency reviews.

This volatility may have a significant impact on the market price of our common stock. Moreover, the possibility exists that the stock market (and in particular the securities of emerging growth companies such as King) could experience extreme price and volume fluctuations unrelated to operating performance. The volatility of our common stock imposes a greater risk of capital losses on our shareholders than would a less volatile stock. In addition, such volatility makes it difficult to ascribe a stable valuation to a shareholder's holdings of our common stock.

Risks Related to Our Industry

Failure to comply with laws and government regulations could affect our ability to operate our business.

Virtually all aspects of our activities are regulated by federal and state statutes and government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution and advertising of our products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies, including the FDA, the DEA, the Federal Trade Commission, the Consumer Product Safety Commission, the U.S. Department of Agriculture, the Occupational Safety and Health Administration, and the EPA, as well as by foreign governments in countries where we distribute some of our products.

Noncompliance with applicable FDA policies or requirements could subject us to enforcement actions, such as suspensions of manufacturing or distribution, seizure of products, product recalls, fines, criminal penalties, injunctions, failure to approve pending drug product applications or withdrawal of product marketing approvals. Similar civil or criminal penalties could be imposed by other government agencies, such as the DEA, the EPA or various agencies of the states and localities in which our products are manufactured, sold or distributed, and could have ramifications for our contracts with government agencies such as the Veterans Administration or the Department of Defense. These enforcement actions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

All manufacturers of human pharmaceutical products are subject to regulation by the FDA under the authority of the FDC Act or the PHS Act or both. New drugs, as defined in the FDC Act, and new human biological drugs, as defined in the PHS Act, must be the subject of an FDA-approved new drug or biologic license application before they may be marketed in the United States. Some prescription and other drugs are not the subject of an approved marketing application but, rather, are marketed subject to the FDA's regulatory discretion and/or enforcement policies. Any change in the FDA's enforcement discretion and/or policies could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We manufacture some pharmaceutical products containing controlled substances and, therefore, are also subject to statutes and regulations enforced by the DEA and similar state agencies which impose security, record keeping, reporting and personnel requirements on us. Additionally, we manufacture biological drug products for human use and are subject to regulatory burdens as a result of these aspects of

our business. There are additional FDA and other regulatory policies and requirements covering issues such as advertising, commercially distributing, selling, sampling and reporting adverse events associated with our products with which we must continuously comply. Noncompliance with any of these policies or requirements could result in enforcement actions which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The FDA has the authority and discretion to withdraw existing marketing approvals and to review the regulatory status of marketed products at any time. For example, the FDA may require an approved marketing application for any drug product marketed if new information reveals questions about a drug's safety or efficacy. All drugs must be manufactured in conformity with cGMPs, and drug products subject to an approved application must be manufactured, processed, packaged, held and labeled in accordance with information contained in the approved application.

While we believe that all of our currently marketed pharmaceutical products comply with FDA enforcement policies, have approval pending or have received the requisite agency approvals, our marketing is subject to challenge by the FDA at any time. Through various enforcement mechanisms, the FDA can ensure that noncomplying drugs are no longer marketed and that advertising and marketing materials and campaigns are in compliance with FDA regulations. In addition, modifications, enhancements, or changes in manufacturing sites of approved products are in many circumstances subject to additional FDA approvals which may or may not be received and which may be subject to a lengthy FDA review process. Our manufacturing facilities and those of our third-party manufacturers are continually subject to inspection by governmental agencies. Manufacturing operations could be interrupted or halted in any of those facilities if a government or regulatory authority is unsatisfied with the results of an inspection. Any interruptions of this type could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We cannot determine what effect changes in regulations, enforcement positions, statutes or legal interpretation, when and if promulgated, adopted or enacted, may have on our business in the future. Changes could, among other things, require changes to manufacturing methods or facilities, expanded or different labeling, new approvals, the recall, replacement or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. These changes, or new legislation, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

An increase in product liability claims, product recalls or product returns could harm our business.

We face an inherent business risk of exposure to product liability claims in the event that the use of our technologies or products are alleged to have resulted in adverse effects. These risks will exist for those products in clinical development and with respect to those products that receive regulatory approval for commercial sale. While we have taken, and will continue to take, what we believe are appropriate precautions, we may not be able to avoid significant product liability exposure. We currently have product liability insurance in the amount of \$80.0 million for aggregate annual claims including a \$20.0 million self-insured retention; however, we cannot assure you that the level or breadth of any insurance coverage will be sufficient to cover fully all potential claims. Also, adequate insurance coverage might not be available in the future at acceptable costs, if at all. For example, we are not able to obtain product liability insurance with respect to our products Prefest®, Menest®, Delestrogen®, Pitocin® and Nordette®, each a women's healthcare product. With respect to any product liability claims relating to these products, we would be responsible for any monetary damages awarded by any court or any voluntary monetary settlements. Significant judgments against us for product liability for which we have no insurance could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Product recalls or product field alerts may be issued at our discretion or at the discretion of the FDA, other government agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons, including failure of our products to maintain their stability through their expiration dates. Any recall or product field alert has the potential of

damaging the reputation of the product. To date, these recalls have not been significant and have not had a material adverse effect on our business, financial condition, results of operations and cash flows. However, we cannot assure you that the number and significance of recalls will not increase in the future. Any significant recalls could materially affect our sales, the prescription trends for the products and damage the reputation of the products. In these cases, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Product returns were approximately 4.3% of gross sales for the year ended December 31, 2003. In the event demand for our products declines or if wholesalers decide to carry less inventory, we cannot assure you that actual levels of returns will not increase or significantly exceed the amounts we have anticipated.

Any reduction in reimbursement levels by managed care organizations or other third-party payors may have an adverse effect on our revenues.

Commercial success in producing, marketing and selling of branded prescription pharmaceutical products depends, in part, on the availability of adequate reimbursement from third-party health care payors, such as government and private health insurers and managed care organizations. Third-party payors are increasingly challenging the pricing of medical products and services. For example, many managed health care organizations limit the pharmaceutical products that are on their formulary lists. The resulting competition among pharmaceutical companies to place their products on these formulary lists has reduced prices across the industry. In addition, many managed care organizations are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. We cannot assure you that our products will be included on the formulary lists of managed care organizations or that downward pricing pressures in the industry generally will not negatively impact our operations.

If we fail to comply with the safe harbors provided under various federal and state laws, our business could be adversely affected.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to include, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify safe harbors or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. We seek to comply with the safe harbors. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly (in the civil context), or knowingly and willfully (in the criminal context), presenting, or causing to be presented for payment to third-party payors (including Medicaid and Medicare) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products are currently a subject of the Office of Inspector General's investigation, and as such they are likely to be subject to scrutiny under these laws. As discussed in this Risk Factors section under the heading The investigations by the SEC and Office of Inspector General of the Department of Health and Human Services, other possible governmental investigations, and securities and ERISA litigation could have a material adverse effect on our business and elsewhere in this report, we are in the process of quantifying and reporting to governmental agencies our underpayment of amounts due under Medicaid and other governmental pricing programs.

Violations of fraud and abuse laws may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In the future, the publication of negative results of studies or clinical trials may adversely impact our products.

From time to time studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. One example of these types of studies is the Women's Health Initiative, which we discuss more fully in this Risk Factors section under the heading of Sales of certain of our women's health products have been and may continue to be negatively affected by the perception of an increase in certain health risks associated with the use of combination hormone therapies and oral estrogen therapies. In the event of the publication of negative results of studies or clinical trials related to our branded pharmaceutical products or the therapeutic areas in which our products compete, our business, financial condition, results of operations and cash flows could be materially adversely affected.

New legislation or regulatory proposals may adversely affect our revenues.

A number of legislative and regulatory proposals aimed at changing the health care system, including the cost of prescription products, importation and reimportation of prescription products from countries outside the United States and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products, have been proposed. While we cannot predict when or whether any of these proposals will be adopted or the effect these proposals may have on our business, the pending nature of these proposals, as well as the adoption of any proposal, may exacerbate industry-wide pricing pressures and could have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, in 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at a lower price. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003 the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we receive for our products. Additionally sales of our products in the United States could be adversely affected by the importation of products that some may deem to be equivalent to ours that are manufactured by others and are available outside the United States.

Changes in the Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our earnings. These programs are highly regulated and subject to frequent and substantial changes and cost containment measures. In recent years, changes in these programs have limited and reduced reimbursement to providers. *The Medicare Prescription Drug, Improvement and Modernization Act of 2003*, creates a new, voluntary prescription drug benefit under the Social Security Act, which we refer to as Medicare Drug Benefit. Beginning in 2006, Medicare beneficiaries entitled to Part A or enrolled in Part B, as well as certain other Medicare enrollees, will be eligible for the Medicare Drug Benefit. Regulations implementing the Medicare Drug Benefit have not yet been published, and the Medicare Drug Act requires that the Federal Trade Commission conduct a study and make recommendations regarding additional legislation that may be needed concerning the Medicare Drug Benefit. We are unable at this time to predict or estimate the financial impact of this new legislation.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and related rules, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Failure to comply with the new rules and regulations could result in enforcement actions or assessment of other penalties. The new laws and regulations could make it more difficult for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The

impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause our general and administrative costs to increase beyond what we currently have planned. We are presently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

The industry is highly competitive, and other companies in our industry have much greater resources than we do.

In the industry, comparatively smaller pharmaceutical companies like us compete with large, global pharmaceutical companies with substantially greater financial resources for the acquisition of products in development, currently marketed products, technologies and companies. We cannot assure you that

we will be able to continue to acquire commercially attractive pharmaceutical products, companies or technologies;

additional competitors will not enter the market; or

competition for acquisition of products in development, currently marketed products, companies and technologies will not have a material adverse effect on our business, financial condition and results of operations.

We also compete with pharmaceutical companies in marketing and selling pharmaceutical products. The selling prices of pharmaceutical products typically decline as competition increases. Further, other products now in use, developed or acquired by other pharmaceutical companies may be more effective or offered at lower prices than our current or future products. Competitors may also be able to complete the regulatory process sooner and, therefore, may begin to market their products in advance of ours. We believe that competition for sales of our products will be based primarily on product efficacy, safety, reliability, availability and price.

Competition for Acquisitions. We compete with other pharmaceutical companies for product and product line acquisitions. These competitors include Biovail Corporation, Forest Laboratories, Inc., Galen Holdings plc, Medicis Pharmaceutical Corporation, Shire Pharmaceuticals Group plc, Watson Pharmaceuticals, Inc., and other companies which also acquire branded pharmaceutical products and product lines, including those in development, from other pharmaceutical companies. We cannot assure you that

we will be able to continue to acquire commercially attractive pharmaceutical products, companies or technologies;

additional competitors will not enter the market; or

competition for acquisition of products in development, currently marketed products, companies and technologies will not have a material adverse effect on our business, financial condition and results of operations.

Product Competition. Additionally, since our currently marketed products are generally established and commonly sold, they are subject to competition from products with similar qualities.

Our largest product Altace® competes in the market with other cardiovascular therapies, including in particular, the following ACE inhibitors or any generic equivalents:

Zestril® (AstraZeneca plc),

Acupril® (Pfizer, Inc.),

Prinivil® (Merck & Co., Inc.),

Lotensin® (Novartis AG),

Monopril® (Bristol-Myers Squibb Company),

Vasotec® (Biovail Corporation),

Capoten® (Bristol-Myers Squibb Company), and

Mavik® (Abbott Laboratories).

Our product Levoxyl® competes with levothyroxine sodium products, including in particular the following and any generic equivalents:

Synthroid® (Abbott Laboratories),

Levothroid® (Forest Laboratories, Inc.), and

Unithroid® (Jerome Stevens Pharmaceuticals, Inc.).

Our product Skelaxin® competes in the market with other muscle relaxants including in particular the following and any generic equivalents:

Flexeril® (Johnson & Johnson),

Soma® (Medpointe),

Robaxin® (Schwarz Pharma), and

Norflex® (3M Pharmaceuticals).

Our product Sonata® competes with other insomnia treatments, including in particular Ambien®, a product of Sanofi-Synthelabo Inc., and Estorra®, a product of Sepracor Inc.

We intend to market these products aggressively by, among other things

detailing and sampling to the primary prescribing physician groups, and

sponsoring physician symposiums, including continuing medical education seminars.

Many of our branded pharmaceutical products have either a strong market niche or competitive position. Some of our branded pharmaceutical products face competition from generic substitutes. For example, the FDA-approved for sale generic substitutes for Florinef® in March 2002 and in January 2003 and for Cortisporin® ophthalmic suspension in April 2003. During the second half of 2004, we anticipate the market entry of generic substitutes for Adenocard®, a product for which we receive royalty revenues on its net sales.

The manufacturers of generic products typically do not bear the related research and development costs and, consequently, are able to offer such products at considerably lower prices than the branded equivalents. There are, however, a number of factors which enable products to remain profitable once patent protection has ceased. For a manufacturer to launch a generic substitute, it must prove to the FDA when filing an application to make a generic substitute that the branded pharmaceutical and the generic substitute have bioequivalence. We believe it typically takes two or three years to prove bioequivalence and receive FDA approval for many generic substitutes. By focusing our efforts in part on patented products, products with challenging bioequivalence or complex manufacturing requirements and products with a strong brand image with the prescriber or the consumer, supported by the development of a broader range of alternative product formulations or dosage forms, we are better able to maintain market share, gross margins and cash flows. However, we cannot assure you that any of our products will remain exclusive without generic competition, or maintain their market share, gross margins and cash flows as a result of these efforts, the failure of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

A Warning About Forward-Looking Statements

This report includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to analyses and other information which are based on forecasts of future results and estimates of amounts not yet determinable. These statements also relate to our future prospects, developments and business strategies.

These forward-looking statements are identified by their use of terms and phrases, such as anticipate, believe, could, estimate, expect, intend, may, plan, predict, project, will and other similar terms and phrases, including references to assumptions. These statements are contained in the Business, Risk Factors, and Management's Discussion and Analysis of Financial Condition and Results of Operations sections, as well as other sections of this report.

Forward-looking statements in this report include, but are not limited to:

the future potential of, including anticipated net sales and prescription trends for our branded pharmaceutical products, particularly Altace®, Skelaxin®, Levoxyl®, Thrombin-JMI® and Sonata®;

expectations regarding the enforceability and effectiveness of product-related patents, including in particular patents related to Altace®, Levoxyl®, Skelaxin® and Prefest®;

expected trends and projections with respect to particular products, reportable segment and income and expense line items;

the adequacy of our liquidity and capital resources;

anticipated capital expenditures;

the development and potential commercialization of Estrasorb™, Androsorb™ and other products by Novavax and King;

the development and approval of binodenoson, our next generation cardiac pharmacologic stress-imaging agent; T-62, an investigational drug for the treatment of neuropathic pain; MRE0094, an investigational drug for the topical treatment of chronic diabetic foot ulcers; pre-clinical programs; and product life-cycle development projects;

the development of a modified-release Altace®;

the development of a modified-release Sonata®;

the development and approval of a diazepam-filled auto-injector, and new inhaler for Intal® and Tilade® using the alternative propellant HFA;

our continued successful execution of our growth strategies;

anticipated developments and expansions of our business;

our plans for the manufacture of some of our products, including but not limited to, the anticipated expansion of our manufacturing capacity for Thrombin-JMI®;

anticipated increases in sales of acquired products or royalty revenues;

the success of our Co-Promotion Agreement with Wyeth;

the high cost and uncertainty of research, clinical trials and other development activities involving pharmaceutical products;

the development of product line extensions;

the unpredictability of the duration or future findings and determinations of the FDA, including the pending applications related to our diazepam-filled auto-injector and a new Intal® inhaler formulation utilizing HFA, and other regulatory agencies worldwide;

the products which we expect to offer;

the intent, belief or current expectations, primarily with respect to our future operating performance;

expectations regarding sales growth, gross margins, manufacturing productivity, capital expenditures and effective tax rates;

expectations regarding potential patent approvals including those patents pending for Levoxyl® and Tigan® 300mg capsules and the protections to be provided by these patents if issued;

expectations regarding the outcome of various pending legal proceedings including the Altace®, Levoxyl®, Skelaxin® and Prefest® patent challenges, the SEC and Office of Inspector General investigations, other possible governmental investigations, securities litigation, and other legal proceedings described in this report;

the ongoing implementation of our new information technology system; and

expectations regarding our financial condition and liquidity as well as future cash flows and earnings.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those contemplated by our forward-looking statements. These known and unknown risks, uncertainties and other factors are described in detail in the Risk Factors section and in other sections of this annual report.

Item 2. Properties

The location and business segments served by our primary facilities are as follows:

Location	Business Segment(s)
Bristol, Tennessee	Branded Pharmaceuticals and Meridian Medical Technologies
Rochester, Michigan	Branded Pharmaceuticals and Contract Manufacturing
St. Louis, Missouri	Meridian Medical Technologies
St. Petersburg, Florida	Branded Pharmaceuticals
Middleton, Wisconsin	Branded Pharmaceuticals

We own each of these primary facilities, with the exception of that portion of the facilities in St. Louis, Missouri that is associated with our acquisition of Meridian, which is leased. For information regarding production capacity and extent of utilization, please see Item 1, Manufacturing, on page 14.

The Bristol, Rochester, and St. Louis owned facilities are pledged as collateral for our senior secured revolving credit facility dated April 23, 2002.

Our corporate headquarters and centralized distribution center are located in Bristol, Tennessee. We consider our properties to be generally in good condition, well maintained, and generally suitable and adequate to carry on our business.

Item 3. Legal Proceedings

SEC Investigation and Securities Litigation

As previously reported, in March 2003 the SEC initiated a formal investigation of King. We received SEC subpoenas relating to, among other topics, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and the Audit Committee's internal review of issues raised by the SEC investigation. As also previously reported, on

November 13, 2003, we received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®.

In connection with our determination that we have underpaid amounts due to Medicaid and other governmental pricing programs, we have continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Public Health Service. We expect that these discussions will include a detailed review by the appropriate agencies of our calculations of our underpayments, and it is possible that this review could result in material changes. The SEC, the Office of Inspector General, the Department of Justice, the Department of Veterans Affairs, the Public Health Service, the Centers for Medicare and Medicaid Services and other governmental agencies that might be investigating or might commence an investigation of us could impose, based on a claim of a violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time. For additional information, please see the section entitled **Risk Factors** under the heading **If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business** and the section entitled **Management's Discussion and Analysis of Financial Condition and Results of Operations** under the heading **Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters**.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of our securities against us, our directors, a former director of the subsidiary, executive officers, former executive officers, a subsidiary, and a former directors in the United States District Court for the Eastern District of Tennessee, alleging violations of the Securities Act of 1933 and/or the Securities Exchange Act of 1934. These 22 complaints have been consolidated in the United States District Court for the Eastern District of Tennessee. In addition, holders of our securities filed two class action complaints alleging violations of the Securities Act of 1933 in Tennessee state court. We removed these two cases to the United States District Court for the Eastern District of Tennessee, where these two cases were consolidated with the other class actions. Plaintiffs in these actions unsuccessfully moved to remand these two cases back to Tennessee state court. These two actions therefore remain part of the consolidated action. The district court has appointed lead plaintiffs in the consolidated action, and those lead plaintiffs filed a consolidated amended complaint on October 21, 2003 alleging that we, through some of our executive officers, former executive officers, directors and former directors, made false or misleading statements concerning our business, financial condition and results of operations during periods beginning February 16, 1999 and continuing until March 10, 2003. Plaintiffs in the consolidated action have also named the underwriters of our November 2001 public offering as defendants. We and other defendants have filed motions to dismiss the consolidated amended complaint, and those motions are currently pending.

Seven purported shareholder derivative complaints have also been filed in federal and state courts in Tennessee alleging a breach of fiduciary duty, among other things, by some of our officers and directors. The derivative cases in state court were consolidated and are currently stayed. The stay will remain in place at least until the motions to dismiss the consolidated federal class securities action are decided. The derivative cases in federal court are stayed until there is a decision on the merits in the state court derivative suits. Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act, which we refer to as ERISA. As amended, the complaint alleges that we and certain of our executive officers, former executive officers, directors, former directors and an employee violated fiduciary duties that were allegedly owed our 401(k) Retirement Savings Plan's participants and beneficiaries under ERISA. The allegations underlying

each of these additional lawsuits are similar in many respects to those in the class action litigation described above. We filed a motion to dismiss the ERISA action on March 5, 2004; this motion to dismiss is currently pending.

We intend to defend all of these lawsuits vigorously but are unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

If any governmental sanctions are imposed, or if we were not to prevail in the pending litigation, neither of which we can predict or reasonably estimate at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the governmental investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending us in the pending litigation has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees.

Altace® Patent Challenge

Cobalt has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA's Orange Book: United States Patent Nos. 4,587,258, the '258 patent, and 5,061,722, the '722 patent, two composition of matter patents related to Altace®, and United States Patent No. 5,403,856, the '856 patent, a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the Hatch-Waxman Act, any generic manufacturer may file an ANDA with a Paragraph IV certification, challenging the validity or infringement of a patent listed in the FDA's Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the '722 patent, and we filed suit on March 14, 2003 to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt's ANDA for 30 months from no earlier than February 5, 2003. Should the court find in favor of a Cobalt summary judgment motion on the '722 patent, however, we would not receive the full benefit of that 30 month stay. Subsequent to filing our original complaint, we amended our complaint to add an allegation of infringement of the '856 patent. In its answer to the amended complaint, Cobalt denied infringement and alleged that the '856 patent is invalid. Pursuant to FDA regulations, however, Cobalt is not required to certify against the '856 patent. We intend to vigorously enforce our rights under the '722 and '856 patents. Regardless of the outcome of the lawsuit involving the '722 and '856 patents, however, Cobalt has not challenged the validity of the '258 patent and, therefore, cannot market a generic version of Altace® prior to the expiration of that patent in January 2005.

Levoxyl® Patent Challenge

Mylan and KV have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. United States Patent No. 6,555,581, the '581 patent, a utility patent with formulation claims relating to Levoxyl®, was issued to us on April 29, 2003. The '581 patent is listed in the FDA's Orange Book and does not expire until February 15, 2022. No earlier than April 30, 2003, we received notice of Mylan's Paragraph IV certification, which alleges noninfringement of the '581 patent. We filed suit against Mylan on June 13, 2003 in the Eastern District of Pennsylvania and on June 16, 2003 in the Northern District of West Virginia; these suits have been consolidated in the Northern District of West Virginia and trial is currently scheduled for June 2005. Pursuant to the Hatch-Waxman Act, the filing of the suits against Mylan provides us with an automatic stay of FDA approval of Mylan's ANDA for 30 months from no earlier than April 30, 2003. On June 24, 2003, we received notice of KV's Paragraph IV certification, which alleges noninfringement and invalidity of the '581 patent. We filed suit against KV on August 7, 2003. Pursuant to the Hatch-Waxman Act, the filing of the suit against KV provides us with an automatic stay of FDA approval of KV's ANDA for 30 months from no earlier than June 24, 2003 and trial is currently scheduled to begin on December 6, 2004. We intend to vigorously enforce our rights under the '581 patent to the full extent of the law. If we are unsuccessful in enforcing our patent, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Skelaxin® Patent Challenge

Eon Labs, CorePharma and Mutual have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. United States Patent Nos. 6,407,128, the 128 patent, and 6,683,102, the 102 patent, two method-of-use patents relating to Skelaxin®, are listed in the FDA's Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 and 102 patents. Mutual has filed a Paragraph IV certification alleging noninfringement and invalidity of the 102 patent. We filed separate suits against Eon Labs on January 2, 2003 and CorePharma on March 7, 2003 and are currently assessing our right to bring suit against Mutual. Pursuant to the Hatch-Waxman Act, the filing of the suits against Core and Eon provides us with an automatic stay of FDA approval of Eon's ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of Core's ANDA for 30 months from no earlier than January 24, 2003. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law. If we are unsuccessful in enforcing this patent, our business, financial condition, results of operations and cash flows could be materially adversely affected.

On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA's Orange Book for the 128 patent may be deleted from the ANDA applicants' product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA's previous position on this issue. We are currently assessing our administrative and legal options and may request the FDA to reinstate its previous policy on this issue and reject any ANDAs that delete such use from their product labeling. If we are unable to persuade the FDA to reinstate its previous policy, however, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

Prefest® Patent Challenge

Barr has filed an ANDA, which included a Paragraph IV certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995, (the 995 patent, a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573, the 573 patent, a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the FDA's Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 15, 2003, we received notice of Barr's Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. On November 26, 2003, we filed a complaint against Barr in the Southern District of New York for infringement of the 995 and 573 patents. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Barr's ANDA for 30 months from no earlier than October 15, 2003. We intend to vigorously enforce our rights under both patents.

Thimerosal/Vaccine Related Litigation

King and/or its wholly owned subsidiary, Parkedale Pharmaceuticals, have been named as defendants in California, Mississippi and Illinois, along with Abbott Laboratories, Wyeth, Aventis Pharmaceuticals, and other pharmaceutical companies, which have manufactured or sold products containing the mercury-based preservative, thimerosal.

In these cases, the plaintiffs attempt to link the receipt of the mercury-based products to neurological defects. The plaintiffs claim unfair business practices, fraudulent misrepresentations, negligent misrepresentations, and breach of implied warranty, which are all arguments premised on the idea that the defendants promoted products without any reference to the toxic hazards and potential public health ramifications resulting from the mercury-containing preservative. The plaintiffs also allege that the defendants knew of the dangerous propensities of thimerosal in their products.

King's product liability insurance carrier has been given proper notice of all of these matters and defense counsel are vigorously defending our interests. We seek to be dismissed from the litigation due to, among other things, lack of product identity in plaintiff's complaints. In 2001, King and Parkedale were dismissed on this basis in a similar case.

Fen/Phen Litigation

Many distributors, marketers and manufacturers of anorexigenic drugs have been subject to claims relating to the use of these drugs. Generally, the lawsuits allege that the defendants (1) misled users of the products with respect to the dangers associated with them, (2) failed to adequately test the products, and (3) knew or should have known about the negative effects of the drugs, and should have informed the public about the risks of such negative effects. The actions generally have been brought by individuals in their own right and have been filed in various state and federal jurisdictions throughout the United States. They seek, among other things, compensatory and punitive damages and/or court-supervised medical monitoring of persons who have ingested the product. We are one of many defendants in no more than 10 lawsuits, which claim damages for personal injury arising from our production of the anorexigenic drug phentermine under contract for GlaxoSmithKline. We expect to be named in additional lawsuits related to our production of the anorexigenic drug under contract for GlaxoSmithKline.

While we cannot predict the outcome of these suits, we believe that the claims against us are without merit and intend to vigorously pursue all defenses available to us. We are being indemnified in all of these suits by GlaxoSmithKline for which we manufactured the anorexigenic product, provided that neither the lawsuits nor the associated liabilities are based upon our independent negligence or intentional acts, and intend to submit a claim for all unreimbursed costs to our product liability insurance carrier. However, in the event that GlaxoSmithKline is unable to satisfy or fulfill its obligations under the indemnity, we would have to defend the lawsuit and be responsible for damages, if any, which are awarded against us or for amounts in excess of our product liability coverage.

In addition, Jones, a wholly-owned subsidiary of King, is a defendant in 926 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine, and phentermine. These suits have been filed in various jurisdictions throughout the United States, and in each of these suits, Jones is one of many defendants, including manufacturers and other distributors of these drugs. Although Jones has not at any time manufactured dexfenfluramine, fenfluramine, or phentermine, Jones was a distributor of a generic phentermine product, and, after its acquisition of Abana Pharmaceuticals, was a distributor of Obenix, its branded phentermine product. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs and are seeking compensatory and punitive damages as well as medical care and court supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to product liability, strict liability, negligence, breach of warranty, and misrepresentation.

While we cannot predict the outcome of these suits, we believe that the claims against us are without merit and intend to vigorously pursue all defenses available to us. Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. The manufacturers of fenfluramine and dexfenfluramine have settled many of these cases. In the event Jones' insurance coverage is inadequate to satisfy any resulting liability, Jones will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

Other Legal Proceedings

The Parkedale facility was one of six facilities owned by Pfizer subject to a Consent Decree of Permanent Injunction issued August 1993 in *United States of America v. Warner-Lambert Company and Melvin R. Goodes and Lodewijk J.R. DeVink* (U.S. Dist. Ct., Dist. of N.J.). We acquired the Parkedale facility from Pfizer in February 1998. The Parkedale facility is currently manufacturing pharmaceutical products subject to the Consent Decree which prohibits the manufacture and delivery of specified drug products unless, among other things, the products conform to cGMPs and are produced in accordance with approved drug applications. We intend, when appropriate, to petition for relief from the Consent Decree.

We are involved in various routine legal proceedings incident to the ordinary course of our business.

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

At the annual meeting of shareholders on November 4, 2003, the shareholders voted on the following proposals with the results as indicated:

1. Elected five directors to serve as follows:

	For	Withhold Authority
James R. Lattanzi (term expiring 2004)	215,573,652	4,297,221
Ted G. Wood (term expiring 2005)	216,227,111	3,643,762
Earnest W. Deavenport, Jr. (term expiring 2006)	213,420,085	6,450,788
Elizabeth M. Greetham (term expiring 2006)	216,202,567	3,668,306
Philip M. Pfeffer (term expiring 2006)	213,567,422	6,303,451

Directors continuing in service include: Jefferson J. Gregory;
Gregory D. Jordan; R. Charles Moyer; and D. Greg Rooker.

2. Ratified the appointment of PricewaterhouseCoopers LLP as the independent accountants and auditors for 2003 as follows:

For	209,811,102
Against	8,964,512
Abstention	1,095,259

PART II**Item 5. Market for Common Equity and Related Stockholder Matters**

The following table sets forth the range of high and low sales prices per share of our common stock for the periods indicated. Our common stock is listed on the New York Stock Exchange, where our stock trades under the symbol **KG**. There were approximately 1,260 shareholders on March 9, 2004, based on the number of record holders of the common stock.

	2002	
	High	Low
First quarter	\$42.13	\$29.25
Second quarter	35.10	18.30
Third quarter	21.98	15.85
Fourth quarter	19.42	15.00

	2003	
	High	Low
First quarter	\$18.13	\$11.01
Second quarter	16.51	9.46
Third quarter	16.87	13.25
Fourth quarter	16.10	12.29

On March 11, 2004, the closing price of our common stock as reported on the New York Stock Exchange was \$18.06.

We have never paid cash dividends on our common stock. The payment of cash dividends is subject to the discretion of the board of directors and will be dependent upon many factors, including our earnings, our capital needs, and our general financial condition. We currently anticipate that for the foreseeable future, we will retain our earnings.

The following table provides information about our equity compensation plans as of December 31, 2003.

EQUITY COMPENSATION PLAN INFORMATION

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by shareholders	3,849,864	\$ 22.48	8,802,537
Equity compensation plans not approved by shareholders		n/a	
Total	3,849,864		8,802,537

Item 6. Selected Financial Data

The table below should be read in conjunction with the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and our audited consolidated financial statements and related notes included elsewhere in this report.

	For the year ended December 31,				
	1999	2000	2001	2002	2003
(in thousands, except per share data)					
Statement of Income Data:					
Net sales(1)	\$ 480,815	\$ 578,769	\$ 825,488	\$ 1,069,960	\$ 1,453,023
Royalty revenue	31,650	41,474	46,774	58,375	68,365
Total revenues	512,465	620,243	872,262	1,128,335	1,521,388
Gross profit	368,637	448,972	685,698	833,359	1,136,625
Operating income(5)	209,895	184,728	366,266	294,200	166,114
Interest income	10,507	11,875	10,975	22,395	6,849
Interest expense	(55,371)	(36,974)	(12,684)	(12,419)	(13,396)
Valuation (charge) benefit convertible notes receivable				(35,629)	18,151
Extinguishment of debt expense(4)	(1,150)	(20,348)	(22,903)		
Other income (expenses), net	(3,239)	3,333	6,313	(884)	(629)
Income before income taxes, extraordinary item and cumulative effect of change in accounting principle	160,642	142,614	347,967	267,663	177,089
Income tax expense	60,705	68,752	129,486	85,143	71,233
Income before extraordinary item and cumulative effect of change in accounting principle	99,937	73,862	218,481	182,520	105,856
Extraordinary item, net of income taxes(2)		(9,353)			
	99,937	64,509	218,481	182,520	105,856
Cumulative effect of change in accounting principle(3)			(545)		
Net income	\$ 99,937	\$ 64,509	\$ 217,936	\$ 182,520	\$ 105,856
Income per common share:					
Basic:					
Income before extraordinary item and cumulative effect of change in accounting principle	\$ 0.48	\$ 0.34	\$ 0.94	\$ 0.75	\$ 0.44
Extraordinary item		(0.04)			
Cumulative effect of change in accounting principle					
	\$ 0.48	\$ 0.30	\$ 0.94	\$ 0.75	\$ 0.44

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Diluted:

Income before extraordinary item
and cumulative effect of change in
accounting principle

\$	0.47	\$	0.33	\$	0.93	\$	0.74	\$	0.44
----	------	----	------	----	------	----	------	----	------

Extraordinary item

(0.04)

Cumulative effect of change in
accounting principle

	<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>
\$	0.47	\$	0.29	\$	0.93	\$	0.74	\$	0.44
	<u> </u>		<u> </u>		<u> </u>		<u> </u>		<u> </u>

	December 31,		
	2001	2002	2003
Balance Sheet Data:			
Working capital	\$ 1,086,116	\$ 891,738	\$ 277,454
Total assets	2,506,611	2,750,660	3,177,734
Total debt	347,754	346,393	345,097
Shareholders' equity	1,908,284	1,931,183	2,042,180

- (1) Results for 2002 reflect (a) a \$22,113 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001, (b) a \$12,399 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and (c) an \$11,970 charge arising from changes in accounting estimates related to Medicaid and other governmental pricing programs. Results for 2003 reflect an \$18,000 charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$900 charge for correction of immaterial errors related to Medicaid for the years 1994 to 1997. For additional information, please see the section entitled *Management's Discussion and Analysis of Financial Condition and Results of Operations* under the heading *Governmental Investigation, Medicaid Accrual Adjustment, and Related Matters* and Note 7 to our audited consolidated financial statements.
- (2) Reflects an asset impairment charge related to discontinuing the production and distribution of Fluogen® in the amount of \$9,353 (net of taxes of \$5,612) during 2000.
- (3) Reflects the cumulative effect of a change in accounting principle of \$545 (net of taxes of \$325) due to the adoption of SFAS No. 133 *Accounting for Derivative Instruments and Hedging Activities*, during the first quarter of 2001.
- (4) Reflects early extinguishment of debt expense in connection with the repayment of some of our debt instruments during 1999, 2000, and 2001.
- (5) Results for 2003 reflect a \$15,212 reduction in the co-promotion fees paid to our Altace® co-promotion colleague as a result of the charges described above for amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2002. Specifically (a) we recovered on a pre-tax basis \$9,514 in fees we previously accrued during the fourth quarter of 2002 and have reduced the accrual for these fees by this amount in the fourth quarter of 2003 and (b) fees under our Co-Promotion Agreement for Altace® in the fourth quarter of 2003 were reduced on a pre-tax basis by an additional \$5,698 as a result of the Medicaid accrual adjustment recorded in that quarter.

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

The following discussion should be read in conjunction with the other parts of this report, the audited consolidated financial statements and related notes. Historical results and percentage relationships set forth in the statement of income, including trends that might appear, are not necessarily indicative of future operations. Please see the *Risk Factors* and *Forward-Looking Statements* sections for a discussion of the uncertainties, risks and assumptions associated with these statements.

Overview

Our growth in total revenues during 2003 primarily resulted from our acquisition of the primary care business in the United States and Puerto Rico of Elan Corporation, plc on June 12, 2003, which includes Skelaxin® and Sonata® and our acquisition of Meridian Medical Technologies, Inc. on January 8, 2003. We believe that these acquisitions, which include expanded pipeline opportunities, together with the prescription growth potential of many of our existing key products position King for future growth.

Sales of Key Products

In the following discussion, net sales for 2002 reflect a \$22.1 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001; a \$12.4 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002; and a \$12.0 million charge arising from changes made in 2002 in accounting estimates for the years 1998 to 2002 related to Medicaid and other governmental pricing programs. Net sales for 2003 reflect an \$18.0 million charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$0.9 million charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997. For additional information, please see the section below entitled Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters.

Altace®

Net sales of Altace® grew to \$527.1 million for the year ended December 31, 2003, a 17.1% increase from \$450.0 million during the prior year. Altace® new prescriptions totaled approximately 3.9 million and total prescriptions equaled approximately 12.7 million during 2003, increases of 12.0% and 19.2%, respectively, over the prior year according to IMS America monthly prescription data. Contributing also to the continued sales growth of Altace® is the sustained shift to 10mg Altace®, the same dose used in the landmark Heart Outcome Prevention Evaluation, which we refer to as the HOPE trial. Specifically, total prescriptions for 10mg Altace® during 2003 increased approximately 32.7% over the prior year, in comparison to an increase of 12.9% for the other strengths of Altace combined, according to NDC Health monthly prescription data. Total net units of Altace® sold increased 5.1% for the year ended December 31, 2003 in comparison to the prior year. Additionally, price increases contributed to the continued sales growth of Altace® during 2003.

Based on Altace®'s differentiating indications, positive clinical data and prescription trends, along with our marketing strategies and a composition of matter patent that should protect Altace® from generic competition through 2008, we anticipate that annual prescriptions of Altace® should continue to grow, but not necessarily at as high a rate as that achieved in 2003. For additional information and a description of anticipated effect of wholesale channel inventory on net sales of Altace®, please see the section below entitled Wholesale Channel Inventory Reductions.

Skelaxin® and Sonata®

During 2003, we recorded net sales of Skelaxin® in the amount of \$179.1 million and net sales of Sonata® totaling \$72.5 million. We acquired Skelaxin® and Sonata® from Elan on June 12, 2003. For additional information, see the section entitled Strategic Developments, Elan's Primary Care Business below. Net sales of Skelaxin® and Sonata® should increase during 2004, as we will record sales on these products for the entire year.

Thrombin-JMI®

Net sales of Thrombin-JMI® totaled \$141.7 million in 2003, a 46.8% increase from \$96.5 million during the prior year. Total net units sold of Thrombin-JMI® increased 4.5% for the year ended December 31, 2003 from the prior year. We are near maximum capacity at our facility in Madison, Wisconsin which will limit our ability to increase unit sales of Thrombin-JMI® during 2004. We are currently working on strategies to expand our production capacity for Thrombin-JMI® which should potentially be completed in approximately two years. We anticipate that annual net sales of Thrombin-JMI® should continue to grow during 2004, but not at as high a rate as that achieved in 2003.

Levoxyl®

Levoxyl® net sales were \$134.1 million for the year ended December 31, 2003, a 20.9% decrease from \$169.5 million during the prior year. Total net units of Levoxyl® sold decreased 28.2% for the year ended

December 31, 2003 in comparison to the prior year. Total prescriptions decreased approximately 1.0% from 2002 to 2003, according to IMS America prescription data. During 2003, wholesale channel inventories of Levoxyl® were reduced. If our sales of Levoxyl® during 2003 had been commensurate with the number of units dispensed over the same period according to IMS America prescription data, we estimate that our net sales of Levoxyl® would have been higher than that actually recorded during 2003. Accordingly, we are anticipating an increase in Levoxyl® net sales during 2004 as sales of the product created by continued demand become more normalized.

Wholesale Channel Inventory Reductions

In order to facilitate improved management of wholesale channel inventory levels, we are actively engaged in negotiations with our wholesale customers to establish inventory management agreements related to our products. While we cannot assure that we will successfully negotiate mutually beneficial inventory management agreements, we believe that sales of some of our key products, particularly Altace®, may be dramatically lower during the first half of 2004, particularly in the first quarter of 2004, than prescription demand would indicate.

Research and Development

Our research and development activities involve the discovery and development of chemical compounds, including new chemical entities, which provide us with strategic pipeline opportunities for the commercialization of new branded prescription pharmaceutical products. In addition to discovering and developing these chemical compounds, we pursue means of enhancing the value of existing products through new uses and formulations that may provide additional benefits to patients, and improvements in the quality and efficiency of our manufacturing processes.

Recent FDA Approvals

On June 20, 2003, we received U.S. Food and Drug Administration, which we refer to as the FDA, approval of a supplemental New Drug Application covering pediatric and adult formulations of our nerve gas antidote AtroPen®. This approval is particularly significant because it is the first time that pediatric formulations of this important homeland security product have been approved for use in the United States.

On October 10, 2003, Novavax, Inc. received FDA approval of its new drug application, which we refer to as an NDA, for EstrasorbTM, a topical estrogen therapy in unique lotion-like formulation for symptomatic menopausal women. We have an exclusive worldwide license to promote, market, distribute, and sell EstrasorbTM, except in the United States and Puerto Rico, where we and Novavax will co-market the product. We will share equally with Novavax both gross profits from net sales of EstrasorbTM and associated costs of promotion within the United States and Puerto Rico. Novavax will receive royalties on net sales outside of these areas. Novavax, working together with our company, plans to launch EstrasorbTM in the United States and Puerto Rico in the first half of 2004.

Product Applications Under Review by the FDA

An abbreviated new drug application, which we refer to as an ANDA, covering our diazepam-filled auto-injector is presently under review by the FDA. We currently manufacture this product for the military as a treatment for seizures. Once approved, this product will be the only commercially available therapy of its kind for epileptic seizures. We anticipate FDA approval for this product during 2004.

During the third quarter of 2003, we received an approvable letter for Intal® HFA from the FDA. Intal® HFA, a new inhaler formulation of our currently marketed product Intal® for the long-term management of asthma, utilizes the environmentally friendly propellant hydrofluoroalkane, which we refer to as HFA. With a patent that extends through September 2017, Intal® HFA is an important product line extension.

Sonata® Extended Release Formulation

We commenced our Phase II clinical trial program for an extended release formulation of Sonata®, a nonbenzodiazepine treatment for insomnia, in March 2004. The Phase II clinical trial program is designed to select the most effective extended release formulation of Sonata® utilizing Elan's commercially proven Spheroidal Oral Drug Absorption System, which we refer to as SODAS, as the drug delivery technology. The goal of the Phase II clinical trial program is to determine which new formulation is the most efficacious for the purpose of increasing total sleep time and reducing any potential for premature awakenings, while continuing to build upon the quick onset profile currently available in the immediate release formulation of Sonata®.

With U.S. patent coverage that extends to 2018, the extended release formulation should establish Sonata® as a long-term cornerstone product for our Company. Moreover, this development program should provide us with the opportunity to procure additional patents potentially covering, among other things, unique biopharmaceutical characteristics and methods-of-use related to the extended release formulation of Sonata®.

Altace® Product Life-Cycle Projects

We entered into a licensing agreement with SkyePharma PLC in May 2003 for the purpose of developing and commercializing a modified-release formulation of our Altace® product utilizing SkyePharma's patented oral drug delivery technology Geomatrix®. SkyePharma's Geomatrix® range of technologies involves a fully-developed, multi-layered tablet technology that controls the release of a product's active ingredient for the purpose of optimizing a drug's pharmacokinetic behavior. The specific Geomatrix® technology planned for use in the development of a modified-release formulation of Altace should provide the product with extended duration of action and improved bioavailability. SkyePharma has various issued patents covering the Geomatrix® drug delivery technologies, with U.S. patent protection extending to 2017. Also, SkyePharma has patent applications for additional patents under review covering its Geomatrix® drug delivery technologies.

During the fourth quarter of 2003, we completed enrollment in the ongoing Phase IV clinical trial to determine the safety and effectiveness of Altace® in the treatment of hypertension (high blood pressure) in children. This important trial, which we refer to as TOPHAT (Treatment of Pediatric Hypertension with Altace Trial), is scheduled to conclude by the end of 2004.

Binodenoson

On December 5, 2003, we commenced the pivotal Phase III clinical trial program involving binodenoson. Binodenoson is an adenosine A2a receptor agonist that we are developing for cardiac pharmacologic stress SPECT imaging, a procedure used to diagnose the presence and severity of coronary artery disease. The data from the Phase II dose ranging study indicates that binodenoson, at effective doses, is better tolerated than adenosine, the current market leader, which was previously developed by King.

Approximately 3 million pharmacologic stress tests are performed in the United States each year to diagnose heart disease in patients who cannot perform traditional exercise stress tests. Adenosine and dipyridamole are the current agents of choice to achieve the coronary vasodilation necessary for cardiac imaging in the United States, but these drugs do not distinguish between the four subtypes of adenosine receptors. Our Phase II clinical trials showed that by targeting the adenosine A2a receptor subtype, binodenoson appears to detect myocardial ischemia as well as adenosine, and produces fewer and less severe side effects like heart block, dyspnea and chest pain than adenosine and dipyridamole. Unlike the currently used drugs, which are administered over 4 to 6 minutes, binodenoson will be given as an intravenous bolus dose. This advantage, coupled with the improved safety profile, promises to make these diagnostic tests safer for patients and easier and more efficient for physicians to administer.

T62

During the fourth quarter of 2003, we commenced the Phase I clinical trial program for T-62, a new chemical entity that we are developing as a potential treatment for neuropathic pain. When given orally, T-62 enhances the effect of endogenous adenosine in the spinal cord and should provide effective relief for neuropathic pain by the same mechanism as intrathecally administered adenosine. Adenosine, a neurotransmitter that affects the adenosine A1 receptors in the spinal cord to normalize the pain response, has been shown to be an effective treatment for neuropathic pain when injected into the spinal cord via intrathecal administration. The initial Phase I trial for T-62 is a single-center, randomized double-blind, placebo-controlled evaluation of the safety and pharmacokinetics of escalating single oral doses of this new chemical entity in healthy adult subjects.

MRE0094

MRE0094, a new chemical entity, is an adenosine A2a receptor agonist that we are developing as a potential topical treatment for chronic diabetic foot ulcers. This product is designed to utilize a novel approach to treating this condition by concentrating on the inflammation associated with such foot ulcers. Adenosine A2a receptor agonists have been shown to promote wound closure in mice and diabetes-induced rats by regulating the response of inflammatory cells and mediators, promoting tissue formation through various mechanisms including endothelial cell proliferation and migration, and promoting tissue remodeling. In January 2004 we completed the dosing of the initial concentration of MRE0094 in our ongoing Phase I clinical trial program evaluating the safety of the drug in patients.

Strategic Developments

Elan's Primary Care Business

On June 12, 2003, we acquired the primary care business of Elan and that of some of its subsidiaries, in the United States and Puerto Rico, including the rights to Sonata® and Skelaxin® and the rights pertaining to potential new formulations of these products, together with Elan's United States primary care field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan's sale of Skelaxin® included related NDAs, copyrights, trademarks, patents and rights pertaining to potential new formulations of Skelaxin®. Elan's sale of Sonata® included its rights to the product, as well as certain related copyrights and U.S. rights to potential new formulations of Sonata®. We also acquired certain intellectual property, regulatory, and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, we secured an exclusive license to the intellectual property rights in this territory of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals. The total estimated purchase price was \$814.4 million, which included the cost of acquisition, assumed liabilities and a portion of contingent liabilities. The purchase price also includes the transfer of inventory with a value of approximately \$40.4 million. In addition to the initial purchase price, we paid \$25.0 million during January 2004 as a milestone payment to Elan relating to the continued exclusivity of Skelaxin® and we paid \$11.0 million during March 2004, as a milestone payment to Elan in connection with the development of new formulations of Sonata®. We also

will pay royalties on the current formulation of Skelaxin® from the date of closing,

will pay up to an additional \$60.0 million if Elan achieves certain milestones in connection with the development of a reformulated version of Sonata®,

will pay \$15.0 million as a milestone payment to Elan if annual net sales of a reformulated version of Sonata® exceed \$100.0 million and

will pay for costs associated with the development of the reformulated version of Sonata®.

Meridian Medical Technologies, Inc.

On January 8, 2003, we completed our acquisition of Meridian, for a cash price totaling \$253.9 million. Meridian pioneered the development, and is a leading manufacturer, of auto-injectors for the self-administration of injectable drugs. An auto-injector is a pre-filled, pen-like device that allows a patient or caregiver to automatically inject a precise drug dosage quickly, easily, safely, and reliably. This acquisition provides us with additional lines of growing exclusive pharmaceutical products, auto-injector technology, and enhanced pipeline opportunities.

Meridian's growing commercial pharmaceutical business primarily consists of EpiPen®, an auto-injector filled with epinephrine for the emergency treatment of anaphylaxis resulting from severe or allergic reactions to insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise induced anaphylaxis. Dey L.P. markets EpiPen® pursuant to a supply agreement that expires December 31, 2010. Under the terms of the supply agreement, we grant Dey the exclusive right and license to market, distribute, and sell EpiPen® worldwide.

Meridian also has growing lines of pharmaceutical products that are presently sold primarily to the U.S. Department of Defense, also known as the DoD, under an Industrial Base Maintenance Contract. These products include AtroPen® and ComboPen® which are nerve agent antidotes. AtroPen® is an atropine-filled auto-injector and ComboPen® consists of an atropine-filled auto-injector and a pralidoxime-filled auto-injector. Other products sold to the DoD include a diazepam-filled auto-injector for the treatment of seizures and a morphine-filled auto-injector for pain management. Additionally, in January 2004, Meridian began selling a new auto-injector to the DoD called the Antidote Treatment Nerve Agent Auto-injector, which we refer to as ATNAA. ATNAA, also a nerve agent antidote, utilizes a dual chambered auto-injector and injection process to administer atropine and pralidoxime, which provides an improved, more efficient means of delivering these nerve agent antidotes. The ATNAA auto-injector and injection process has U.S. patent coverage that extends to April 12, 2010.

Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters

As previously reported, in March 2003 the Securities and Exchange Commission, which we refer to as the SEC, initiated a formal investigation of our company. We received SEC subpoenas relating to, among other topics, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and our Audit Committee's internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, we received a subpoena duces tecum from the Office of Inspector General of the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®.

In March 2003, upon the recommendation of our management and with the assistance of independent counsel and an independent accounting firm, the Audit Committee of our Board of Directors initiated an assessment and internal review of issues raised by the SEC investigation. In connection with the internal review, we estimated that we had underpaid amounts due under Medicaid and other governmental pricing programs, and recorded an adjustment of \$46.5 million to net sales and accrued expenses in the fourth quarter of 2002. This amount represented our best estimate as of July 2003 of the extent to which we had underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002.

The July 2003 estimate was based upon an extensive sample of available data supporting the calculation of Medicaid rebates paid from 1998 to 2002, and was generated with the assistance of outside consultants. Since that time, our outside consultants have undertaken a comprehensive audit to determine the actual amount of underpayments under Medicaid during the period from 1998 to 2002. As a result of that recently completed audit, we have determined that our accrual for estimated amounts due under Medicaid and other governmental pricing programs through December 31, 2002, should be increased by

\$18.0 million. In addition, based on the results of the comprehensive audit for the period from 1998 through 2002, we estimate that we underpaid amounts due Medicaid by \$0.9 million during the period from 1994 through 1997. Accordingly, results for the fourth quarter of 2003 include an adjustment of \$18.9 million to net sales and accrued expenses.

Following the accrual adjustment recorded in the fourth quarter of 2002, we recovered on a pre-tax basis approximately \$9.5 million in fees we previously paid under our Co-Promotion Agreement for Altace®, and have reduced the accrual for these fees by this amount in the fourth quarter of 2003. In addition, fees under our Co-Promotion Agreement for Altace® in the fourth quarter of 2003 were reduced on a pre-tax basis by approximately \$5.7 million as a result of the accrual adjustment recorded in that quarter.

Under generally accepted accounting principles, the \$18.0 million adjustment in our accrual for Medicaid rebates for the period from 1998 through 2002 constitutes a change in an accounting estimate effective as of December 31, 2003. The change resulted principally from two factors. First, the recently completed Medicaid audit included additional data that was used to refine the July 2003 estimate. Second, we received legal advice that, in calculating amounts payable under Medicaid, we should revise the methodology we had previously been advised to use for calculating best price in respect of a complex issue concerning rebates to pharmacy benefit managers. The \$0.9 million adjustment in our accrual for Medicaid rebates for the period from 1994 through 1997 reflects the correction of immaterial errors that occurred during that period.

The Medicaid audit did not result in any changes to our accruals for programs other than Medicaid. We are currently in the process of conducting detailed audits of our compliance with the requirements of several other governmental pricing programs, but our obligations under these programs are substantially less than our obligations under Medicaid, and we do not expect the audits to result in material adjustments to our accruals.

Although the amounts described above constitute our best estimate of amounts owed in respect of Medicaid and other governmental pricing programs, our calculations are subject to review and challenge by the applicable governmental agencies. In connection with the pending governmental investigations, we have continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Public Health Service. We expect that these discussions will include a detailed review of our calculations by the appropriate agencies, and it is possible that this review could result in material changes. The accruals described above relate solely to our estimated underpayments and exclude any interest, fines, penalties or other amounts that might be owed in connection with the underpayments, as we cannot predict or reasonably estimate their likelihood or magnitude at this time.

Pending determination of the precise amount of our obligations, we have placed a total of \$65.5 million in an interest-bearing escrow account. In addition, since the first quarter of 2003, we voluntarily have been making our Medicaid payments on a basis that we believe represents an overpayment of amounts actually due, and we would expect to offset these payments against the amounts ultimately determined to be due in respect of prior years. Based on the results of our Medicaid audit, we estimate that these overpayments total approximately \$18.6 million as of December 31, 2003.

The governmental investigations of King described above are continuing. The SEC, the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Public Health Service, the Centers for Medicare and Medicaid Services and other governmental agencies that might be investigating or might commence an investigation of us could impose, based on a claim of a violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time. For additional information, please see section entitled the Risk

Factors under the heading If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of our securities against us, our directors, former directors, executive officers, former executive officers, a subsidiary, and a former director of the subsidiary in the United States District Court for the Eastern District of Tennessee, alleging violations of the Securities Act of 1933 and/or the Securities Exchange Act of 1934. These 22 complaints have been consolidated in the United States District Court for the Eastern District of Tennessee. In addition, holders of our securities filed two class action complaints alleging violations of the Securities Act of 1933 in Tennessee state court. We removed these two cases to the United States District Court for the Eastern District of Tennessee, where these two cases were consolidated with the other class actions. Plaintiffs in these actions unsuccessfully moved to remand these two cases back to Tennessee state court. These two actions therefore remain part of the consolidated action. The district court has appointed lead plaintiffs in the consolidated action, and those lead plaintiffs filed a consolidated amended complaint on October 21, 2003 alleging that we, through some of our executive officers, former executive officers, directors and former directors, made false or misleading statements concerning our business, financial condition and results of operations during periods beginning February 16, 1999 and continuing until March 10, 2003. Plaintiffs in the consolidated action have also named the underwriters of our November 2001 public offering as defendants. We and other defendants have filed motions to dismiss the consolidated amended complaint, and those motions are currently pending.

Seven purported shareholder derivative complaints have also been filed in federal and state courts in Tennessee alleging a breach of fiduciary duty, among other things, by some of our officers and directors. The derivative cases in state court were consolidated and are currently stayed. The stay will remain in place at least until the motions to dismiss the consolidated federal securities class action are decided. The derivative cases in federal court are stayed until there is a decision on the merits in the state court derivative suits. Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under ERISA. As amended, the complaint alleges that we and certain of our executive officers, former executive officers, directors, former directors and an employee violated fiduciary duties that we allegedly owed our 401(k) Retirement Savings Plan's participants and beneficiaries under ERISA. The allegations underlying each of these additional lawsuits are similar in many respects to those in the class action litigation described above. We filed a motion to dismiss the ERISA action on March 5, 2004; this motion to dismiss is currently pending.

We intend to defend all of these lawsuits vigorously but are unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

If any governmental sanctions are imposed, or if we were not to prevail in the pending litigation, neither of which we can predict or reasonably estimate at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the government investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending us in the pending litigation has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees. For additional information, please see the Risk Factors section under the heading The governmental investigations and pending litigation could have a material adverse effect on our business. As previously disclosed, we determined in July 2003 as a result of the Audit Committee's internal review that we needed to dedicate additional resources to ensure compliance with all applicable reporting requirements for Medicaid rebates and other governmental pricing programs. We have recently implemented a new information technology system which better enables us to collect and process data needed to more precisely determine our obligations under Medicaid and other governmental pricing programs. Although the new information technology system is intended to significantly enhance the accuracy of our calculations for estimating amounts due under Medicaid and other governmental pricing programs, our processes for these calculations and judgments involved in making these calculations continue to involve subjective

decisions and manual input, and, as a result, these calculations remain subject to the risk of errors arising from manual processes. Additionally, notwithstanding this increased automation, compliance with the requirements of government pricing programs will continue to require that we make judgments and estimates with respect to complex matters as to which there may be little or no regulatory or legal guidance.

In addition to improvements to our systems, we have made several important hires, and we are continuing to search for and hire additional qualified personnel. We have also established a corporate compliance office, and are in the process of implementing a compliance program intended to comport with guidance issued by the Office of Inspector General of the Department of Health and Human Services. We are committed to further enhancements and continue to identify and implement actions that improve our compliance with Medicaid and other governmental pricing programs. The Audit Committee has stated that it intends to monitor carefully our ongoing discussions with appropriate regulatory authorities, as well as the implementation of proposed improvements to systems, processes, training and personnel.

Other Developments

Altace® Patent Challenge

Cobalt Pharmaceuticals, Inc. has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is known as the Orange Book: U.S. Patent Nos. 4,587,258, the 258 patent, and 5,061,722, the 722 patent, two composition of matter patents related to Altace®, and U.S. Patent No. 5,403,856, the 856 patent, a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the Hatch-Waxman Act, any generic manufacturer may file an ANDA with Paragraph IV certification challenging the validity or infringement of a patent listed in the FDA's Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and we filed suit on March 14, 2003 to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt's ANDA for 30 months from no earlier than February 5, 2003. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, we would not receive the full benefit of that 30 month stay. Subsequent to filing our original complaint, we amended our complaint to add an allegation of infringement of the 856 patent. In its answer to the amended complaint, Cobalt denied infringement and alleged that the 856 patent is invalid. Pursuant to FDA regulations, however, Cobalt is not required to certify against the 856 patent. We intend to vigorously enforce our rights under the 722 and 856 patents. Regardless of the outcome of the lawsuit involving the 722 and 856 patents, however, Cobalt has not challenged the validity of the 258 patent and, therefore, cannot market a generic version of Altace® prior to the expiration of that patent in January 2005.

Levoxyl® Patent Challenge

Mylan Pharmaceuticals, Inc. and KV Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. United States Patent No. 6,555,581, the 581 patent, a utility patent with formulation claims relating to Levoxyl®, was issued to us on April 29, 2003. The 581 patent is listed in the FDA's Orange Book and does not expire until February 15, 2022. No earlier than April 30, 2003, we received notice of Mylan's Paragraph IV certification, which alleges noninfringement of the 581 patent. We filed suit against Mylan on June 13, 2003 in the Eastern District of Pennsylvania and on June 16, 2003 in the Northern District of West Virginia; these suits have been consolidated in the Northern District of West Virginia and trial is currently scheduled for June 2005. Pursuant to the Hatch-Waxman Act, the filing of the suits against Mylan provides us with an automatic stay of FDA approval of Mylan's ANDA for 30 months from no earlier than April 30, 2003. On June 24, 2003, we received notice of KV's Paragraph IV certification, which alleges noninfringement and invalidity of the 581 patent. We filed suit against KV on August 7, 2003 and trial is currently scheduled to begin on December 6, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suit against KV provides us with

an automatic stay of FDA approval of KV's ANDA for 30 months from no earlier than June 24, 2003. We intend to vigorously enforce our rights under the 581 patent to the full extent of the law.

Skelaxin® Patent Challenge

Eon Labs, Inc., CorePharma, LLC and Mutual Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin®. United States Patent Nos. 6,407,128, the 128 patent, and 6,683,102, the 102 patent two method-of-use patents relating to Skelaxin®, are listed in the FDA's Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 and 102 patents. Mutual has filed a Paragraph IV certification alleging noninfringement and invalidity of the 102 patent. We filed separate suits against Eon Labs on January 2, 2003 and CorePharma on March 7, 2003 and are currently assessing our right to bring suit against Mutual. Pursuant to the Hatch-Waxman Act, the filing of the suits against Core and Eon provides us with an automatic stay of FDA approval of Eon's ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of Core's ANDA for 30 months from no earlier than January 24, 2003. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA's Orange Book for the 128 patent may be deleted from the ANDA applicants' product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA's previous position on this issue. We are currently assessing our administrative and legal options and may request the FDA to reinstate its previous policy on this issue and reject any ANDAs that delete such use from their product labeling. If we are unable to persuade the FDA to reinstate its previous policy, however, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

Prefest® Patent Challenge

Barr Laboratories, Inc. has filed an ANDA, which included a Paragraph IV certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995 the 995 patent, a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573, the 573 patent, a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the FDA's Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 15, 2003, we received notice of Barr's Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. On November 26, 2003, we filed a complaint against Barr in the Southern District of New York for infringement of the 995 and 573 patents. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Barr's ANDA for 30 months from no earlier than October 15, 2003. We intend to vigorously enforce our rights under both patents.

Women's Health Initiative Clinical Trial

An ongoing clinical trial, the Women's Health Initiative, is being conducted by the National Institutes of Health. Data from that trial released in July 2002 indicated that an increase in certain health risks may result from the long-term use of a competitor's combination hormone replacement therapy for women. News of this data and the perception it has created have negatively affected the entire combination hormone therapy and the oral estrogen therapy, which include our products Prefest®, Delestrogen® and Menest® and may affect our future marketing efforts for Estrasorb®. Total net sales of these women's health products, together with Nordette®, an oral contraceptive, decreased to \$27.0 million for the year ended December 31, 2003, a 57.1% decrease from \$62.9 million during the year ended December 31, 2002. Total prescriptions for these products decreased an average of 29.3% during 2003, in comparison to 2002.

Lorabid®

We acquired the antibiotic Lorabid® in the United States and Puerto Rico from Eli Lilly and Company on August 19, 1999 for a purchase price of \$91.7 million, including acquisition costs. Since the acquisition, sales have declined for a variety of reasons. During the fourth quarter of 2002, we decided to divest our rights to Lorabid®. Also during the fourth quarter of 2002, based on our management's cash flow expectations, we determined that the Lorabid® intangible assets were impaired and recorded an impairment charge of \$66.8 million to write down the assets to their estimated fair value. Additionally, based on estimated prescription trends, we believe our minimum purchase commitments under our supply agreement with Eli Lilly for Lorabid® were greater than the amount we would be able to sell to our customers. As a result, during the fourth quarter of 2002 we also recorded a \$49.9 million charge related to the liability associated with the amount of our purchase commitments in excess of expected demand. Due to the continued decline in prescriptions for Lorabid®, we recorded an additional \$30.0 million charge during the fourth quarter of 2003 related to the liability associated with the amount of our purchase commitments in excess of expected demand.

As of December 31, 2003, our net intangible assets related to Lorabid® equal \$7.0 million. In addition, there is \$5.2 million of remaining exposure related to the supply agreement.

Intangible Asset Issues Related to Some Non-Key Products and Our Rochester Facility

On March 18, 2002, the FDA approved Impax Labs' ANDA for Fludrocortisone Acetate Tablets, a generic for Florinef®. On January 21, 2003, the FDA approved Barr Laboratories' ANDA for a second generic for Florinef®. As of December 31, 2002, we had intangible assets related to Florinef® with carrying values of \$135.0 million. During the first quarter of 2003, we recorded an impairment charge in the amount of \$111.0 million reflecting the reduction in the fair value of the Florinef® intangible assets. We determined the fair value of our Florinef® product based on management's discounted cash flow projections for the product. As of December 31, 2003, we had net intangible assets related to Florinef® of approximately \$22.6 million. If prescriptions for Florinef® continue to decline, we may incur additional asset impairment charges related to this product in the future.

In March 2003, we also became aware that an ANDA for Cortisporin® ophthalmic suspension which was previously inactive, has been reactivated by the FDA with a new sponsor. We understand the sponsor entered the market as of April 14, 2003 with a generic equivalent for Cortisporin® ophthalmic suspension. The entry of the generic has negatively affected our market share for this product. As of December 31, 2003, we have net intangible assets related to our Cortisporin® product line in the approximate amount of \$18.3 million. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows, however, if prescription declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with those products in the future.

Prescriptions for our women's health products, particularly Nordette® and Prefest®, have continued to decline over the past year. As of December 31, 2003, the Nordette® and Prefest® products have net intangible assets associated with them of \$96.0 million and \$108.5 million, respectively. Management currently believes that these assets are not impaired based on estimated undiscounted future cash flows, however, if prescription declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with these products in the future.

Prescriptions for Tapazole® have continued to decline since the entry of a generic substitute in August 2000. As of December 31, 2003, Tapazole® had net intangible assets associated with it of \$18.2 million. Management currently believes that this asset is not impaired based on estimated undiscounted future cash flows. However, if prescription declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with this product in the future.

Our Rochester facility manufactures products for us and various third-party manufacturers. As of December 31, 2003, the net carrying value of the property, plant, and equipment at the Rochester facility and the net intangible assets considered parts of the Rochester asset group were \$82.2 million and

\$18.3 million, respectively. Overall production volume at this facility has declined. We currently have plans to transfer to this facility the manufacture of some of our branded prescription pharmaceutical products that are currently manufactured for us by third parties. This should increase production and overall profitability at our Rochester facility. Management currently believes that these long-term assets are not impaired based on estimated undiscounted future cash flows. However, if production volumes continue to decline and/or if we are not successful in transferring additional production to the facility, we may have to write-off a portion of the property, plant, equipment, and intangible assets associated with the facility.

Results of Operations

The following summarizes net revenues by operating segment (in thousands):

	For the Years Ended December 31,		
	2001	2002	2003
Branded pharmaceuticals(1)	\$ 793,543	\$ 1,032,831	\$ 1,300,948
Meridian Medical Technologies			124,157
Royalties	46,774	58,375	68,365
Contract manufacturing	29,680	35,936	27,290
Other	2,265	1,193	628
Total	\$ 872,262	\$ 1,128,335	\$ 1,521,388

- (1) Branded pharmaceuticals segment net revenues for 2002 reflect (a) a \$22,113 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001, (b) a \$12,399 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and (c) an \$11,970 charge arising from changes in accounting estimates related to Medicaid and other governmental pricing programs. Branded pharmaceuticals segment net revenues for 2003 reflect an \$18,000 charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$900 charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997. For additional information, please see the section above entitled Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters and Note 17 to our audited consolidated financial statements.

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

Revenues

Total net revenue increased \$393.1 million, or 34.8%, to \$1,521.4 million in 2003 from \$1,128.3 million in 2002, due primarily to the acquisition and growth of branded pharmaceutical products.

Net sales from branded pharmaceutical products increased \$268.1 million, or 26.0%, to \$1,300.9 million in 2003 from \$1,032.8 million in 2002. This increase was primarily due to our acquisition of Sonata® and Skelaxin® on June 12, 2003, increased net sales of some of our branded pharmaceutical products, particularly Altace® and Thrombin-JMI® and the acquisition of Intal®, Tilade®, and Synercid® on December 30, 2002, partially offset by lower sales of Levoxyl®, our women's health products, Lorabid®, Cortisporin®, and Florinef®. Net sales from branded pharmaceutical products for 2002 reflect

a \$22.1 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001,

a \$12.4 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and

an \$12.0 million charge arising from changes in accounting estimates related to Medicaid and other governmental pricing programs.

Branded pharmaceuticals segment net revenues for 2003 reflect

an \$18.0 million charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and

a \$0.9 million charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997.

Net sales from branded pharmaceutical products in 2002 have not been adjusted to reflect the amount of the \$18.9 million adjustment made in 2003 for estimated underpayments of amounts due under Medicaid and other governmental pricing programs which actually related to 2002.

For additional information, please see the section above entitled Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters and Note 17 to our audited consolidated financial statements. We expect continued growth in net sales from branded pharmaceuticals products during 2004, but not at as high a rate as that experienced in 2003.

Revenues from Meridian totaled \$124.2 million in 2003. This is a new segment in 2003 due to our acquisition of Meridian on January 8, 2003.

Revenues from royalties is derived from payments we receive based on sales of Adenoscan® and Adenocard®. Revenues from royalties increased \$10.0 million, or 17.1%, to \$68.4 million in 2003 from \$58.4 million in 2002 primarily due to an increase in sales of Adenoscan®. While we anticipate continued growth from royalty revenues, we are not responsible for the marketing of these products and, thus, are not able to predict whether growth in 2004 will continue at the rate experienced in 2003. Additionally, we anticipate the entry of generic competitors for Adenocard® during the second half of 2004. Adenocard® accounted for approximately 11.9% of our royalty revenues during 2003.

Revenues from contract manufacturing decreased \$8.6 million, or 24.0%, to \$27.3 million in 2003 from \$35.9 million in 2002. We anticipate contract revenue should be lower in 2004.

Operating Costs and Expenses

Total operating costs and expenses increased \$521.2 million, or 62.5%, to \$1,355.3 million in 2003 from \$834.1 million in 2002. This increase was primarily due to special items during 2003 resulting in a net charge equaling \$371.9 million, compared to a net charge totaling \$152.8 million during 2002, operating costs associated with Meridian which we acquired in January 2003, cost of revenues and amortization associated with branded pharmaceutical products acquired during 2003, expenses associated with the expansion of our sales force during 2003, and cost of revenues associated with increased unit sales of some of our branded pharmaceutical products. Special items are those particular material income or expense items that our management believes are not related to our ongoing, underlying business, are not recurring, or are not generally predictable. These items include, but are not limited to, merger and restructuring expenses; non-capitalized expenses associated with acquisitions, such as in-process research and development charges and one-time inventory valuation adjustment charges; charges resulting from the early extinguishments of debt; asset impairment charges; expenses of drug recalls; and gains and losses resulting from the divestiture of assets. We believe the identification of special items enhances an analysis of our ongoing, underlying business and an analysis of our financial results when comparing those results to that of a previous or subsequent like period. However, it should be noted that the determination of whether to classify an item as a special charge involves judgments by us.

Cost of revenues increased \$89.8 million, or 30.4%, to \$384.8 million in 2003 from \$295.0 million in 2002. The increase was primarily due to costs associated with sales of branded pharmaceutical products we acquired during 2003, cost of revenues associated with Meridian which we acquired in January 2003, partially offset by special items related to inventory in 2002 resulting in a net charge equaling \$68.1 million

during that year, compared to a net charge of \$36.5 million during 2003. Special items included in cost of revenues during 2002 and 2003 are as follows:

As a result of declining Lorabid® prescriptions, during the fourth quarter of 2002 we determined that we will not sell all of the Lorabid® inventory that we were required to purchase under our supply agreement with Eli Lilly. Accordingly, we recorded a \$49.9 million charge in 2002 related to the liability associated with the amount of the purchase commitments in excess of expected demand. During the fourth quarter of 2003, primarily as a result of the continuing decline of Lorabid® prescriptions, we recorded an additional \$30.0 million charge for purchase commitments in excess of expected demand.

We incurred a charge of \$2.1 million in 2003 relating to the step-up in the cost of Meridian's inventory at the time of acquisition.

We incurred a charge in the amount of \$4.3 million in 2003 primarily related to the voluntary recalls of certain lots of Levoxyl®.

We incurred a charge of \$15.2 million relating to inventory donations during the fourth quarter of 2002, attributable to our decision to divest our rights to Lorabid®.

We incurred a charge in the amount of \$3.0 million in 2002 primarily related to the voluntary recalls of Liqui-Char and Theravac® and products manufactured for us by DSM Pharmaceuticals.

Cost of revenues from branded pharmaceutical products increased \$28.1 million, or 11.7%, to \$267.5 million in 2003 from \$239.4 million in 2002. The increase was primarily due to cost of revenues associated with our acquisitions and an increase in cost of sales related to Altace®, partially offset by a decrease in the net charge for special items associated with our inventory of branded pharmaceutical products as described above.

Cost of revenues from Meridian Medical Technologies was \$66.2 million in 2003. This is a new segment in 2003 due to our acquisition of Meridian on January 8, 2003.

Cost of revenues from royalties increased \$0.8 million, or 7.6%, to \$11.3 million in 2003 from \$10.5 million in 2002.

Cost of revenues associated with contract manufacturing decreased \$4.5 million, or 10.3%, to \$39.2 million in 2003 from \$43.7 million in 2002 due to decreased unit production of products we manufacture for third parties.

As a percentage of revenues, cost of revenues decreased to 25.3% in 2003 from 26.1% in 2002 primarily due to a reduction in the amount of the net charge for special items related to inventory during 2003 as described above, partially offset by cost of revenues associated with Meridian which we acquired in January 2003 and whose products have lower gross margins.

Total selling, general and administrative expenses, including co-promotion fees paid under our Co-Promotion Agreement with Wyeth Pharmaceuticals, increased \$128.4 million, or 35.0%, to \$495.3 million in 2003 from \$366.9 million in 2002. This increase was primarily attributable to special items resulting in a net charge equaling \$28.9 million for professional fees that are primarily related to the ongoing investigations of our company by the SEC and the Office of Inspector General of the Department of Health and Human Services and a legal settlement related to Lorabid®, expenses associated with expansion of our sales force during 2003 and selling, general and administrative expenses associated with Meridian which we acquired in January 2003. Fees under our Co-Promotion Agreement for Altace® were reduced by \$15.2 million during 2003 as a result of the accrual adjustments during 2002 and 2003 for amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2002. As a percentage of revenues, total selling, general, and administrative expense was 32.6% in 2003 compared to 32.5% in 2002. We believe that selling, general, and administrative expenses will continue to increase during 2004 but at a lower rate than that experienced in 2003.

Depreciation and amortization expense increased \$65.3 million, or 110.1%, to \$124.6 million in 2003 from \$59.3 million in 2002. This increase was primarily attributable to the amortization of the intangible assets associated with our acquisitions of Sonata® and Skelaxin® on June 12, 2003; Meridian on January 8, 2003; and Intal®, Tilade® and Synercid® on December 30, 2002. As a percentage of total revenues, depreciation and amortization expense increased to 8.2% in 2003 compared to 5.3% in 2002. Our depreciation and amortization expense is anticipated to increase at a substantially reduced rate during 2004 compared to 2003. For additional information, please see Note 8 to our audited consolidated financial statements.

Total research and development expenses increased \$197.9 million to \$238.1 million in 2003 from \$40.2 million in 2002. This increase was primarily due to an increase in special items resulting in a charge equaling \$194.0 million in 2003 for acquired in-process research and development associated with our acquisition of the rights to new formulations of Sonata® presently under development and our acquisition of Meridian, partially offset by a special item resulting in a charge equaling \$12.0 million during 2002 for in-process research and development associated with our acquisition of Intal® in December 2002. We anticipate that research and development expense should equal approximately \$70.0 million during 2004.

In addition to the special items related to inventory, total selling, general and administrative expense and research and development expense described above, we incurred other special items affecting operating costs and expenses resulting in a net charge totaling \$112.6 million during 2003 compared to a net charge totaling \$72.7 million in 2002. These other special items included the following:

During the year ended December 31, 2003, we incurred an intangible asset impairment charge of \$111.0 million reflecting the reduction in the fair value of the Florinef® intangible assets on the approval of a second generic on January 21, 2003.

During the year ended December 31, 2003, we incurred an intangible asset impairment charge of \$13.6 million related to three of our smallest branded pharmaceutical products and the write-off of certain unutilized intangible assets.

During the year ended December 31, 2003, we had income of \$12.0 million due to a gain on the sale of our animal health products and certain non-income producing intangible assets.

During the year ended December 31, 2002, we incurred an intangible asset impairment charge of \$66.8 million related to our decision to divest Lorabid®.

During the year ended December 31, 2002, we incurred merger, restructuring and executive retirement charges of \$5.9 million primarily resulting from the consolidation of our international division into our operations in Bristol, Tennessee, and the retirement of two executives.

Operating Income

Operating income decreased \$128.1 million, or 43.5%, to \$166.1 million in 2003 from \$294.2 million in 2002. As a percentage of net revenues, operating income decreased to 10.9% in 2003 from 26.1% in 2002. This decrease was primarily due to the special items described above, particularly special charges totaling \$194.0 million for acquired in-process research and development relating to our acquisition of rights to new formulations of Sonata® presently under development and our acquisition of Meridian, and \$111.0 million intangible asset impairment special charges related to Florinef®. While we believe operating income in 2004 will grow due to increased net sales from our branded pharmaceutical segment and decreased special charges, we refer you to the Risk Factors section in this report where we describe events that could cause results to materially differ.

Other Income (Expense)

Interest income decreased \$15.6 million, or 69.6%, to \$6.8 million in 2003 from \$22.4 million in 2002 primarily due to lower balances of invested cash, cash equivalents and marketable securities during 2003 as compared to 2002.

Interest expense increased \$1.0 million, or 8.1%, to \$13.4 million in 2003 from \$12.4 million in 2002.

Our financial results in 2003 include a special income item in the amount of \$18.2 million to reflect the decrease in the valuation allowance for the convertible notes receivable from Novavax. We will adjust the amount of the valuation allowance in future periods on an as-if-converted basis until the loan is no longer considered to be impaired. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities. For additional information, please see Note 2 to our audited consolidated financial statements.

Income Tax Expense

The effective tax rate was 40.2% in 2003 and 31.8% in 2002. The effective tax rate in 2002 was different than the federal statutory rate of 35.0% primarily due to favorable adjustments in the overall state tax rate, research and development tax credits, donations of branded prescription pharmaceutical products and tax-exempt interest. The effective tax rate in 2003 was higher than the federal statutory rate primarily due to state income taxes and non-deductible in-process research and development charges incurred in connection with our acquisition of Meridian. We anticipate the effective tax rate in 2004 to be approximately 36.0%.

Net Income

Due to the factors set forth above, net income decreased \$76.6 million, or 42.0%, to \$105.9 million in 2003 from \$182.5 million in 2002.

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

Revenues

Total net revenue increased \$256.1 million, or 29.4%, to \$1,128.3 million in 2002 from \$872.3 million in 2001, due primarily to the growth and acquisition of branded pharmaceutical products.

Net sales from branded pharmaceutical products increased \$239.3 million, or 30.1%, to \$1,032.8 million in 2002 from \$793.5 million in 2001. This increase was due primarily to growth in net sales of Altace®, Levoxyl and Thrombin-JMI®, the acquisition of Corzide®, Delestrogen® and Florinef® and a license to Corgard® in August 2001, and the acquisition of Prefest® on May 29, 2002. This increase was partially offset by a \$22.1 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001; a \$12.4 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002; a \$12.0 million charge arising from changes made in 2002 in accounting estimates for the years 1998 to 2002 related to Medicaid and other governmental pricing programs; and decreases in net sales of Lorabid®, Tapazole® and several women's health products. Net sales from branded pharmaceutical products for 2002 and 2001 have not been reduced by estimated underpayments of amounts due under Medicaid and other governmental pricing programs for that year.

Revenue from royalties is derived from payments we receive based on sales of Adenoscan® and Adenocard®. Revenues from royalties increased \$11.6 million, or 24.8%, to \$58.4 million in 2002 from \$46.8 million in 2001 primarily due to an increase in unit sales of Adenoscan®.

Revenues from contract manufacturing increased \$6.2 million, or 20.9%, to \$35.9 million in 2002 from \$29.7 million in 2001. The majority of the increase was due to increased unit volume of products manufactured for third parties in 2002 compared to 2001.

Operating Costs and Expenses

Total operating costs and expenses increased \$328.1 million, or 64.8%, to \$834.1 million in 2002 from \$506.0 million in 2001. The increase was primarily due to special items during 2002 resulting in a net

charge of \$152.8 million, cost of revenues associated with increased unit sales of our branded pharmaceutical products, and increased fees associated with the promotion of Altace® under our Co-Promotion Agreement with Wyeth, offset by special items during 2001 resulting in a net charge of \$12.1 million.

Cost of revenues increased \$108.4 million, or 58.1%, to \$295.0 million in 2002 from \$186.6 million in 2001. The increase was primarily due to costs associated with increased unit sales of our branded pharmaceutical products, including Altace®, Levoxyl® and Thrombin-JMI®, and an increase in special items related to inventory totaling \$68.1 million during 2002, as compared to a net charge totaling \$8.0 million during 2001. Special items were as follows:

As a result of a continuing decline of Lorabid® prescriptions and our inability, to date, to divest our rights to Lorabid®, we determined that we will be unable to sell all of the Lorabid® inventory that we are required to purchase under our supply agreement with Eli Lilly. Accordingly, we recorded in the fourth quarter of 2002 a \$49.9 million charge related to the liability associated with the amount of the purchase commitments in excess of expected demand.

We incurred a charge of \$15.2 million relating to inventory donations during the fourth quarter of 2002, attributable to our decision to divest our rights to Lorabid®.

We incurred a charge in the amount of \$5.9 million during the fourth quarter of 2001 and \$1.2 million in 2002 related to our voluntary recall of products manufactured for us by DSM Pharmaceuticals as a result of regulatory issues related to DSM's manufacturing facility in Greenville, North Carolina. Distribution of the affected products was resumed during 2002.

We incurred a charge in the amount of \$1.8 million during the second-quarter of 2002, due primarily to the voluntary recalls of Liqui-Char® and Theravac®, two of our smaller products.

We incurred a charge in the amount of \$2.1 million during the third quarter of 2001, relating to the write off of obsolete Levoxyl® inventory. The FDA approved the NDA for our new formulation of Levoxyl® on May 25, 2001. Pursuant to FDA guidance, we have distributed only the FDA approved new formulation of Levoxyl® since August 14, 2001.

Cost of revenues from branded pharmaceutical products increased \$100.2 million, or 72.0%, to \$239.4 million in 2002 from \$139.2 million in 2001. This increase was primarily due to an increase in special items affecting cost of revenues in 2002 as described above, as well as increases in cost of revenues due to increased unit sales of our branded pharmaceutical products, especially the Altace®, Levoxyl® and Thrombin® product lines.

Cost of revenues from royalties increased \$2.2 million, or 26.5%, to \$10.5 million in 2002 from \$8.3 million in 2001. The increase is primarily due to our increased royalty expense that is directly related to the increase in royalty revenue attributable to Adenocard® and Adenoscan®.

Cost of revenues associated with contract manufacturing increased \$6.8 million, or 18.4%, to \$43.7 million in 2002 from \$36.9 million in 2001 due primarily to an increase in contract manufacturing unit sales of products we manufactured for third parties.

As a percentage of revenues, cost of revenues increased to 26.1% in 2002 from 21.4% in 2001 due to the increase in special items as described above, partially offset by an increase in sales of higher margin products.

Total selling, general and administrative expenses increased \$126.0 million, or 52.3%, to \$366.9 million in 2002 from \$240.9 million in 2001. As a percentage of total revenues, selling, general and administrative expenses increased to 32.5% in 2002 from 27.6% in 2001. These increases were primarily attributable to fees and expenses associated with the promotion of Altace® under the Co-Promotion Agreement with Wyeth.

Depreciation and amortization expense increased \$11.3 million, or 23.5%, to \$59.3 million in 2002 from \$48.0 million in 2001. This increase was primarily attributable to capital expenditures in 2001 and

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

2002, a full year of amortization of the intangible assets related to the acquisitions of Corzide®, Delestrogen® and Florinef® and a license to Corgard® from Bristol-Myers Squibb in August 2001, and the acquisition of Prefest® from Ortho-McNeil on May 29, 2002. As a percentage of total revenues, depreciation and amortization expenses decreased modestly to 5.3% in 2002 compared to 5.5% in 2001.

Total research and development expenses increased \$13.7 million to \$40.2 million in 2002 from \$26.5 million in 2001. The increase is primarily due to a special item resulting in a charge of \$12.0 million for in-process research and development related to our acquisition of Intal® on December 30, 2002.

In addition to the special items related to inventory and research and development described above, King incurred other special items affecting operating costs and expenses resulting in a net charge totaling \$72.7 million during 2002 compared to a net charge totaling \$4.1 million during the same period of the prior year. These other special items included the following:

During the year ended December 31, 2002, we incurred an intangible asset impairment charge of \$66.8 million related to our decision to divest Lorabid®, reflecting management's cash flow expectations as of July 2003.

During the year ended December 31, 2002, we incurred merger, restructuring and executive retirement charges of \$5.9 million primarily resulting from the consolidation of our international division into our operations in Bristol, Tennessee, and the retirement of two executives.

During the year ended December 31, 2001, we incurred merger, restructuring and other charges of \$4.1 million resulting from the further integration of Jones Pharma Incorporated.

Operating Income

Operating income decreased \$72.1 million, or 19.7%, to \$294.2 million in 2002 from \$366.3 million in 2001. As a percentage of net revenues, operating income decreased to 26.1% in 2002 from 42.0% in 2001 due primarily to an increase in the net charge related to special items during 2002 and the reduction in total revenue during 2002 due to (a) a \$22.1 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001, (b) a \$12.4 million charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and (c) a \$12.0 million charge arising from changes made in 2002 in accounting estimates for the years 1998 to 2002 related to Medicaid and other governmental pricing programs. Operating income for 2001 has not been reduced to reflect the estimated underpayments of amounts due under Medicaid and other governmental pricing programs for that year as the underpayments were immaterial.

Other Income (Expense)

Interest income increased \$11.4 million, or 103.6%, to \$22.4 million in 2002 from \$11.0 million in 2001. This increase was primarily due to higher average investments, offset by reduced rates of return on investments in 2002.

Interest expense decreased \$0.3 million, or 2.4%, to \$12.4 million in 2002 from \$12.7 million in 2001 due primarily to substantially lower interest rates on long-term debt.

Special items during 2002 also included a charge of \$35.6 million relating to the establishment of a valuation allowance against the convertible notes receivable from Novavax. SFAS No. 114, requires that we treat the Novavax convertible notes as an impaired loan because of the decline in the share price of Novavax common stock to levels below that established by our common stock conversion options associated with the convertible notes.

During the year ended December 31, 2001, we wrote off \$22.9 million of unamortized financing costs and premiums paid resulting from the repayment of debt during this period.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

We recorded other expenses of \$0.9 million in 2002 as compared to other income of \$6.3 million in 2001. During 2001, other income related primarily to unrealized gains on the conversion options associated with our Novavax convertible notes.

Income Tax Expense

The effective tax rate was 31.8% in 2002 and 37.2% in 2001. The effective tax rate in 2002 was different than the federal statutory rate of 35.0% primarily due to favorable adjustments in the overall state tax rate, research and development tax credits, donations of branded prescription pharmaceutical products and tax-exempt interest. The effective rate in 2001 was different than the federal statutory rate of 35.0% primarily due to state income taxes.

Income before Cumulative Effect of Change in Accounting Principle

Due to the factors set forth above, income before the cumulative effect of change in accounting principle decreased \$36.0 million, or 16.5%, to \$182.5 million in 2002 from \$218.5 million in 2001.

Cumulative Effect of Change in Accounting Principle

We recognized the cumulative effect of a change in accounting principle of \$0.5 million, net of income taxes of \$0.3 million, during the first quarter of 2001, due to the adoption of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, which establishes accounting and reporting standards for derivative instruments and hedging activities.

Net Income

Due to the factors set forth above, net income decreased \$35.4 million, or 16.2%, to \$182.5 million in 2002 from \$217.9 million in 2001.

Off Balance Sheet Arrangements, Contractual Obligations and Commercial Commitments

We do not have any off balance sheet arrangements, except for operating leases in the normal course of business as described in Note 10 to the our audited consolidated financial statements included in this report, and as reflected in the table below.

The following summarizes contractual obligations and commitments as of December 31, 2003 (in thousands):

	Payments Due by Period				
	Total	Less Than One Year	One to Three Years	Four to Five Years	After Five Years
Contractual Obligations:					
Long-term debt	\$ 345,097	\$ 97	\$ 345,000	\$	\$
Operating leases	75,519	13,315	23,814	18,749	19,641
Unconditional purchase obligations	523,065	137,850	207,109	178,106	

Our unconditional purchase obligations are primarily related to minimum purchase requirements under contracts with suppliers to purchase raw materials and finished goods related to our branded pharmaceutical products. The above table does not reflect any potential milestone payments in connection with research and development projects or acquisitions.

We have a supply agreement with Aventis to produce ramipril, the active ingredient in Altace®. This supply agreement is reflected in the unconditional purchase obligations above. This supply agreement requires us to purchase certain minimum levels of ramipril. If sales of Altace® do not increase at the currently anticipated rates, if we are unable to maintain market exclusivity for Altace® in accordance with our current expectations, if our product life cycle management is not successful, or if we do not terminate the supply agreement at an optimal time for us, we may incur losses in connection with the purchase

commitments under the supply agreement. In the event we incur losses in connection with the purchase commitments under the supply agreement, there may be a material adverse effect upon our results of operations and cash flows.

We have a supply agreement with Eli Lilly to produce Lorabid® which is reflected in the unconditional purchase obligations above. This supply agreement requires us to purchase certain minimum levels of inventory of Lorabid® through September 1, 2005. Based on changes in estimated prescription trends, we believe our minimum purchase commitments under the supply agreement are greater than that which we will be able to sell to our customers. As a result, we recorded charges of \$49.9 million during December 2002 and \$30.0 million during December 2003 related to the liability associated with the amount of our purchase commitments in excess of expected demand. As of December 31, 2003, we have \$5.2 million of additional exposure related to the supply agreement if prescriptions for Lorabid® continue to decline.

Liquidity and Capital Resources

General

We believe that existing balances of cash, cash equivalents and marketable securities, cash generated from operations, existing revolving credit facility and funds available to us under our universal shelf registration are sufficient to finance our current operations and working capital requirements on both a short term and long term basis. However, in the event we make significant future acquisitions or change our capital structure, we may be required to raise funds through additional borrowings or the issuance of additional debt or equity securities.

On January 8, 2003, we completed our acquisition of Meridian. We paid \$44.50 per common share to Meridian shareholders, totaling approximately \$253.9 million. We financed the acquisition using our available cash.

On June 12, 2003, we acquired the primary care business of Elan and of some of its subsidiaries in the United States and Puerto Rico, which includes the rights to two branded prescription pharmaceutical products, including the rights pertaining to potential new formulations, of Sonata® and Skelaxin®, together with Elan's United States primary care field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan's sale of Skelaxin® included the related NDAs, copyrights, trademarks, patents and rights pertaining to potential new formulations of Skelaxin®. Elan's sale of Sonata® included its rights to the product, as well as certain related copyrights. We also acquired certain intellectual property, regulatory, and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, we secured an exclusive license to the intellectual property rights, in this territory, of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals. The total estimated purchase price of \$814.4 million includes the cost of acquisition, assumed liabilities and a portion of contingent liabilities. The purchase price also includes the transfer of inventory with a value of approximately \$40.4 million. In connection with this acquisition, we placed \$163.4 million into escrow to satisfy the deferred obligations to Wyeth that we assumed. In addition to the initial purchase price, we paid \$25.0 million during January 2004, as a milestone payment to Elan relating to the continued exclusivity of Sonata® and we paid \$11.0 million during March 2004, as a milestone payment to Elan in connection with the development of new formulations of Sonata®. We will also

pay royalties on the current formulation of Skelaxin® from the date of closing,

pay up to an additional \$60.0 million if Elan achieves certain milestones in connection with the development of a reformulated version of Sonata®,

will pay \$15.0 million as a milestone payment if annual net sales of a reformulated version of Sonata® exceed \$100.0 million and

will pay for costs associated with the development of the reformulated version of Sonata®.

We drew down a total of \$125.0 million on our \$400.0 million senior secured revolving credit facility on June 3 and June 6, 2003, the proceeds of which were used to fund a portion of the Elan acquisition on June 12, 2003. During the third quarter of 2003, we paid off the principal balance and have no outstanding balance as of December 31, 2003.

SEC Investigation and Securities Litigation

Pending determination of the precise amount of our obligations related to the governmental investigations, the Medicaid accrual adjustment and related matters, we have placed a total of \$65.5 million in an interest-bearing escrow account. Our accruals for amounts owed in respect of Medicaid and other governmental pricing programs relate solely to our estimated underpayments and exclude any interest, fines, penalties or other amounts that might be owed in connection with the underpayments, as we cannot predict or reasonably estimate their likelihood or magnitude at this time. For additional information, please see the section above entitled Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters.

Year ended December 31, 2003

We generated net cash from operations of \$437.3 million for the year ended December 31, 2003. Our net cash provided from operations was primarily the result of \$105.9 million in net income, adjusted for non-cash charges for depreciation and amortization of \$125.5 million, the write-off of in-process research and development of \$194.0 million primarily related to the acquisitions of Meridian and the primary care business of Elan, and the impairment charge for intangible assets of \$124.6 million primarily related to Florinef®. Working capital changes reducing cash flow from operations were due primarily to increases in inventory and accounts receivable resulting from increased sales. Working capital changes increasing cash flow from operations were due primarily to increases in accrued expenses due to the timing of our payments for rebates.

Cash flows used in investing activities were \$882.0 million primarily due to our purchase of Meridian of \$238.5 million, our purchase of the primary care business of Elan of \$761.7 million, net proceeds from the sale of investment securities of \$227.2 million, transfers to escrow of \$67.7 million and capital expenditures of \$51.2 million.

Cash flows from financing activities were \$2.5 million, principally comprised of debt payments of \$1.3 million offset by proceeds in the amount of \$4.1 million from the exercise of employee stock options. Included in financing activities is \$125.0 million of proceeds and \$125.0 million of payments both related to borrowings on our credit facility.

Year ended December 31, 2002

We generated net cash from operations of \$456.0 million for the year ended December 31, 2002. Our net cash provided from operations was primarily the result of \$182.5 million in net income, adjusted for non-cash charges for depreciation and amortization of \$62.9 million, the write-off of in-process research and development of \$12.0 million related to our acquisition of Intal®, the impairment charge for intangible assets of \$66.8 million related to Lorabid®, and the reserve on convertible senior notes of \$35.4 million, partially offset by changes in working capital and deferred income taxes.

Cash flows used in investing activities were \$574.3 million primarily due to the purchase of intangible assets of \$322.1 million related to our acquisitions of Intal®, Tilade®, Synercid® and Prefest®, capital expenditures of \$73.6 million, the net purchase of investment securities of \$177.3 million, and the purchase of Novavax convertible senior notes of \$10.0 million.

Financing activities used \$168.1 million of cash flows comprised principally of the repurchase of some of our common stock for \$166.3 million.

Year ended December 31, 2001

We generated net cash from operations of \$279.6 million for the year ended December 31, 2001. Our net cash provided from operations was primarily the result of \$217.9 million in net income, adjusted for non-cash charges for depreciation and amortization of \$48.0 million and charges of \$22.9 million related to the write-off of debt financing costs related to the early extinguishment of our subordinated debentures partially offset by changes in working capital.

Cash flows used in investing activities were \$382.7 million primarily due to the purchase of intangible assets of \$286.5 million related to our acquisition of products from Bristol-Myers Squibb, capital expenditures of \$40.2 million, the purchase of investment securities of \$49.9 million, loans of \$15.0 million to a supplier, and the purchase of Novavax convertible senior notes of \$10.0 million offset by \$14.1 million representing proceeds from the repayment of loans made to a supplier.

Financing activities provided \$901.3 million of cash flow comprised principally of \$75.0 million in proceeds from the revolving credit facility, \$684.4 million in proceeds from the issuance of common shares and the exercise of stock options and \$345.0 million in proceeds from the issuance of convertible debentures, offset by repayments of \$75.0 million on the revolving credit facility, \$115.1 million on the senior subordinated notes, and \$11.1 million of debt issuance costs.

Certain Indebtedness and Other Matters

As of December 31, 2003, we had \$345.1 million of long-term debt (including current portion) outstanding, up to \$388.4 million available under our revolving credit facility, and \$616.0 million available under our universal shelf registration.

On September 20, 2001, we registered a \$1.3 billion universal shelf registration statement on Form S-3 with the Securities and Exchange Commission. This universal shelf registration statement allows us to sell any combination of debt and/or equity securities in one or more offerings up to a total of \$1.3 billion. During November 2001, we completed the sale of 17,992,000 newly issued shares of common stock for \$38.00 per share (\$36.67 per share net of commissions and expenses) resulting in net proceeds of \$659.8 million. Additionally, during November 2001, we issued \$345.0 million of 2 3/4% Convertible Debentures due November 15, 2021 in a private placement. Holders may require us to repurchase for cash all or part of these debentures on November 15, 2006, November 15, 2011 or November 15, 2016 at a price equal to 100% of the principal amount of the debentures plus accrual interest up to but not including the date of repurchase.

On April 23, 2002, we established a \$400.0 million five year senior secured revolving credit facility. The facility has been collateralized in general by all real estate with a value of \$5.0 million or more and all of our personal property and that of our significant subsidiaries. Our obligations under the senior secured revolving credit facility are unconditionally guaranteed on a senior basis by most of our subsidiaries. The senior secured revolving credit facility accrues interest at our option, at either (a) the base rate, which is based on the greater of (1) the prime rate or (2) the federal funds rate plus one-half of 1%, plus an applicable spread ranging from 0.0% to 0.75% (based on a leverage ratio) or (b) the applicable LIBOR rate plus an applicable spread ranging from 1.0% to 1.75% (based on a leverage ratio). In addition, the lenders under the senior secured revolving credit facility are entitled to customary facility fees based on (a) unused commitments under the facility and (b) letters of credit outstanding. We incurred \$5.1 million of deferred financing costs, which are being amortized over five years, the life of the senior secured revolving credit facility. This facility requires us to maintain a minimum net worth of no less than \$1.2 billion plus 50% of our consolidated net income for each fiscal quarter after April 23, 2002, excluding any fiscal quarter for which consolidated income is negative; an EBITDA to interest expense ratio of no less than 3.00 to 1.00; and a funded debt to EBITDA ratio of no greater than 3.50 to 1.00 prior to April 24, 2004 and of no greater than 3.00 to 1.00 on or after April 24, 2004. As of December 31, 2003, we have complied with these covenants. As described above, on June 3 and June 6, 2003, we drew down a total of \$125.0 million under our senior secured revolving credit facility to fund a portion of our acquisition of Elan's primary care business on June 12, 2003. During the third quarter of 2003, we repaid the principal

balance owed on our senior secured revolving credit facility and have no outstanding borrowings as of December 31, 2003.

As of December 31, 2003, there were no outstanding borrowings under this facility, however, we had \$11.6 million outstanding for letters of credit under this facility.

Capital Expenditures

Capital expenditures, including capital lease obligations, were \$51.2 million for the year ended December 31, 2003 and \$73.6 million for the year ended December 31, 2002. The principal capital expenditures for the year ended December 31, 2003 included property and equipment purchases, new information technology system implementation costs and building improvements for facility upgrades and increased capacity.

We anticipate capital expenditures, including capital lease obligations, for the year ending December 31, 2004 of approximately \$75.0 to \$90.0 million, which will be funded with cash from operations. The principal capital expenditures are anticipated to include property and equipment purchases, new information technology system implementation costs, building improvements for facility upgrades, cost associated with improving our production capabilities, and costs associated with moving production of some of our pharmaceutical products to our facilities in St. Louis, Bristol and Rochester.

Impact of Inflation

We have experienced only moderate raw material and labor price increases in recent years. While we have passed some price increases along to our customers, we have primarily benefited from sales growth negating most inflationary pressures.

Recent Accounting Pronouncements

In the first quarter of 2002, we adopted SFAS No. 141 Business Combinations, and SFAS No. 142 Goodwill and Other Intangible Assets. SFAS No. 141 requires all business combinations to be accounted for under the purchase method of accounting. SFAS No. 141 was effective for all business combinations initiated after June 30, 2001. SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. The results for the year ended December 31, 2002 include the effect of adopting SFAS Nos. 141 and 142, which resulted in a \$1.6 million reduction in expenses, or \$1.1 million net of tax, and no increase in basic and diluted earnings per share.

In August 2001, the Financial Accounting Standards Board issued SFAS No. 143, Accounting for Asset Retirement Obligations and SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 144 addresses financial accounting and reporting for the impairment or disposal of long-lived assets. We adopted these standards effective January 1, 2002. The implementation of these standards did not have any effect on our financial statements.

In May 2002, the Financial Accounting Standards Board issued SFAS No. 145, Revision of FAS Nos. 4, 44 and 64, Amendment of FAS 13 and Technical Corrections as of April 2002. SFAS No. 145 is effective for fiscal periods beginning after May 15, 2002. The primary impact of adopting SFAS No. 145 is that gains and losses incurred upon the extinguishment of debt will no longer qualify for treatment as an extraordinary item in the income statement but will be presented as non-operating gain or loss. Accordingly, for purposes of comparison in our 2003 Form 10-K, we reclassified the loss incurred on the extinguishment of debt during the year ended December 31, 2001 as other expense.

In July 2002, the Financial Accounting Standards Board issued SFAS No. 146, Accounting for Exit or Disposal Activities. SFAS No. 146 addresses the recognition, measurement, and reporting of costs that

are associated with exit and disposal activities, including costs related to terminating a contract that is not a capital lease and termination benefits that employees who are involuntarily terminated receive under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 was effective for exit or disposal activities initiated after December 31, 2002. The implementation of this standard did not have any effect on our financial statements.

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46, Consolidation of Variable Interest Entities, which we refer to as FIN 46. FIN 46 requires a variable interest entity to be consolidated by a company if that company is required to absorb a majority of the variable interest entity's expected losses or entitled to receive a majority of the entity's residual returns or both. We are in the process of assessing what impact this pronouncement will have on our consolidated financial statements. Based on our preliminary analysis of the impact of FIN 46, we believe that it is reasonably possible that Novavax could be a variable interest entity and our interest in Novavax may require us to consolidate Novavax in the first quarter of 2004.

During the period from December 2000 through June 2002, we provided \$40.0 million in financing to Novavax in the form of notes receivable convertible to common stock of Novavax. In addition, during 2001, we obtained an exclusive worldwide license to promote, market, distribute and sell EstrasorbTM and AndrosorbTM, following approval, except in the United States and Puerto Rico, where we and Novavax will co-market the products. Once approved, we will pay Novavax a royalty based on a percentage of net sales of the products outside of the United States and Puerto Rico. Novavax will pay us a co-promotion fee equal to 50% of net sales less cost of revenues of the products within the United States and Puerto Rico. The NDA for EstrasorbTM was approved by the FDA during October 2003. As of December 31, 2003, we owned approximately 0.9% of Novavax common stock.

At September 30, 2003, Novavax reported total assets of \$61.6 million, total liabilities of \$48.7 million, revenues for the nine months ended September 30, 2003 of \$7.7 million, and a net loss of \$14.2 million for the nine months ended September 30, 2003.

Critical Accounting Policies

We have chosen accounting policies that we believe are appropriate to accurately and fairly report our operating results and financial position, and apply those accounting policies in a consistent manner.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires that management make estimates and assumptions. Assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities are affected by such estimates and assumptions. The most significant assumptions are employed in estimates used in determining values of inventories and intangible assets, accruals for rebates, returns and chargebacks, as well as estimates used in applying the revenue recognition policy. We are subject to risks and uncertainties that may cause actual results to differ from those estimates, such as changes in the healthcare environment, competition, legislation and regulation. We believe the following accounting policies are the most critical because they involve the most significant judgments and estimates used in preparation of our consolidated financial statements.

Inventories. Our inventories are valued at the lower of cost or market value. We evaluate all of our inventory for short dated or slow moving product and inventory commitments under supply agreements based on projections of future demand and market conditions. For those units in inventory that are so identified, we estimate their market value or net sales value based on current realization trends. If the projected net realizable value is less than cost, on a product basis, we provide a provision to reflect the lower value of that inventory. This methodology recognizes projected inventory losses at the time such losses are evident rather than at the time goods are actually sold. We maintain supply agreements with some of our vendors which contain minimum

purchase requirements. We estimate future inventory requirements based on current facts and trends. Should our minimum purchase requirements under supply agreements or if our estimated future inventory requirements exceed estimated inventory quantities which we will be able to sell to our customers, we record a charge in costs of revenues.

Intangible assets, goodwill, and other long-lived assets. When we acquire product rights in conjunction with either business or asset acquisitions, we allocate an appropriate portion of the purchase price to intangible assets, goodwill and other long-lived assets. The purchase price is allocated to product rights and trademarks, patents, acquired research and development and other intangibles using the assistance of valuation experts. We estimate the useful lives of the assets by factoring in the characteristics of the products such as: patent protection, competition by products prescribed for similar indications, estimated future introductions of competing products, and other issues. The factors that drive the estimate of the life of the asset are inherently uncertain.

We review our property and intangible assets for possible impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. We review our goodwill for possible impairment annually, or whenever events or circumstances indicate that the carrying amount may not be recoverable. In evaluating goodwill for impairment, we estimate the fair value of our individual business reporting units on a discounted cash flow basis. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include projections of future cash flows and, in some cases, the current fair value of the asset. In addition, our depreciation and amortization policies reflect judgments on the estimated useful lives of assets.

Accruals for rebates, returns, and chargebacks. We establish accruals for rebates, returns, and chargebacks in the same period we recognize the related sales. The accruals reduce revenues and are included in accrued expenses. Accrued rebates include amounts due under Medicaid, managed care rebates and other commercial contractual rebates. We estimate accrued rebates based on a percentage of selling price determined from historical experience. With respect to accruals for estimated Medicaid rebates, we evaluate our historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. At the time of rebate payment, which generally occurs with a delay after the related sale, we record a reduction to accrued expenses and, at the end of each quarter, adjust accrued expenses for any differences between estimated and actual payments. Due to estimates and assumptions inherent in determining the amount of the rebate, rebate payments remain subject to retroactive adjustment. Returns are accrued based on historical experience. Chargebacks are based on the estimated days of unprocessed claims using historical experience. In all cases, judgment is required in estimating these reserves, and actual claims for rebates, returns and chargebacks could be different from the estimates. Medicaid and certain other governmental pricing programs involve particularly difficult interpretations of relevant statutes and regulatory guidance, which are complex and, in certain respects, ambiguous. Moreover, prevailing interpretations of these statutes and guidance can change over time.

Revenue recognition. Revenue is recognized when title and risk of loss are transferred to customers, collection of sales is reasonably assured, and we have no further performance obligations. This is generally at the time products are received by the customer. Accruals for estimated returns, rebates and chargebacks, determined based on historical experience, reduce revenues at the time of sale and are included in accrued expenses. Medicaid and certain other governmental pricing programs involve particularly difficult interpretations of relevant statutes and regulatory guidance, which are complex and, in certain respects, ambiguous. Moreover, prevailing interpretations of these statutes and guidance can change over time. Royalty revenue is recognized based on a percentage of sales (namely, contractually agreed-upon royalty rates) reported by third parties. See Note 2, Summary of Significant Accounting Policies, in our Notes to Consolidated Financial Statements included in this report. For the year ended December 31, 2002, we deferred recognition of revenue associated with a purchase of our products by the King Benevolent Fund. We have and will recognize the deferred revenue as the purchased products are distributed by the King Benevolent

Fund. See the Certain Relationships and Related Transactions in Item 13 and Note 19, Related Party Transactions, in our Notes to Consolidated Financial Statements included in this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Certain of our financial instruments are subject to market risks, including interest rate risk. Our financial instruments are not currently subject to foreign currency risk or commodity price risk. We have no financial instruments held for trading purposes.

We have marketable securities which are carried at fair value based on current market quotes. Gains and losses on securities are based on the specific identification method.

The fair market value of long-term fixed interest rate debt is subject to interest rate risk. Generally, the fair market value of fixed interest rate debt will increase as interest rates rise and decrease as interest rates fall. In addition, the fair value of our convertible debentures would be impacted by our stock price. The estimated fair value of our total long-term debt at December 31, 2003 was \$322.7 million. Fair values were determined from available market prices, using current interest rates and terms to maturity. If interest rates were to increase or decrease 1%, the fair value of our long-term debt would increase or decrease by approximately \$9.0 million.

At December 31, 2003, 2002 and 2001, we did not hold any derivative financial instruments.

Item 8. Financial Statements and Supplementary Data

Our audited consolidated financial statements and related notes as of December 31, 2003 and 2002 and for each of the three years ended December 31, 2003 are included under Item 15 and begin on page F-1.

Item 9. Changes in Accountants and Disagreement on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

- (a) *Evaluation of Disclosure Controls and Procedures.* At the end of the period covered by this report, our chief executive officer and chief financial officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-14(c)). Based on that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective to ensure that material information relating to King and our consolidated subsidiaries is made known to these officers by others within these entities, particularly during the period this annual report was prepared, in order to allow timely decisions regarding required disclosure.
- (b) *Changes in Internal Controls.* As set forth in the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations under the heading Governmental Investigations, Medicaid Accrual Adjustment, and Related Matters, we have undertaken a substantial process to enhance our compliance with Medicaid and other governmental pricing program requirements. Also, effective August 1, we appointed a corporate compliance officer whose responsibilities include oversight of internal controls. In addition, during July 2003, we implemented a new information technology system. This implementation has resulted in certain improvements in our business processes and internal controls impacting financial reporting. We are taking the necessary steps to monitor and maintain appropriate internal controls during this period of change. These steps include deploying resources to mitigate internal control risks and performing additional verifications and testing to ensure data integrity. There have not been any additional significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

PART III**Item 10. Directors and Executive Officers of the Registrant**

Our executive officers and directors as of March 8, 2004 were as follows:

Name	Age	Position Held
Jefferson J. Gregory	48	Chairman of the Board and Chief Executive Officer
Kyle P. Macione	40	President
Brian A. Markison	44	Chief Operating Officer
James R. Lattanzi	49	Chief Financial Officer and Director
John A. A. Bellamy	42	Executive Vice President, Legal Affairs and General Counsel
Frederick Brouillette, Jr.	53	Corporate Compliance Officer
Earnest W. Deavenport, Jr.	65	Director
Elizabeth M. Greetham	54	Director
Gregory D. Jordan	52	Director
R. Charles Moyer	58	Director
Philip M. Pfeffer	59	Director
D. Greg Rooker	56	Director
Ted G. Wood	66	Director

Jefferson J. Gregory has served as Chairman of the Board of King since June 2002 and as Chief Executive Officer since January 2002. He has served as a director of King since 1995. He had served as President of King since 1993. He was formerly the Director of Regulatory Affairs and Product Information for General Injectables and Vaccines, Inc. from 1991 to 1993 and was a consultant to the pharmaceutical industry from 1989 to 1991. He formerly served as a registered pharmacist in retail pharmacies in the Washington D.C. and Baltimore, Maryland metropolitan areas. He graduated from the University of Maryland School of Law with a Juris Doctor in 1985, University of Maryland School of Pharmacy with a Bachelor of Science degree in Pharmacy in 1979, and Montgomery College with an Associate of Arts degree in 1976.

Kyle P. Macione has served as President of King since April 2002. He had served as Executive Vice President, Corporate Affairs since January 1998 and as Corporate Counsel since March 1996. He was formerly a corporate attorney with the law firm of Elliott Lawson & Pomrenke in Bristol, Virginia from 1992 to 1996. He graduated from Washington & Lee University School of Law with a Juris Doctor in 1991, University of Alabama with a Masters of Accountancy in 1987, and University of Mississippi with a Bachelor of Accountancy in 1986. He is a Certified Public Accountant and licensed to practice law in Tennessee and Virginia.

Brian A. Markison has served as Chief Operating Officer of King since March 8, 2004. Prior to joining King, Mr. Markison had served in various positions with Bristol-Myers Squibb since 1982. From 2001 until he joined King, he served as President of Bristol-Myers Squibb's Oncology, Virology and Oncology Therapeutics Network businesses. Between 1998 and 2001, he served variously as Senior Vice President, Neuroscience/Infectious Disease; President, Neuroscience/Infectious Disease/Dermatology; and Vice President, Operational Excellence and Productivity. He previously served in various positions with Bristol-Myers Squibb relating to marketing and sales. Mr. Markinson graduated from Iona College in 1982 with a Bachelor of Science degree.

James R. Lattanzi has served as King's Chief Financial Officer since September 2000 and as a director since October 2002. Prior to joining King, Mr. Lattanzi, a Certified Public Accountant, was with

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

PricewaterhouseCoopers for 24 years (11 years as a business assurance partner), serving in the Pittsburgh office, New York national office and most recently as the managing partner of PricewaterhouseCoopers Greensboro, North Carolina office. Mr. Lattanzi graduated from Indiana University of Pennsylvania in 1976 with a degree in accounting.

John A. A. Bellamy has served as Executive Vice President of Legal Affairs and General Counsel since February 1995. He was formerly a corporate attorney with the law firm of Hunter, Smith & Davis in Kingsport, Tennessee from 1990 to 1995. He graduated from the University of Tennessee College of Law with a Juris Doctor with Honors in 1990, and graduated Summa Cum Laude with Honors in Independent Study from King College in 1984 with a Bachelor of Arts degree in Classics and English. He is a member of the Licensing Executives Society and related professional organizations.

Frederick Brouillette, Jr. has served as Corporate Compliance Officer since August 2003. He served as Executive Vice President, Finance from January 2003 until August 2003 and as Vice President, Risk Management beginning in February 2001. Prior to joining King, Mr. Brouillette, a Certified Public Accountant, was with PricewaterhouseCoopers for 4 years, serving most recently in that firm's Richmond, Virginia office providing internal audit outsourcing and internal control consulting services. He was formerly the chief internal audit executive for two major public corporations and served for 12 years in the public accounting audit practice of Peat, Marwick Mitchell & Co., the predecessor firm to KPMG. Mr. Brouillette is a member of the Virginia Society of Certified Public Accountants, the American Institute of Certified Public Accountants, and the Institute of Internal Auditors. He graduated with honors from the University of Virginia's McIntire School of Commerce in 1973 with a Bachelor of Science degree in accounting.

Ernest W. Deavenport, Jr., has served as a director since May 2000. He was formerly Chairman of the Board and Chief Executive Officer of Eastman Chemical Company, Kingsport, Tennessee, where he had served in various capacities since 1960. He was Chairman of the National Association of Manufacturers in 1998 and is currently a member of the National Academy of Engineering. Mr. Deavenport is also a member of the boards of directors of Acuity Brands, Inc., AmSouth Bancorporation and Theragenics Corporation, each a publicly-held corporation. Mr. Deavenport graduated from Massachusetts Institute of Technology with a Masters of Science in Management in 1985 and from Mississippi State University with a Bachelor of Science degree in Chemical Engineering in 1960.

Elizabeth M. Greetham has served as director since November 2003. She has served as a director of DrugAbuse Sciences, Inc. since 1998 and as its Chief Executive Officer since August 2000. Ms. Greetham previously served as the Chief Financial Officer and Senior Vice President, Business Development of Drug Abuse Sciences from April 1999 to August 2000. Prior to joining DrugAbuse Sciences, Ms. Greetham was a portfolio manager with Weiss, Peck, & Greer, an institutional investment management firm, where she managed the WPG Life Sciences Funds, L.P., which invests in select biotechnology stocks. Prior to that Ms. Greetham was a consultant to F. Eberstadt & Co. In total, Ms. Greetham has over 25 years of experience as a portfolio manager and health care analyst in the United States and Europe. She is also a member of the board of directors of Guilford Pharmaceuticals Inc. and Stressgen Biotechnologies Corporation, each a publicly-held corporation. Ms. Greetham earned a Master of Arts (Honours) degree in Economics from the University of Edinburgh, Scotland in 1971.

Gregory D. Jordan has served as a director since June 2001. He has served as President of King College in Bristol, Tennessee since 1997, having joined the King College faculty in 1980. He received his Bachelor of Arts degree from Belhaven College in 1973; his Masters of Arts and Divinity degrees from Trinity Evangelical Divinity School in 1976 and 1977, respectively; his Doctorate in Hebraic and Cognate Studies from Hebrew Union College - Jewish Institute of Religion in 1987; and his Masters of Business Administration from the Babcock Graduate School of Management at Wake Forest University in 2004.

R. Charles Moyer, Ph.D., has served as a director since December 2000. Dr. Moyer is Dean Emeritus of the Babcock Graduate School of Management at Wake Forest University, having served as Dean from 1996 until his retirement as Dean in August 2003. Dr. Moyer currently holds the GMAC Insurance Chair of Finance at Wake Forest University. Prior to joining the faculty at Wake Forest in 1988, Dr. Moyer was

Finance Department Chairman at Texas Tech University. Dr. Moyer earned his Doctorate in Finance and Managerial Economics from the University of Pittsburgh in 1971, his Masters of Business Administration from the University of Pittsburgh in 1968, and his Bachelor of Arts degree in Economics from Howard University in 1967.

Philip M. Pfeffer has served as a director since February 2003. Mr. Pfeffer is President and Chief Executive Officer of Treemont Capital, Inc., a private equity investment company, which he founded in 1999. He previously served as Chief Executive Officer and director of Borders Group, Inc., a publicly-held book, music and video retailer from November 1998 to April 1999. Mr. Pfeffer was also a Director and President and Chief Operating Officer of Random House, Inc. from May 1996 to September 1998 and a member of the board of directors and audit committee of Ingram Micro Inc., a company that became publicly-held in November 1996, from April 1981 to June 2001. Prior to that, Mr. Pfeffer was Executive Vice President and a director of Ingram Industries from January 1981 to March 1996 and served in various other positions including Chairman and Chief Executive Officer of Ingram Distribution Group Inc. and its predecessor companies from December 1977 to March 1996. Mr. Pfeffer earned a Bachelor of Arts degree in Mathematics and Chemistry in 1965 and a Master of Arts degree in Economics in 1966, and received an honorary Doctor of Humane Letters degree in 1997, each from Southern Illinois University.

D. Greg Rooker has served as a director since October 1997. Mr. Rooker is the former owner and President of Family Community Newspapers of Southwest Virginia, Inc., Wytheville, Virginia, which consists of six community newspapers and a national monthly motor sports magazine. He is a co-founder of the Jason Foundation and Brain Injury Services of SWVA, Inc., each a non-profit organization providing services to brain injury survivors. Mr. Rooker serves as Secretary/Treasurer of The Jason Foundation and as President of Brain Injury Services of SWVA, Inc. Mr. Rooker graduated from Northwestern University with a degree in Journalism in 1969.

Ted G. Wood has served as a director since August 2003. Mr. Wood is retired from The United Company in Bristol, Virginia, where he was the Vice Chairman from January 2003 until August 2003. Prior to that, he served as President of the United Operating Companies from 1998 to 2002. Mr. Wood served as a director of King from April 1997 to May 2000. From 1992 to 1993, he was President of Boehringer Mannheim Pharmaceutical Corporation in Rockville, Maryland. From 1993 to 1994, he was President of KV Pharmaceutical in St. Louis, Missouri. From 1975 to 1991, he was employed by SmithKline Beecham Corporation where he served as President of Beecham Laboratories from 1988 to 1989 and Executive Vice President of SmithKline from 1990 to 1991. Mr. Wood is also a member of the board of directors of Pozen, Inc., a publicly-held corporation. He graduated from the University of Kentucky with a Bachelor of Science degree in Commerce in 1960. In 1986 he completed the Advanced Management Program at Harvard University.

Compensation of Directors

For 2003 each non-employee director of King received an annual fee of \$30,000, payable quarterly, plus a fee of \$1,500 for participation in each board meeting. Non-employee directors also received \$750 for each committee meeting attended which was held on a day when a meeting of the board was convened and \$1,200 for each meeting attended that was held on a day when a meeting of the board was not convened. Upon the specific approval of the Compensation and Human Resources Committee, non-employee directors may be compensated \$250 per hour for extraordinary board-related service for which compensation is not otherwise received. The chairman of the Audit Committee was paid an annual fee of \$10,000 and the chairmen of the Compensation and Human Resources Committee and the Nominating and Corporate Governance Committee were paid an annual fee of \$5,000. Committee members received an annual fee of \$4,000. In addition, the board has agreed to pay members who serve on the newly appointed search committee for candidates for chief executive officer the same fees as those described above, including \$5,000 for the Chairman of that committee. Also, independent members of the board will receive \$1,200 for each executive session they attend if the session is held on a day that a meeting of the board is not held. They will receive no additional compensation if they meet on the same day that a meeting of the board is held. Travel expenses related to board or committee meetings were reimbursed.

Non-employee directors may use corporate aircraft up to 10 hours of flight time per year, but only for flights for which the primary purpose relates to King's business. Use of corporate aircraft is treated as compensation to the director as may be required by the Internal Revenue Code. During 2003 the following non-employee directors used corporate aircraft, and their use was treated as compensation in the amounts indicated: Earnest W. Deavenport, \$343; James E. Gregory, \$7,681; Gregory D. Jordan, \$731; and D. Greg Rooker, \$4,511. In addition, Audit Committee Chairman D. Greg Rooker, received approximately \$38,000 for extraordinary work performed during the course of the Audit Committee's 2003 investigation of issues related to the SEC's investigation of our company. Members of the Board also receive continuing education fees of up to \$2,000 per day for up to three days per year. Each non-employee director is annually awarded an option for 10,000 shares of common stock under our 1998 Non-Employee Director Stock Option Plan. Options exercisable for 191,697 shares of common stock have been issued to our current non-employee directors.

Meetings of Directors

The Board of Directors held 16 meetings during 2003. No director attended less than 75% of all meetings held.

Classification of Board of Directors

Pursuant to our Bylaws, the Board of Directors is divided into three classes of directors, each containing, as nearly as possible, an equal number of directors. Directors within each class are elected to serve three-year terms and approximately one-third of the directors sit for election at each annual meeting of the shareholders. A classified board of directors may have the effect of deterring or delaying any attempt by any group to obtain control of King by a proxy contest since such third party would be required to have its nominees elected at two separate meetings of the shareholders in order to elect a majority of the members of the Board of Directors.

Committees of the Board of Directors

The Board of Directors has appointed an Audit Committee, a Compensation and Human Resources Committee and a Nominating and Corporate Governance Committee.

Audit Committee. The Audit Committee, which currently consists of D. Greg Rooker, Chairman, Gregory D. Jordan, R. Charles Moyer, and Philip M. Pfeffer, is responsible for overseeing our financial reporting process, including the development and maintenance of systems of internal accounting and financial controls. The Committee is solely responsible for retaining outside auditors to audit our books, records and financial statements and review our systems of accounting. The Committee is also solely responsible for the compensation, termination and oversight of our outside auditors, who report directly to the Committee. The Audit Committee's other principal responsibilities include: reviewing and discussing with management and the outside auditors the audited financial statements to be included in the annual report on Form 10-K and, based on this review and discussion, recommending to the Board that the audited financial statements be included in the annual report on Form 10-K; reviewing and discussing with management and the outside auditors the quarterly financial statements to be included in the quarterly report on Form 10-Q; discussing and reviewing earnings press releases; overseeing the performance of our internal audit function; and overseeing compliance with legal and regulatory requirements. The Audit Committee met nineteen times in 2003.

The Board has determined that there is at least one audit committee financial expert, Philip M. Pfeffer, serving on the Audit Committee and that Mr. Pfeffer is independent of King under the independence standards of the New York Stock Exchange.

Compensation and Human Resources Committee. The Compensation and Human Resources Committee, which currently consists of Earnest W. Deavenport, Jr., Chairman, Elizabeth M. Greetham, and Ted G. Wood, is responsible for administering and determining executive compensation and awards under our stock option plans (other than our 1998 Non-Employee Director Stock Option Plan) and for

oversight of other human resources issues. The principal responsibilities of the Committee are to maintain a general compensation philosophy for the executive officers of the Company; to establish the corporate goals and objectives upon which the compensation of the Chief Executive Officer is based and to set the Chief Executive Officer's compensation in light of the Chief Executive Officer's performance; to review and approve the recommendations of the Chief Executive Officer with regard to the compensation and benefits of other executive officers; to oversee the administration of the Company's compensation and benefit plans; to oversee the administration of the Company's management development process, including the plans for succession of executive officers; and to oversee regulatory compliance with respect to compensation matters. The Compensation Committee met five times in 2003.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee currently consists of Gregory D. Jordan, Chairman, Earnest W. Deavenport, Jr., and D. Greg Rooker. The principal responsibilities of the Committee are: to identify individuals qualified to become Board members and recommend these individuals to the Board for appointment or nomination for election to the Board; to oversee corporate governance matters; to assist the principal committees of the Board in developing written charters; and to develop, recommend and assist in implementing corporate governance guidelines for our company.

Corporate Code of Conduct and Ethics

The Board has adopted a Corporate Code of Conduct and Ethics which applies to all of our directors, officers and employees. A copy of the Code is available through our website, www.kingpharm.com.

Item 11. Executive Compensation

The following table summarizes all compensation earned by our chief executive officer and by each of the four other most highly compensated executive officers whose total annual salary and bonus exceeded \$100,000 for services rendered in all capacities for the year ended December 31, 2003.

SUMMARY COMPENSATION TABLE

Name and Current Principal Position	Year	Annual Compensation		Long-term Compensation	All Other Compensation (\$)(2)
		Salary(\$)	Bonus\$(1)	Securities Underlying Options(#)	
Jefferson J. Gregory	2003	594,071			76,445
Chief Executive Officer and	2002	450,000	75,000	30,000	25,462
Chairman of the Board	2001	450,540	75,000	25,000	30,408
Joseph R. Gregory(3)	2003	75,000	1,425,000		25,683
Former Vice Chairman of the Board and	2002	450,000	75,000	25,000	46,802
former President, Monarch Pharmaceuticals, Inc.	2001	450,810	75,000	25,000	45,749
Kyle P. Macione(4)	2003	450,000			21,489
President	2002	384,874	20,000	25,000	7,585
	2001	215,008	20,000	7,500	5,586
James R. Lattanzi	2003	450,000			33,771
Chief Financial Officer	2002	325,000	35,000	10,000	60,370
	2001	300,810	35,000	10,000	17,238
John A. A. Bellamy	2003	300,000			13,200
Executive Vice President of Legal	2002	225,000	20,000	7,500	45,774
Affairs and General Counsel	2001	131,017	20,000	7,500	5,586
Frederick Brouillette, Jr.(5)	2003	207,646	6,000		8,742
Corporate Compliance Officer	2002	173,250	5,000	2,500	7,293
	2001	146,384	5,000	9,166	10,138

- (1) Bonuses paid in an indicated year are in consideration of performance in the prior year.
- (2) Reflects matching contribution to the 401(k) plan, relocation expense reimbursement and income related to the personal use of corporate aircraft.
- (3) Joseph R. Gregory retired effective February 28, 2003.
- (4) Mr. Macione was named President of King in April 2002. He formerly was Executive Vice President, Corporate Affairs.
- (5) Mr. Brouillette was named Corporate Compliance Officer of King in August 2003. He formerly was Executive Vice President, Finance.

There were no options to purchase shares of common stock or stock appreciation rights granted to executive officers named in the Summary Compensation Table above during the year ended December 31, 2003.

The following table discloses information regarding stock options held at the end of or exercised in fiscal year 2003 for executive officers named in the summary Compensation Table above as of December 31, 2003.

AGGREGATED OPTION/SAR EXERCISES IN LAST FISCAL YEAR

AND FISCAL YEAR-END OPTION/SAR VALUES

Name	Shares acquired on exercise	Value realized	Securities underlying unexercised options at December 31, 2003		Value of unexercised in-the- money options at December 31, 2003(1)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Jefferson J. Gregory		\$	213,331		\$ 794,497	\$
Joseph R. Gregory	75,000	\$ 675,622			\$	\$
Kyle P. Macione		\$	62,000		\$ 47,670	\$
James R. Lattanzi		\$	66,665		\$	\$
John A. A. Bellamy		\$	53,165		\$ 139,467	\$
Frederick Brouillette, Jr.		\$	11,666		\$	\$

(1) Based on \$15.26 per share, the closing price of the common stock as quoted on the New York Stock Exchange at December 31, 2003.

Compensation Committee Interlocks and Insider Participation

The Compensation and Human Resources Committee of the Board of Directors is responsible for developing and administering compensation philosophy. Committee members who served at various times in 2003 were Earnest W. Deavenport, Jr., Chairman, former director Frank W. DeFriece, Jr., Elizabeth M. Greetham, Gregory D. Jordan, R. Charles Moyer, Philip M. Pfeffer, Greg Rooker and Ted G. Wood. No member of the Compensation and Human Resources Committee during 2003 was a current or former officer of King or any of its subsidiaries.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the ownership of the common stock as of March 9, 2004, for (i) each person who owns more than 5% of the common stock, (ii) each director and executive officer of King, and (iii) all executive officers and directors of King as a group.

Executive Officer, Directors and 5% Shareholders	Beneficial Ownership of Common Stock	
	Number of Shares	Percentage Outstanding Shares(1)
Jefferson J. Gregory(2)	1,979,900	*
Kyle P. Macione(3)	75,920	*
Brian A. Markison	0	*
James R. Lattanzi(4)	68,969	*
John A. A. Bellamy(5)	155,141	*
Frederick Brouillette, Jr. (6)	12,152	*
Earnest W. Deavenport, Jr.(7)	24,833	*
Elizabeth M. Greetham	0	*
Gregory D. Jordan(8)	10,000	*
R. Charles Moyer(9)	23,466	*
D. Greg Rooker(10)	193,812	*
Philip M. Pfeffer	0	*
Ted G. Wood	46,666	*
All executive officers and directors as a group (13 persons)(11)	2,590,859	1.1
Wellington Management Company, LLP(12)	29,162,464	12.1
Putnam, LLC d/b/a Putnam Investments(13)	12,964,933	5.4

* Less than 1%

- (1) Unless otherwise indicated, beneficial ownership consists of sole voting and investing power based on 241,354,416 shares issued and outstanding as of March 9, 2004. Options to purchase shares which are exercisable or become exercisable within 60 days of March 9, 2004 are deemed to be outstanding for the purpose of computing the percentage of outstanding shares owned by each person to whom a portion of such options relate but are not deemed to be outstanding for the purpose of computing the percentage owned by any other person.
- (2) Includes 1,539,880 shares jointly owned with Mr. Gregory's spouse and 87,333 shares beneficially owned by Gregory Investments, L.P., the general partners of which are Mr. Gregory and his spouse, and 213,331 shares issuable upon the exercise of options granted to Mr. Gregory.
- (3) Includes 62,000 shares issuable upon the exercise of options.
- (4) Includes 300 shares jointly owned with Mr. Lattanzi's spouse, 2,004 shares held in Mr. Lattanzi's 401(k) retirement plan account and 66,665 shares issuable upon the exercise of options.
- (5) Includes 62,499 shares issuable upon the exercise of options.
- (6) Includes 11,666 shares issuable upon the exercise of options.
- (7) Includes 23,333 shares issuable upon the exercise of options.
- (8) Includes 10,000 shares issuable upon the exercise of options.

- (9) Includes 23,333 shares issuable upon the exercise of options.

- (10) Includes 33,332 shares held in trust for the benefit of Mr. Rooker's children, 8,549 shares held by Mr. Rooker's spouse, 13,420 shares owned by The Jason Foundation, a private foundation controlled by Mr. Rooker, and 73,333 shares issuable upon the exercise of options.
- (11) Includes 619,493 shares issuable upon the exercise of options.
- (12) Based on a Schedule 13G filed in February 2004 with the SEC on behalf of Wellington Management Company, LLP, 75 State Street, Boston, Massachusetts 02109.
- (13) Based on a Schedule 13G filed in February 2004 with the SEC on behalf of Putnam, LLC d/b/a Putnam Investments; Marsh & McLennan Companies, Inc.; Putnam Investment Management, LLC; and The Putnam Advisory Company, LLC, One Post Office Square, Boston, Massachusetts 02109.

Item 13. *Certain Relationships and Related Transactions*

In June 2003 we acquired Elan's primary care business. At the time of the acquisition, Jefferson J. Gregory, our Chairman and Chief Executive Officer, owned 45,000 shares of Elan which he had purchased in February 2002. At the time of the acquisition, D. Greg Rooker, the Chairman of our Audit Committee, owned 1,500 shares of Elan, which he had owned for several years.

SJ Strategic Investments LLC, an affiliate of John M. Gregory, our former Chairman of the Board and a brother of Jefferson J. Gregory, purchased, in January 2003, 4.75 million shares of Novavax. Including additional open market purchases, SJ currently owns approximately 19% of the outstanding shares of Novavax. King currently owns approximately 300,000 shares of common stock of Novavax and has a right to convert debt into approximately 5.2 million shares of Novavax.

The King Benevolent Fund, Inc. ("Benevolent Fund") is a nonprofit corporation organized under the laws of the Commonwealth of Virginia and is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code. The Benevolent Fund obtains pharmaceutical products either as gifts-in-kind from manufacturers or by purchase from third-party distributors or wholesalers. The Benevolent Fund donates the pharmaceutical products purchased or received as gifts-in-kind to medical missions in the United States and in foreign countries to advance its humanitarian aid efforts. The Benevolent Fund was founded in 1994 by John M. Gregory, who also founded King and was our Chairman of the Board until June 28, 2002 and our Chief Executive Officer until January 1, 2002. John M. Gregory owned more than 5% of our common stock until May 6, 2002. John M. Gregory, who serves as President of the Board of Directors of the Benevolent Fund, is the brother of Jefferson J. Gregory, who became our Chief Executive Officer on January 1, 2002 and our Chairman of the Board on June 28, 2002, and James E. Gregory, who served as a director from June 2002 to August 2003. In addition, Mary Ann Blessing, a sister of Jefferson J. Gregory and James E. Gregory, served as the Chief Operating Officer of the Benevolent Fund until approximately January 2001 and presently serves as a director and Treasurer of the Board of the Directors of the Benevolent Fund. Carol Shrader, mother of Brian Shrader, Chief Financial Officer of King until September 2000, is presently a director of the Benevolent Fund.

Jefferson J. Gregory and James E. Gregory were members of the Board of Directors of the Benevolent Fund in 1999, 2000, 2001 and 2002, but no longer hold those positions. In addition, Joseph R. Gregory, who was Vice Chairman of our Board and President of our wholly-owned subsidiary Monarch Pharmaceuticals, Inc. until February 2003, served as a director of the Benevolent Fund in 1999, 2000, 2001 and 2002, but no longer holds that position. Joseph R. Gregory is the brother of Jefferson J. Gregory, James E. Gregory, John M. Gregory and Mary Ann Blessing. Herschel Blessing, an Executive Vice-President of King until July 1, 2002, is the husband of Mary Ann Blessing and a director of the Benevolent Fund.

We occasionally donate our products to the Benevolent Fund. We donated inventory with a carrying value of \$4.1 million in 2001, \$22.6 million in 2002, and \$16.3 million in 2003.

In addition to receiving donations of products directly from pharmaceutical manufacturers, the Benevolent Fund also purchases pharmaceutical products, including those manufactured by King, from third-party distributors or wholesalers.

On December 26, 2002, we sold \$4,701,195 of Cortisporin®, Silvadene® and Tigan® to a third-party wholesaler, which in turn resold those products to the King Benevolent Fund in January 2003. We deferred recognition of the revenue from this sale to the third-party wholesaler and treated this sale in a manner analogous to the consignment method. As of the date of shipment of the purchased products to the third-party wholesaler, we recorded deferred revenue in the amount of \$4,701,195 and classified the purchased products as if they were consignment inventory at our cost of such inventory. We are recognizing the deferred revenue as the purchased products are distributed by the Benevolent Fund, which has provided us with the requisite information relating to the timing and amount of such distributions. As of December 31, 2003, we had recognized \$4,270,420 of the deferred revenue.

The Benevolent Fund has made, and may in the future make, additional purchases of our products from third-party distributors or wholesalers, and such purchases may or may not be brought to our attention. We expect that all or nearly all such purchases by the Benevolent Fund are likely to be of product sold by us in the ordinary course of our business. Absent special circumstances that would make those sales material to investors, we would not intend to disclose future indirect sales to the Benevolent Fund even if we do become aware of them.

During 2001, we donated \$103,000 to King College, which is located in Bristol, Tennessee. Gregory D. Jordan, one of our directors, is the president of King College. Jefferson J. Gregory, our Chairman and Chief Executive Officer, served as a member of the King College Board of Trustees from 1994 until 1998, as the Board's Vice Chairman from 1998 until 2001 and as its Chairman from 2001 until 2003.

During 2002, we paid \$73,000 to James E. Gregory, one of our former directors, for consulting services. Of that amount, \$23,000 was paid in the form of personal use of the corporate aircraft.

During the years ended December 31, 2001, 2002 and 2003, we paid \$5,000, \$171,000 and \$88,000, respectively to the Wake Forest University School of Medicine for research and development activities. R. Charles Moyer, one of our directors, is Dean Emeritus of the Babcock Graduate School of Management at Wake Forest University.

Item 14. *Principal Accountant Fees and Services*

Our Audit Committee has adopted a policy which requires that all services to be provided to us by our independent auditors, including audit services, audit-related services, tax services and other services, and fees related to these services, be pre-approved by the Committee. The Committee may provide general pre-approval of certain types of services, but must review all such general pre-approvals not less than annually. A service of any type not generally pre-approved by the Committee requires the Committee's specific pre-approval. Before pre-approving the provision of any service, the Committee must determine that provision of the service by the independent auditor would not impair the auditor's independence. The policy prohibits delegation of the Committee's pre-approval responsibilities to our management.

During 2003, PricewaterhouseCoopers LLP not only acted as independent auditors for us and our subsidiaries (work related to auditing the annual financial statements for fiscal year 2003 and reviewing the financial statements included in our Forms 10-Q) but also rendered on our behalf other services, including tax related services and other accounting and auditing services. The following table sets forth the aggregate fees billed or expected to be billed by PricewaterhouseCoopers LLP for audit services rendered in connection with the financial statements and reports for fiscal years 2002 and 2003 and for other services

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

rendered during fiscal years 2002 and 2003 on our behalf, including all expenses incurred in connection with these services, which have been or will be billed to us.

	2002	2003
Audit Fees	\$2,378,741(1)	\$ 919,761
Audit Related Fees	1,312,255	571,093
Tax Fees	545,648	569,651
All Other Fees	2,800	17,900
Total	\$4,239,444	\$2,078,405

-
- (1) Includes fees relating to the SEC investigation. For additional information, please see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under the heading "Governmental Investigations, Medicaid Accrual Adjustment and Related Matters" and Note 17 to our audited consolidated financial statements.

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

	<u>Page number</u>
Report of Independent Auditors	F-1
Consolidated Balance Sheets as of December 31, 2002 and 2003	F-2
Consolidated Statements of Income for the years ended December 31, 2001, 2002 and 2003	F-3
Consolidated Statements of Shareholders' Equity and Other Comprehensive Income for the years ended December 31, 2001, 2002 and 2003	F-4
Consolidated Statements of Cash Flows for the years ended December 31, 2001, 2002 and 2003	F-5
Notes to Consolidated Financial Statements	F-6
(2) Financial Statement Schedule Valuation and Qualifying Accounts	S-1

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.

(b) Reports on Form 8-K.

During the quarter ended December 31, 2003, we filed one Current Report on Form 8-K. A report was filed on October 28, 2003 furnishing under Item 12 a press release announcing our third quarter 2003 financial results.

(c) Exhibits

The following Exhibits are filed herewith or incorporated herein by reference:

<u>Exhibit Number</u>	<u>Description</u>
3.1(1)	Second Amended and Restated Charter of King Pharmaceuticals, Inc.
3.2(1)	Amended and Restated Bylaws of King Pharmaceuticals, Inc.
4.1(1)	Specimen Common Stock Certificate.
4.2(1)	Form of Rights Agreement by and between King Pharmaceuticals, Inc. and The Bank of New York (successor in interest to Union Planters National Bank).
10.2(2)	Co-Promotion Agreement, dated as of June 22, 2000, between American Home Products Corporation and King Pharmaceuticals, Inc.
10.3(2)	Asset Purchase Agreement, dated as of June 22, 2000, between American Home Products Corporation and King Pharmaceuticals, Inc.
10.4(3)	Convertible Notes of Novavax, Inc. to King Pharmaceuticals, Inc. dated December 19, 2000, September 7, 2001 and June 26, 2002; Note Purchase Agreements by and between Novavax, Inc. and King Pharmaceuticals, Inc. dated as of December 19, 2000, September 7, 2001, and June 26, 2002; Investor Rights Agreement by and between Novavax, Inc. and King Pharmaceuticals, Inc. dated as of December 19, 2000, as amended; and Registration Rights Agreement by and between Novavax, Inc. and King Pharmaceuticals, Inc. dated as of December 19, 2000, as amended.
10.5(4)	Indenture, dated as of November 1, 2001, among King Pharmaceuticals, Inc., certain Subsidiary Guarantors and The Bank of New York, as trustee, relating to King's 2 3/4% Convertible Debentures due November 15, 2021.

Exhibit Number	Description
10.6(6)	1998 King Pharmaceuticals, Inc. Non-Employee Director Stock Option Plan.
10.7(1)	1997 Incentive and Nonqualified Stock Option Plan for Employees of King Pharmaceuticals, Inc.
10.8(4)	King Pharmaceuticals, Inc. 401(k) Retirement Savings Plan.
10.9(5)	The Medco Research, Inc. 1989 Stock Option and Stock Appreciation Rights Plan, as amended through July 29, 1998.
10.10(6)	1989 Incentive Stock Option Plan of Jones Medical Industries, Inc.
10.11(6)	Jones Medical Industries, Inc. 1994 Incentive Stock Plan.
10.12(6)	Jones Medical Industries, Inc. 1997 Incentive Stock Plan.
10.13(7)	Credit Agreement dated as of April 23, 2002, among King Pharmaceuticals, Inc., and the Lenders therein, Credit Suisse First Boston, Cayman Islands Branch, as Administrative Agent, as Collateral Agent and as Swingline Lender, and Bank of America, NA, J.P. Morgan Securities Inc., and UBS Warburg LLC as Co-Syndication Agents, Wachovia Bank National Association, as Documentation Agent, Credit Suisse First Boston as Sole Lead Arranger and Bookrunner.
10.14(8)	Amended and Restated Asset Purchase Agreement by and among Elan Corporation, plc, Elan Pharma International Limited, Elan Pharmaceuticals, Inc., Jones Pharma Incorporated and Monarch Pharmaceuticals, Inc. dated as of May 19, 2003.
10.15	King Pharmaceuticals, Inc. Non-Employee Directors' Deferred Compensation Plan.
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP.
31.1	Certificate of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certificate of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certificate of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to King's Registration Statement on Form S-1 (Registration No. 333-38753) filed October 24, 1997.
- (2) Incorporated by reference to King's Current Report on Form 8-K filed June 30, 2000.
- (3) Incorporated by reference to King's Schedule 13-D filed December 29, 2000, as amended.
- (4) Incorporated by reference to King's Registration Statement on Form S-8 filed February 26, 1999.
- (5) Incorporated by reference to King's Registration Statement on Form S-8 filed March 9, 2000.
- (6) Incorporated by reference to King's Registration Statement on Form S-8 filed September 6, 2000.
- (7) Incorporated by reference to King's Quarterly Report on Form 10-Q filed May 14, 2002.
- (8) Incorporated by reference to King's Current Report on Form 8-K filed June 13, 2003.

REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Shareholders of

King Pharmaceuticals, Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of King Pharmaceuticals, Inc. and its subsidiaries at December 31, 2002 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 22 to the consolidated financial statements, in 2002 the Company adopted SFAS No. 142, Goodwill and Other Intangible Assets.

PricewaterhouseCoopers LLP

Greensboro, North Carolina
February 19, 2004

KING PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

as of December 31, 2002 and 2003

(in thousands, except share data)

	2002	2003
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 588,225	\$ 146,053
Restricted cash		133,969
Marketable securities	227,263	
Accounts receivable, net of allowance of \$7,513 and \$11,055	159,987	246,417
Inventories	167,153	264,898
Deferred income tax assets	106,168	124,930
Prepaid expenses and other current assets	12,906	30,036
Total current assets	1,261,702	946,303
Property, plant and equipment, net	217,114	257,659
Goodwill	12,742	121,355
Intangible assets, net	1,219,571	1,756,993
Other assets (includes restricted cash of \$0 and \$30,265)	39,531	76,117
Deferred income tax assets		19,307
Total assets	\$2,750,660	\$3,177,734
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 49,889	\$ 83,078
Accrued expenses	297,528	506,033
Income taxes payable	21,247	79,641
Current portion of long term debt	1,300	97
Total current liabilities	369,964	668,849
Long-term debt	345,093	345,000
Deferred income tax liabilities	33,596	
Other liabilities	70,824	121,705
Total liabilities	819,477	1,135,554
Commitments and contingencies (Note 17)		
Shareholders' equity:		
Preferred stock, 15,000,000 shares authorized, no shares issued or outstanding		
Common stock, no par value, 300,000,000 shares authorized, 240,624,751 and 241,190,852 shares issued and outstanding	1,201,897	1,205,970
Retained earnings	729,241	835,097
Accumulated other comprehensive income	45	1,113
Total shareholders' equity	1,931,183	2,042,180
Total liabilities and shareholders' equity	\$2,750,660	\$3,177,734

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

F-2

KING PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF INCOME

for the years ended December 31, 2001, 2002 and 2003

(in thousands, except share data)

	2001	2002	2003
Revenues:			
Net sales	\$ 825,488	\$ 1,069,960	\$ 1,453,023
Royalty revenue	46,774	58,375	68,365
Total revenues	872,262	1,128,335	1,521,388
Operating costs and expenses:			
Costs of revenues, exclusive of depreciation shown below	186,564	294,976	384,763
Selling, general and administrative, exclusive of co-promotion fees	151,839	180,266	301,917
Co-promotion fees	89,041	186,657	193,350
Total selling, general and administrative	240,880	366,923	495,267
Research and development	26,507	28,184	44,078
Research and development in process upon acquisition		12,000	194,000
Total research and development	26,507	40,184	238,078
Depreciation and amortization	47,966	59,297	124,575
Intangible asset impairment		66,844	124,616
Merger, restructuring, and other special charges	4,079	5,911	
Gain on sale of intangible assets			(12,025)
Total operating costs and expenses	505,996	834,135	1,355,274
Operating income	366,266	294,200	166,114
Other income (expense):			
Interest income	10,975	22,395	6,849
Interest expense	(12,684)	(12,419)	(13,396)
Valuation benefit (charge) convertible notes receivable		(35,629)	18,151
Extinguishment of debt expense	(22,903)		
Other, net	6,313	(884)	(629)
Total other income (expense)	(18,299)	(26,537)	10,975
Income before income taxes and cumulative effect of change in accounting principle	347,967	267,663	177,089
Income tax expense	(129,486)	(85,143)	(71,233)
	218,481	182,520	105,856

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Income before cumulative effect of change in accounting principle			
Cumulative effect of change in accounting principle, net of taxes of \$325	(545)		
Net income	\$ 217,936	\$ 182,520	\$ 105,856
Income per common share:			
Basic: Income before cumulative effect of change in accounting principle			
	\$ 0.94	\$ 0.75	\$ 0.44
Cumulative effect of change in accounting principle			
Net income	\$ 0.94	\$ 0.75	\$ 0.44
Diluted: Income before cumulative effect of change in accounting principle			
	\$ 0.93	\$ 0.74	\$ 0.44
Cumulative effect of change in accounting principle			
Net income	\$ 0.93	\$ 0.74	\$ 0.44

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

KING PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
AND OTHER COMPREHENSIVE INCOME
for the years ended December 31, 2001, 2002 and 2003
(in thousands, except share data)

	Common Stock		Retained Earnings	Accumulated Other Comprehensive Income	Total
	Shares	Amount			
Balance, December 31, 2000	170,841,178	\$ 658,948	\$ 328,785	\$	\$ 987,733
Comprehensive income:					
Net income			217,936		217,936
Total comprehensive income					217,936
Four for three common stock split	56,941,365	(418)			(418)
Stock option activity	1,918,441	43,287			43,287
Issuance of common shares	17,992,000	659,746			659,746
Balance, December 31, 2001	247,692,984	1,361,563	546,721		1,908,284
Comprehensive income:					
Net income			182,520		182,520
Net unrealized gain on marketable securities, net of tax of \$24				45	45
Total comprehensive income					182,565
Stock option activity	431,767	6,608			6,608
Stock repurchases	(7,500,000)	(166,274)			(166,274)
Balance, December 31, 2002	240,624,751	1,201,897	729,241	45	1,931,183
Comprehensive income:					
Net income			105,856		105,856
Net unrealized gain on marketable securities, net of tax of \$363				674	674
Foreign currency translation, net of tax of \$212				394	394
Total comprehensive income					106,924
Stock option activity	566,101	4,073			4,073
Balance, December 31, 2003	241,190,852	\$ 1,205,970	\$ 835,097	\$ 1,113	\$ 2,042,180

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

KING PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

for the years ended December 31, 2001, 2002 and 2003

(in thousands)

	2001	2002	2003
Cash flows from operating activities:			
Net income	\$ 217,936	\$ 182,520	\$ 105,856
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	47,966	59,971	125,502
Amortization of deferred financing costs	1,040	2,898	3,160
Extinguishment of debt expense	22,902		
Cumulative effect of change in accounting principle	870		
Stock compensation charge	3,229		
Write-off of inventory		15,152	
Deferred income taxes	15,209	(78,061)	(130,593)
Valuation charge on convertible notes receivable		35,443	(18,151)
Net unrealized gain on convertible notes receivable	(8,546)		
Tax benefits of stock options exercised	12,430	2,206	
Impairment of intangible assets		66,844	124,616
In-process research and development charges		12,000	194,000
Gain on sale of intangible assets			(12,020)
Other non-cash items, net	2,948	4,525	6,058
Changes in operating assets and liabilities:			
Accounts receivable	(44,114)	(3,713)	(84,186)
Inventories	(46,489)	(70,727)	(52,320)
Prepaid expenses and other current assets	(484)	(5,090)	27,307
Other assets	3,136	(1,020)	(2,578)
Accounts payable	(9,722)	31,318	34,708
Accrued expenses and other liabilities	41,519	197,304	68,139
Deferred revenue	(9,247)	(9,090)	(9,092)
Income taxes	28,977	13,529	56,898
Net cash provided by operating activities	279,560	456,009	437,304
Cash flows from investing activities:			
Purchases of investment securities	(49,880)	(823,112)	(25,903)
Proceeds from maturity and sale of investment securities		645,798	253,097
Transfer (to)/from restricted cash			(67,743)
Convertible senior notes	(10,000)	(10,000)	
Loans receivable	(15,000)		
Purchases of property, plant and equipment	(40,167)	(73,587)	(51,201)
Acquisition of primary care business of Elan			(761,745)
Acquisition of Meridian			(238,498)
Purchases of intangible assets	(286,500)	(322,100)	(19,300)
Proceeds from loan receivable	14,086	4,310	13,320
Proceeds from sale of intangible assets	3,332		15,659
Other investing activities	1,446	4,388	295
Net cash used in investing activities	(382,683)	(574,303)	(882,019)
Cash flows from financing activities:			
Proceeds from revolving credit facility	75,000		125,000
Payments on revolving credit facility	(75,000)		(125,000)

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Proceeds from issuance of common shares and exercise of stock options, net	684,435	4,402	4,053
Stock repurchases		(166,274)	
Payment of senior subordinated debt	(115,098)		
Payments on other long-term debt	(1,489)	(1,361)	(1,296)
Proceeds from convertible debentures	345,000		
Debt issuance costs	(11,100)	(4,850)	(214)
Other	(418)		
	<u> </u>	<u> </u>	<u> </u>
Net cash (used in) provided by financing activities	901,330	(168,083)	2,543
	<u> </u>	<u> </u>	<u> </u>
Increase (decrease) in cash and cash equivalents	798,207	(286,377)	(442,172)
Cash and cash equivalents, beginning of year	76,395	874,602	588,225
	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents, end of year	\$ 874,602	\$ 588,225	\$ 146,053
	<u> </u>	<u> </u>	<u> </u>
Supplemental disclosure of cash paid for:			
Interest	\$ 15,433	\$ 11,731	\$ 13,396
	<u> </u>	<u> </u>	<u> </u>
Taxes	\$ 96,773	\$ 153,966	\$ 144,918
	<u> </u>	<u> </u>	<u> </u>

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

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share data)

1. The Company

King Pharmaceuticals, Inc. (King or the Company) is a vertically integrated pharmaceutical company that develops, manufactures, markets and sells branded prescription pharmaceutical products. Through a national sales force and co-promotion arrangements, King markets its branded pharmaceutical products to general/family practitioners, internal medicine physicians, cardiologists, endocrinologists, neurologists, psychiatrists, obstetricians/gynecologists, and hospitals across the United States and in Puerto Rico. The Company also provides contract manufacturing for a number of the world's leading pharmaceutical and biotechnology companies. In addition, the Company receives royalties from the rights of certain products (Adenocard® and Adenoscan®) previously sold.

These consolidated financial statements include the accounts of King and all of its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. Assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities are affected by such estimates and assumptions. The most significant assumptions are employed in estimates used in determining allowances for doubtful accounts, values of inventories and intangible assets, accruals for rebates, returns and chargebacks, as well as estimates used in applying the revenue recognition policy and accounting for the Novavax convertible senior notes and the Co-Promotion Agreement with Wyeth. The Company is subject to risks and uncertainties that may cause actual results to differ from those estimates.

Revenue recognition. Revenue is recognized when title and risk of loss are transferred to customers, collection of sales is reasonably assured, and we have no further performance obligations. This is generally at the time products are received by the customer. Accruals for estimated discounts, returns, rebates and chargebacks, determined based on historical experience, reduce revenues at the time of sale and are included in accrued expenses. Medicaid and certain other governmental pricing programs involve particularly difficult interpretations of relevant statutes and regulatory guidance, which are complex and, in certain respects, ambiguous. Moreover, prevailing interpretations of these statutes and guidance can change over time. Royalty revenue is recognized based on a percentage of sales (namely, contractually agreed-upon royalty rates) reported by third parties. For the year ended December 31, 2002, the Company deferred recognition of revenue associated with a purchase of our products by the King Benevolent Fund. The Company is recognizing the deferred revenue as the purchased products are distributed by the King Benevolent Fund. (see Note 19.)

Accruals for rebates, returns, and chargebacks. We establish accruals for rebates, returns, and chargebacks in the same period we recognize the related sales. The accruals reduce revenues and are included in accrued expenses. Accrued rebates include amounts due under Medicaid, managed care rebates and other commercial contractual rebates. We estimate accrued rebates based on a percentage of selling price determined from historical experience. With respect to accruals for estimated Medicaid rebates, we evaluate our historical rebate payments by product as a percentage of historical sales, product pricing and current contracts. At the time of rebate payment, which generally occurs with a delay after the related sale, we record a reduction to accrued expenses and, at the end of each quarter, adjust accrued expenses for any differences between estimated and actual payments. Due to estimates and assumptions inherent in determining the amount of the rebate, rebate payments remain subject to retroactive adjustment. Returns are accrued based on historical experience. Chargebacks are based on the estimated days of unprocessed claims using historical experience. In all cases, judgment is required in estimating

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

these reserves, and actual claims for rebates, returns and chargebacks could be different from the estimates. Medicaid and certain other governmental pricing programs involve particularly difficult interpretations of relevant statutes and regulatory guidance, which are complex and, in certain respects, ambiguous. Moreover, prevailing interpretations of these statutes and guidance can change over time.

Shipping and Handling Costs. The Company incurred \$2,455, \$2,072, \$2,790 in 2001, 2002, and 2003 respectively, related to third-party shipping and handling costs classified with selling, general and administrative expenses in the consolidated statements of operations. The Company does not bill customers for such costs.

Cash and Cash Equivalents. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The Company's cash and cash equivalents are placed in large domestic banks, which limits the amount of credit exposure.

Marketable Securities. The Company classifies its existing marketable securities as available-for-sale. These securities are carried at fair market value based on current market quotes, with unrealized gains and losses reported in shareholders' equity as a component of other comprehensive income. Gains or losses on securities sold are based on the specific identification method. The Company's policy is to only invest in high-grade corporate bonds, government agencies and municipalities. The Company reviews its investment portfolio as deemed necessary and, where appropriate, adjusts individual securities for other-than-temporary impairments. The Company does not hold these securities for speculative or trading purposes.

Inventories. Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out (FIFO) method. Product samples held for distribution to third parties represent 11% and 7% of inventory as of December 31, 2002 and December 31, 2003, respectively. Product sample costs are charged to selling, general and administrative costs in the accompanying consolidated statement of income upon distribution to a third party.

Income Taxes. Deferred tax assets and liabilities are determined based on the difference between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded when, in the opinion of management, it is more likely than not that some or all of the deferred tax assets will not be realized.

Litigation. At various times the Company may be involved in patent, product liability, consumer, commercial, environmental and tax litigations and claims; government investigations; and other legal proceedings that arise from time to time in the ordinary course of business (see Note 17). The Company accrues for amounts related to these legal matters if it is probable that a liability has been incurred and an amount is reasonably estimable.

Financial Instruments and Derivatives. The Company does not use financial instruments for trading purposes. Interest rate protection agreements, which are a type of derivative instrument, are sometimes used to manage interest rate risks. The notional amounts of the interest rate protection agreements entered into by the Company are used to measure the interest to be paid or received and do not represent the amount of exposure to loss. At December 31, 2002 and 2003, the Company did not have any interest rate protection agreements or other derivatives outstanding.

The fair value of financial instruments is determined by reference to various market data or other valuation techniques as appropriate. Unless otherwise disclosed, the fair values of financial instruments approximate their recorded values.

The Company recognized the cumulative effect of a change in accounting principle of \$545, net of income taxes of \$325, during the first quarter of 2001, due to the adoption of Statement of Financial Accounting Standards (SFAS) No. 133, Accounting for Derivative Instruments and Hedging Activities, as amended by SFAS No. 138, which establishes accounting and reporting standards for

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

derivative instruments and hedging activities. As of December 31, 2002 and 2003, the Company held no derivative financial instruments.

Property, Plant and Equipment. Property, plant and equipment are stated at cost. Maintenance and repairs are expensed as incurred. Depreciation is computed over the estimated useful lives of the related assets using the straight-line method for financial statement purposes and accelerated methods for income tax purposes. The estimated useful lives are principally 15 to 40 years for buildings and improvements and 3 to 15 years for machinery and equipment.

The Company capitalizes certain computer software and development costs incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software which generally range from 3 to 7 years.

In the event that facts and circumstances indicate that the carrying amount of property, plant and equipment may be impaired, 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. To the extent such projection indicates that undiscounted cash flow is not expected to be adequate to recover the carrying amount, the asset would be written down to its fair value.

Intangible Assets and Goodwill. Intangible assets, which include primarily acquired product rights, trademarks, and patents, are stated at cost, net of accumulated amortization. Amortization is computed over the estimated useful lives, ranging from 2 to 40 years, using primarily the straight-line method. Beginning in 2002, goodwill and certain other intangible assets are not amortized, but are tested for impairment on an annual basis, or more frequently if conditions warrant interim testing. The Company reviews its intangible assets for possible impairment whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. The Company reviews goodwill for possible impairment annually, or whenever events or circumstances indicate that the carrying amount may not be recoverable. In evaluating goodwill for impairment, the Company estimates fair value of the Company's individual business reporting units on a discounted cash flow basis. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment charges in future periods. Such assumptions include projections of future cash flows and, in some cases, the current fair value of the asset. In addition, the Company's amortization policies reflect judgments on the estimated useful lives of assets.

Research and Development Costs. Research and development costs are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life. Amounts capitalized for such payments are included in intangibles assets. Acquired research and development projects for products that have not received regulatory approval and that do not have alternative future use are expensed.

Deferred Financing Costs. Financing costs related to the \$345,000 convertible debt are being amortized over five years to the first date the debt can be put by the holders to the Company. Financing costs related to the Senior Secured Revolving Credit Facility (Note 12) are being amortized over five years, the term of the facility.

Insurance. The Company is self-insured with respect to its healthcare benefit program. The Company pays a fee to a third party to administer the plan. The Company has stop loss coverage on a per employee basis as well as in the aggregate. Self-insured costs are accrued based upon reported claims and an estimated liability for claims incurred but not reported.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Advertising. The Company expenses advertising costs as incurred and these costs are included as selling, general and administrative expenses. Advertising costs for the years ended December 31, 2001, 2002, and 2003 were \$48,460, \$56,532, and \$71,043 respectively.

Promotional Fees to Wyeth. On June 22, 2000, the Company entered into a Co-Promotion Agreement with Wyeth to promote Altace® in the United States and Puerto Rico through October 29, 2008. Under the agreement, Wyeth paid an upfront fee of \$75,000 to King, which was classified as other liabilities and is being amortized as a reduction of marketing expenses over the term of the agreement.

In connection with the Co-Promotion Agreement with Wyeth, the Company agreed to pay Wyeth an annual promotional fee as follows:

For 2001 and 2002, approximately 20% of Altace® net sales up to \$165,000, 50% of Altace® net sales from \$165,000 to \$465,000 and 52.5% of Altace® net sales in excess of \$465,000.

For years subsequent to 2002 through 2008, approximately 15% of Altace® net sales up to \$165,000, 50% of Altace® net sales from \$165,000 to \$465,000 and 52.5% of Altace® net sales in excess of \$465,000.

The co-promotion fee is accrued quarterly based on a percentage of Altace® net sales at a rate equal to the expected relationship of the expected co-promotion fee for the year to applicable expected Altace® net sales for the year.

Stock Compensation. The Company has adopted the disclosure only provision of SFAS No. 123, Accounting for Stock Based Compensation. Accordingly, since options were granted at fair value, no compensation cost has been recognized for stock options granted to date. Had compensation cost for these plans been determined for options granted, consistent with SFAS No. 123, the Company's net income and diluted income per share would have decreased to the following pro forma amounts for the years ended December 31, 2001, 2002 and 2003:

	2001	2002	2003
Income before cumulative effect of change in accounting principle:			
As reported	\$218,481	\$182,520	\$105,856
Compensation costs for options granted	13,643	8,142	1,506
Pro forma	\$204,838	\$174,378	\$104,350
Net income:			
As reported	\$217,936	\$182,520	\$105,856
Compensation costs for options granted	13,643	8,142	1,506
Pro forma	\$204,293	\$174,378	\$104,350
Diluted income per share:			
Income before cumulative effect of change in accounting principle:			
As reported	\$ 0.93	\$ 0.74	\$ 0.44
Pro forma	\$ 0.88	\$ 0.71	\$ 0.43
Net income:			
As reported	\$ 0.93	\$ 0.74	\$ 0.44
Pro forma	\$ 0.87	\$ 0.71	\$ 0.43

F-9

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in 2001, 2002 and 2003:

	2001	2002	2003
Expected life of option	4.00	4.00	4.00
Risk-free interest rate	3.60%	3.07%	2.79%
Expected volatility	62.38%	71.59%	61.00%
Expected dividend yield	0.00%	0.00%	0.00%

The weighted average fair values of options granted during 2001, 2002 and 2003 are \$19.38, \$10.91, and \$7.63, respectively.

Accounting Standards Not Yet Adopted. In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46). FIN 46 requires a variable interest entity to be consolidated by a company if that company is required to absorb a majority of the variable interest entity's expected losses or entitled to receive a majority of the entity's residual returns or both. The Company is in the process of assessing what impact this pronouncement will have on its consolidated financial statements. Based on its preliminary analysis of the impact of FIN 46, the Company believes that it is reasonably possible that Novavax, Inc. (Novavax) could be a variable interest entity, and our interest in Novavax may require that the Company consolidate Novavax in the first quarter of 2004.

During the period from December 2000 through June 2002, the Company provided \$40.0 million in financing to Novavax in the form of notes receivable convertible to common stock of Novavax. In addition, during 2001, the Company obtained an exclusive worldwide license to promote, market, distribute and sell Estrasorb and Androsorb, following approval, except in the United States and Puerto Rico, where King and Novavax will co-market the products. Once approved, the Company will pay Novavax a royalty based on a percentage of net sales of the products outside of the United States and Puerto Rico. Novavax will pay King a co-promotion fee equal to 50% of net sales less cost of revenues of the products within the United States and Puerto Rico. The New Drug Application for EstrasorbTM was approved by the U.S. Food and Drug Administration during October 2003. King owns approximately 0.9% of Novavax common stock.

At September 30, 2003, Novavax reported total assets of \$61.6 million, total liabilities of \$48.7 million, revenues for the nine months ended September 30, 2003 of \$7.7 million, and a net loss of \$14.2 million for the nine months ended September 30, 2003.

Reclassifications. Certain amounts from the prior consolidated financial statements have been reclassified to conform to the presentation adopted in 2003.

3. Concentrations of Credit Risk

A significant portion of the Company's sales is to wholesaler customers in the pharmaceutical industry. The Company monitors the extension of credit to customers and has not experienced significant credit losses. The following table represents the relative percentage of accounts receivable from significant customers compared to net accounts receivable:

	2001	2002	2003
Customer A	25.4%	15.1%	28.4%
Customer B	15.4%	13.2%	19.2%
Customer C	12.1%	18.5%	20.8%

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	2001	2002	2003
Customer A	20.2%	21.5%	20.8%
Customer B	17.5%	32.9%	26.0%
Customer C	18.4%	24.0%	15.5%

The Company invests its excess cash primarily in government, municipal obligations and high-quality corporate debt securities and commercial paper. The commercial paper securities are highly liquid and the remaining investments typically mature within two years (although there is an established secondary market for sales at any given time). Based on the nature of the financial instruments and/or historical realization of these financial instruments, management believes they bear minimal risk.

4. Marketable Securities

The following table represents the contractual maturities of marketable securities held as of December 31, 2002 and 2003:

	2002	2003
Less than one year	\$ 554,562	\$ 102,925
One to five years	170,930	
Total securities available-for-sale	\$ 725,492	\$ 102,925

All available-for-sale securities are considered current, as the Company intends to use them for current operating and investing purposes. At December 31, 2002 and 2003, approximately \$498,229 and \$102,925, respectively, of available-for-sale securities with original maturities of 90 days or less were included in cash and cash equivalents. The remaining amounts totaling approximately \$227,263 at December 31, 2002 are classified as marketable securities on the Company's balance sheet.

At December 31, 2002, the Company had net unrealized gains from marketable securities of \$45, net of tax, recorded in other comprehensive income. The carrying amount of available-for-sale securities and their approximate fair values at December 31, 2003 were as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Municipal obligations	\$ 70,925	\$	\$	\$ 70,925
Corporate bonds	32,000			32,000
Total	\$ 102,925	\$	\$	\$ 102,925

The Company realized \$1,960 and \$178 of net gains on marketable securities during 2002 and 2003, respectively.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

At December 31, 2002 and December 31, 2003, the Company held Novavax common stock with a market value of \$46 and \$1,952, respectively, which is classified as other assets in the accompanying financial statements (see Note 9). At December 31, 2003, the Company had net unrealized gains from Novavax common stock of \$719, net of tax, recorded in other comprehensive income.

F-11

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. Inventory

Inventory consists of the following:

	2002	2003
Raw materials	\$ 56,778	\$ 139,675
Work-in process	7,810	11,508
Finished goods (including \$17,951 and \$18,252 of sample inventory, respectively)	110,623	144,374
	<u>175,211</u>	<u>295,557</u>
Less inventory valuation allowance	(8,058)	(30,659)
	<u>\$ 167,153</u>	<u>\$ 264,898</u>

DSM Pharmaceuticals, Inc. (DSM) one of the Company's third-party manufacturers, informed the Company on November 21, 2001, that they ceased operations at their sterile manufacturing facilities in Greenville, North Carolina, as a result of U.S. Food and Drug Administration (FDA) concerns relating to compliance issues. Due to the compliance issues, DSM recommended that the Company initiate a voluntary recall of all products that they manufacture for King. The Company initiated a voluntary recall of these products on December 18, 2001. As a result, the Company recorded special charges, included as cost of revenues, of \$5,933, \$1,206, and \$1,227 during 2001, 2002, and 2003, respectively, primarily to provide for product returns and the write-off of inventory.

During 2001, the Company wrote-off obsolete Levoxyl® inventory of \$2,059. The FDA approved the New Drug Application (NDA) for a new formulation of Levoxyl® on May 25, 2001. Pursuant to FDA guidance, the Company may distribute only the FDA-approved new formulation of Levoxyl® after August 14, 2001.

The Company recorded a special charge in the amount of \$1,827 during 2002 relating primarily to the Company's voluntary recall of Liqui-Char® and Theravac®, two of the Company's smaller volume products.

As discussed in Note 8 below, the Company donated \$15,152 of Lorabid® inventory to a charitable organization as a result of the decision in the fourth quarter of 2002 to divest the Lorabid® intangible assets and accrued a \$49,877 liability related to the excess purchase commitments under the Lorabid® supply agreement. In the fourth quarter of 2003, the Company recorded an additional \$29,959 liability related to the excess purchase commitments under the Lorabid® supply agreement.

During 2003, the Company recorded special charges of \$3,088, primarily related to voluntary recalls of certain lots of Levoxyl.

During 2003, the Company recorded special charges of \$2,144 relating to the step-up in the cost of Meridian's inventory at the time of acquisition.

KING PHARMACEUTICALS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. Property, Plant and Equipment**

Property, plant and equipment consists of the following:

	2002	2003
Land	\$ 9,108	\$ 9,476
Buildings and improvements	87,908	102,346
Machinery and equipment	92,104	178,635
Equipment under capital lease	1,018	
Capital projects in progress	73,151	34,160
	<u>263,289</u>	<u>324,617</u>
Less accumulated depreciation	(46,175)	(66,958)
	<u>\$217,114</u>	<u>\$257,659</u>

Included in net property, plant and equipment as of December 31, 2002 and 2003 are computer software costs of \$1,247 and \$29,914, respectively. Computer software costs during 2003 are primarily related to the new information technology system.

Depreciation expense for the years ended December 31, 2001, 2002 and 2003 was \$9,749, \$11,233, and \$21,285, respectively, which includes \$424, \$632 and \$3,687, respectively, related to computer software.

The Company's Rochester facility manufactures products for the Company and various third-party manufacturers. At December 31, 2003, the net carrying value of the property, plant and equipment at the Rochester facility and the intangible assets considered part of the Rochester asset group were \$82,158 and \$18,265, respectively. Overall production volume at this facility declined during the year ended December 31, 2003. The Company currently has plans to transfer to this facility the manufacture of some of its products that are currently manufactured for the Company by third parties. This should increase production and overall profitability at the Rochester facility. Management currently believes that these long-term assets are not impaired based on estimated undiscounted future cash flows. However, if production volumes continue to decline and/or if the Company is not successful in transferring additional production to the facility, the Company may have to write-off a portion of the property, plant, equipment and intangible assets associated with this facility.

7. Acquisitions and Dispositions

On June 12, 2003, the Company acquired the primary care business of Elan Corporation, plc (Elan) and of some of its subsidiaries in the United States and Puerto Rico, including the rights to Sonata® and Skelaxin® and the rights pertaining to potential new formulations of these products, together with Elan's United States primary care field sales force. The Company believes that the acquisition of these branded pharmaceutical products should provide additional growth opportunities in the branded pharmaceuticals segment through promotional activities, development opportunities and a significantly expanded field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan's sale of Skelaxin® included related New Drug Applications, copyrights, trademarks, patents and rights pertaining to potential new formulations of Skelaxin®. Elan's sale of Sonata® included its rights to the product, as well as certain related copyrights. The Company also acquired certain intellectual property, regulatory and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, the Company secured an exclusive license to the intellectual property rights, in this territory, of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The total initial purchase price of \$814,368 includes the cost of acquisition, assumed liabilities and a portion of contingent liabilities. See the allocation of the purchase price in the table below. The identifiable intangible assets have been assigned useful lives with a weighted-average range of 16.5 years. The acquired business is included in the branded pharmaceuticals segment. In connection with this acquisition, \$163,416 was placed into escrow to satisfy the deferred obligations to Wyeth that were assumed by the Company in connection with the acquisition. Since the Company is entitled to the interest income and can direct investments of the escrow fund, the Company has included the escrow amount in current restricted cash and other long-term assets as restricted cash. The \$163,416 placed into escrow was included in the purchase price as liabilities acquired. These deferred obligations are payable on a quarterly basis through March 2005. As of December 31, 2003, \$96,375 remains in the escrow fund.

The Company also will pay royalties on net sales of the current formulation of Skelaxin® from the date of closing and certain significant development and regulatory milestones relating to the ongoing reformulation of Sonata®. Contingent liabilities include a portion of the following conditional obligations of the Company:

an additional \$60,000 if Elan achieves specific milestones in connection with the development of new formulations of Sonata®; and

\$15,000 if annual net sales of a reformulation of Sonata® exceed \$100.0 million.

In addition to the initial purchase price, the Company paid \$25,000 in January 2004 as a milestone payment to Elan relating to the continued exclusivity of Skelaxin® and an \$11,000 during March 2004 as a milestone payment to Elan in connection with the development of new formulations of Sonata®.

Of the total estimated purchase price, \$175,000 was allocated to an acquired in-process research and development project associated with the Company's acquisition of rights to new formulations of Sonata®. Specifically, the goal of the project is to successfully develop a modified-release formulation of Sonata® that enables patients who have difficulty staying asleep to remain asleep for a longer period of time when utilizing the reformulated product. The value of the acquired in-process research and development project was expensed on the date of acquisition, as it had not received regulatory approval as of that date and had no alternative future use. The project was valued through the application of a probability-weighted, discounted cash flow approach with the assistance of an independent valuation specialist. The estimated cash flows were projected over a 25-year period utilizing a discount rate of 20%. The estimated cost to complete the project at the time of the acquisition was approximately \$120,000, which includes up to \$71,000 that will be paid upon successful attainment of certain significant development milestones of the project. At the time of the acquisition, the project was in Phase I of clinical development. The Company believes that there is a reasonable probability of completing the project successfully. However, the success of the project depends on the outcome of future clinical trials involving a modified-release formulation of Sonata® and the FDA approval of the product. Management currently anticipates that the completion of the project should occur no earlier than 2006. If the project is not successfully completed before 2008, the Company's business, financial position, results of operations and cash flows could be materially adversely affected.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The allocation of the initial purchase price of the primary care business of Elan is as follows:

Cash consideration, including transaction fees(1)	\$ 598,332
Liabilities acquired	216,036
	<hr/>
Total purchase price	\$ 814,368
	<hr/>
Allocation of purchase price:	
Intangible assets	\$ 597,000
Prepaid expenses	2,000
In process research and development (net of tax benefit of \$61,250)	113,750
Inventory	40,368
Deferred tax asset	61,250
	<hr/>
	\$ 814,368
	<hr/>

(1) Excludes restricted cash placed in escrow.

The Company has recorded \$123,000 of the purchase price as patents and \$474,000 of the purchase price as trademarks and product rights within intangible assets.

On January 8, 2003, the Company completed its acquisition of Meridian Medical Technologies, Inc. (Meridian). Meridian is a leading manufacturer of auto-injectors for the self-administration of injectable pharmaceuticals. The Company believes the acquisition of Meridian provides additional lines of pharmaceutical products, auto-injector technology and development opportunities. The Company paid a cash price of \$44.50 per common share to Meridian shareholders, totaling approximately \$246,592, and incurred \$7,317 of expenses related to the transaction resulting in a total purchase price of \$253,909.

The allocation of the purchase price of Meridian is as follows:

Current assets	\$ 37,574
Property, plant and equipment	14,674
Goodwill	108,597
Intangible assets trademark and product rights	150,300
In process research and development	19,000
Other assets	662
Current liabilities	(14,505)
Deferred income taxes	(61,118)
Other liabilities	(1,275)
	<hr/>
	\$ 253,909
	<hr/>

None of the goodwill is expected to be deductible for tax purposes. The identifiable intangible assets have been assigned useful lives with a weighted-average range of 32.2 years. The acquisition is allocated to the Meridian Medical Technologies segment. The Company financed the acquisition using available cash on hand.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

As mentioned above, \$19,000 of the purchase price was allocated to an acquired in-process research and development project, an auto-injector pre-filled with diazepam indicated for, among other things, the treatment of epileptic seizures and management of anxiety disorders. The value of the acquired in-process research and development project was expensed on the date of acquisition, as it had not received regulatory approval and had no alternative future use. The project was valued through the application of a probability-weighted, discounted cash flow approach with the assistance of an independent valuation specialist. The estimated cash flows were projected over a 30-year period utilizing a discount rate of 21%. Pre-tax margins (after an adjustment to reflect the use of auto-injector core technology) were assumed to

F-15

KING PHARMACEUTICALS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

be (10%) in 2003 and improving to 23% in 10 years. The estimated cost to complete the project was less than \$700. The project was submitted to the FDA as an Abbreviated New Drug Application (ANDA), which references an approved New Drug Application (NDA) owned by the United States Army for a diazepam-filled auto-injector currently manufactured under contract exclusively by Meridian. The application for the project is under review by the FDA and the Company must satisfactorily respond to chemistry, microbiology, manufacturing and other questions from the FDA that arise as a result of its normal review and approval process. The Company anticipates FDA approval of the project during 2004. The project was substantially complete as of the valuation date. The success of the project is dependent upon whether the FDA approves the ANDA for the Company's diazepam-filled auto-injector. The Company is not aware of any material issues with respect to the FDA's review of the ANDA. Even if the project is not successfully completed, it would not materially adversely affect the Company's results of operations.

The following unaudited pro forma summary presents the financial information as if the acquisitions of Meridian and the primary care business of Elan had occurred on January 1, 2003 for the year ended December 31, 2003 and on January 1, 2002 for the year ended December 31, 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 been made on January 1, 2003 or January 1, 2002, nor are they indicative of future results.

	Year Ended December 31,	
	2002	2003
Total revenues	\$ 1,414,119	\$ 1,638,153
Net income	\$ 61,383	\$ 115,730
Basic earnings per common share	\$ 0.25	\$ 0.48
Diluted earnings per common share	\$ 0.25	\$ 0.48

On December 30, 2002, the Company acquired or licensed the exclusive rights, including the NDA, trademarks, product rights and certain patents, to three branded prescription pharmaceutical products from Aventis for \$197,500, plus \$4,300 in expenses. The products include the rights in the United States, Puerto Rico, and Canada to Intal® and Tilade®, inhaled anti-inflammatory agents for the management of asthma, and worldwide rights, excluding Japan, to Synercid®, an injectable antibiotic. The acquisition was financed with cash on hand. The Company has recorded \$35,864 of the purchase price as patents and \$155,937 of the purchase price as trademarks and product rights within intangible assets.

In connection with the acquisition, \$12,000 of the purchase price was allocated to an in-process research and development project. The value of the in-process research and development project was expensed on the date of acquisition as it had not received regulatory approval and had no alternative future use. The project was for a new formulation of Intal® using a new propellant that was valued through the application of a probability-weighted, discounted cash flow approach by independent valuation specialists. The estimated cash flows were projected over periods ranging from zero to 16 years using a discount rate of 20.5%. Operating margins were assumed to be similar to historical margins of similar products. The estimated cost to complete the project was less than \$2,000 and the project was expected to be completed during 2004. The project was substantially complete as of the valuation date. The success of the project is dependent upon whether the Company receives FDA approval. The Company received an approvable letter pertaining to this product from the FDA during the third quarter of 2003. The Company currently anticipates final approval of the product during 2004. If the project is not successfully completed it would not materially adversely affect the Company's results of operations.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As additional consideration to Aventis for Synercid®, the Company agreed to potential milestone payments totaling \$75,000. On December 31, 2003, the Company paid Aventis a milestone payment of \$10,300 for the continued recognition of Synercid® as an effective treatment for vancomycin-resistant enterococcus faecium. The Company will potentially pay Aventis additional milestone payments totaling \$39,800 over the next two years, payable in annual installments of \$21,200, and \$18,600 on December 31, 2004 and December 31, 2005, respectively, which relate to the continued recognition of Synercid® as an effective treatment for vancomycin-resistant enterococcus faecium. The remaining \$25,000 milestone is payable to Aventis if Synercid® should receive FDA approval to treat methicillin resistant staphylococcus aureus, or King will pay Aventis a one-time payment of \$5,000 the first time during any twelve-month period net sales of Synercid® exceed \$60,000, and a one-time payment of \$20,000 the first time during any twelve-month period net sales of Synercid® exceed \$75,000.

On May 29, 2002, the Company acquired the exclusive rights to Prefest® tablets in the United States, its territories and possessions and Puerto Rico, including the related NDA, Investigational NDA, copyrights, and patents or licenses to the related patents from Ortho-McNeil Pharmaceutical, Inc., a Johnson & Johnson subsidiary. The Company paid \$108,000 for the product rights upon closing plus approximately \$3,300 of expenses. During February 2003 the Company paid Ortho-McNeil an additional \$7,000 upon receipt of the FDA's approval to rename the product Prefest®, which was previously named Ortho-Prefest. The acquisition was financed with cash on hand. Of the total purchase price of \$111,300 at December 31, 2002, \$80,442 was allocated to trademarks and product rights and \$30,858 was allocated to patents. The patent is being amortized over eleven years and five months, the remaining life on the primary patent. The trademark and product rights are being amortized over 25 years.

On August 8, 2001, the Company acquired three branded pharmaceutical products and a fully paid license to a fourth product from Bristol-Myers Squibb for \$285,000 plus approximately \$1,500 of expenses. The products acquired include Bristol-Myers Squibb's rights to the NDAs, trademarks and product rights in the United States to Corzide®, Delestrogen® and Florinef®. King also acquired a fully paid license to and trademark for Corgard® in the United States. The acquisition was financed with a combination of borrowings under the Company's Senior Secured Credit Facility and cash on hand. The product rights are being amortized over 20 to 30 years. See Note 8 for a discussion of an intangible asset impairment charge related to Florinef® that the Company recorded during the first quarter of 2003.

On September, 8, 2003, the Company sold the Soloxine®, Pancrezyme®, Tumil-K®, Uroetze®, and Ammonil product lines (the animal health products) to Virbac Corporation (Virbac) for \$15,133, including \$1,823 allocated to the contract manufacturing obligation. These assets included related product assets, intellectual property, unfilled customer orders, inventories and manufacturing equipment. As part of the transaction, the Company will contract manufacture the Soloxine® product for Virbac for up to one year. Of the selling price, \$1,500 was placed into escrow and is not available to the Company until the earlier of one year from the closing date or the occurrence of certain events. This escrow is included in restricted cash in the Company's financial statements. The Company recorded a \$10,307 gain on the sale the animal health products, which is included as a reduction in total operating costs and expenses in the financial statements.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. Intangible Assets and Goodwill

Intangible assets consist of the following:

	2002		2003	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Trademarks and product rights	\$ 1,197,686	\$ 123,176	\$ 1,722,619	\$ 185,651
Patents	173,027	30,697	289,158	71,393
Other intangibles	9,526	6,795	9,804	7,544
Total intangible assets	\$ 1,380,239	\$ 160,668	\$ 2,021,581	\$ 264,588

Amortization expense for the years ended December 31, 2001, 2002, and 2003 was \$38,217, \$48,738, and \$103,290, respectively. Estimated annual amortization expense at December 31, 2003 for each of the five succeeding fiscal years is as follows:

Fiscal Year Ended December 31,	Amount
2004	\$ 138,122
2005	117,943
2006	98,467
2007	95,865
2008	88,938

During January 2003, the Company was notified of the approval by the FDA of a second generic fludrocortisone acetate, USP, a product that represents additional competition for the Company's Florinef® (fludrocortisone acetate, USP) product. The Company recorded an impairment charge in the amount of \$110,970 in the first quarter of 2003 reflecting the reduction in the fair value of the Florinef® intangible assets. The Company determined the fair value of its Florinef® product rights based on management's discounted cash flow projections for the product. Florinef® is included in the Company's branded pharmaceuticals reporting segment. As of December 31, 2003, net intangible assets associated with the Florinef® product equal \$22,599. If sales of Florinef® continue to decline, we may incur additional write-offs in the future.

The Company acquired the antibiotic Lorabid® in the United States and Puerto Rico from Eli Lilly and Company (Eli Lilly) on August 19, 1999 for a purchase price of \$91,700, including acquisition costs. Since the acquisition, prescriptions declined for a variety of reasons. During the fourth quarter of 2002, the Company decided to divest its rights to Lorabid®.

As a result of a continuing decline of Lorabid® prescriptions, management determined that it would not be able to sell all the Lorabid® product the Company is required to purchase under its supply contract with Eli Lilly. Accordingly, under the requirements of Accounting Research Bulletin No. 43, the Company recorded a \$49,877 liability related to Lorabid® purchase commitments in excess of expected demand as a charge to cost of revenues in the fourth quarter of 2002. During the fourth quarter of 2003, primarily as a result of the continuing decline of Lorabid® prescriptions, the Company recorded an additional \$29,959 for purchase commitments in excess of expected demand as a charge to cost of revenues. As of December 31, 2003, the excess purchase commitment accrual totals \$53,740.

The Company also reviewed the Lorabid® intangible assets for impairment under SFAS No. 144. Based on that review, the Company determined that the Lorabid® intangible assets were impaired and recorded an impairment charge of \$66,844 in the fourth quarter of 2002 to write down the assets to their

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

estimated fair value as of December 31, 2002. As of December 31, 2003, net intangible assets associated with the Lorabid® product equals \$6,955. If prescriptions of Lorabid® continue to decline, the Company's maximum additional exposure for purchase commitments in excess of demand is \$5,174.

In addition, as a result of the decision in the fourth quarter of 2002 to divest the Lorabid® intangible assets, the Company donated \$15,152 of Lorabid® inventory to a charitable organization. This donation was classified within cost of revenues during 2002 in the accompanying statements of income. Lorabid® is included in the Company's branded pharmaceutical reporting segment.

In March 2003, the Company also became aware that an ANDA for Cortisporin® ophthalmic suspension which was previously inactive had been reactivated by the FDA with a new sponsor. The Company understands the sponsor entered the market as of April 14, 2003 with a generic equivalent for Cortisporin® ophthalmic suspension. The entry of the generic has negatively affected the Company's market share for this product. At December 31, 2003, the Company had net intangible assets related to Cortisporin® of approximately \$18,304. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows, however, if prescription declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with those products.

Prescriptions for the Company's women's health products, particularly Nordette® and Prefest®, have continued to decline over the past year. As of December 31, 2003, the Nordette® and Prefest® products have net intangible assets associated with them of \$96,019 and \$108,482, respectively. Management currently believes that these assets are not impaired based on estimated undiscounted future cash flows, however, if prescription declines exceed current expectations, the Company may have to write-off a portion or all of the intangible assets associated with those products in the future.

Prescriptions for Tapazole® continued to decline over the past two years. At December 31, 2003, Tapazole® has net intangible assets associated with it totaling \$18,240. Management currently believes that this asset is not impaired based on estimated undiscounted future cash flows. However, if prescription declines exceed current expectations, the Company may have to write-off a portion or all of the intangible assets associated with this product.

During the fourth quarter of 2003, the Company incurred intangible asset impairment charges totaling \$13,646 that were related to three of the Company's smallest branded pharmaceutical products and the write-off of some unutilized intangible assets. The impairment charges related to the branded pharmaceutical products were primarily the result of declining prescriptions and manufacturing issues with respect to these products. The impairment charge related to the unutilized intangible assets were the result of the Company's assessment of the prospects for commercialization of products utilizing those intangible assets. All of the affected intangible assets were part of the branded pharmaceuticals segment.

Goodwill at December 31, 2001, 2002 and 2003 is as follows:

	Branded Segment	Meridian Segment	Total
Goodwill at December 31, 2001	\$ 12,742	\$	\$ 12,742
Goodwill at December 31, 2002	12,742		12,742
Goodwill associated with Meridian acquisition		108,613	108,613
Goodwill at December 31, 2003	12,742	108,613	121,355

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. Other Assets

Other assets consist of the following:

	2002	2003
Convertible senior notes receivable from Novavax	\$ 12,345	\$ 32,404
Restricted cash		30,265
Loan receivable	14,277	1,101
Deferred financing costs, net	12,339	9,393
Other	570	2,954
	<u>\$ 39,531</u>	<u>\$ 76,117</u>

On December 19, 2000, September 7, 2001, and June 24, 2002, the Company acquired convertible senior notes of \$20,000, \$10,000 and \$10,000, respectively, from Novavax, Inc. (Novavax). The convertible senior notes earn interest at 4% payable semi-annually in June and December. The convertible senior notes are due December 19, 2007. The convertible senior notes are convertible to common shares of Novavax at a specified conversion price. At December 31, 2002 and 2003, the convertible senior notes were convertible to 17.0% and 12.4%, respectively, of the outstanding common shares of Novavax. During 2001, the Company recognized an unrealized gain net of amortization of \$8,081 related to the conversion option on the convertible senior notes in accordance with SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. The gain has been recorded in other income in the accompanying financial statements. During September 2001, the Company modified the agreement with Novavax, which resulted in the option no longer being considered a derivative. During 2002, the convertible senior notes were deemed to be impaired as defined under SFAS No. 114, Accounting by Creditors for Impairment of a Loan. The Company recorded a valuation allowance of \$35,443 during 2002. During 2003, this valuation allowance was reduced by \$18,151. The Company determined the amount of the valuation allowance by reference to the December 31, 2002 and December 31, 2003 quoted market price of the Novavax common stock. The amount of the valuation allowance will be adjusted in future periods until such time as the loan is no longer considered to be impaired. During the year ended December 31, 2001, Novavax paid interest due on the convertible senior notes in cash of \$722 and Novavax common stock with a value of \$232. During the year ended December 31, 2002, Novavax paid interest due on the convertible senior notes in cash of \$604 and Novavax common stock with a value of \$800. For the year ended December 31, 2003, Novavax paid the interest related to the convertible notes in cash of \$1,600. During 2002 and 2003, the value of Novavax common stock fluctuated. Accordingly, the Company incurred a charge in the amount of \$186 during 2002 and income of \$1,106 during 2003 to adjust the carrying value of the Novavax common stock the Company received interest earned on the Novavax Convertible Senior Notes during 2001 and 2002.

On June 22, 2000, the Company entered into an agreement with Aventis Pharma Deutschland GmbH (Aventis) to provide Aventis with funds for a facilities expansion that provides additional production capacity for an outsourced product of the Company. During 2000 and 2001, the Company loaned Aventis \$15,000 and \$15,000, respectively, under this agreement. This loan bears interest at 8% and is being repaid by reducing amounts otherwise payable on the purchase of inventory. During 2001, 2002, and 2003, inventory in the amount of \$14,086, \$4,310, and \$13,321, respectively, was received as principle and interest payments against these loans.

Amortization expense related to deferred financing costs was \$1,040, \$2,898, and \$3,163 for 2001, 2002, and 2003, respectively, and is included in interest expense.

KING PHARMACEUTICALS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In connection with the acquisition of the primary care business of Elan (see Note 7) in June 2003, \$163,416 was placed into the escrow to satisfy Elan's deferred obligations to Wyeth that were assumed by the Company. Interest income during 2003 includes \$710 that is related to interest earned on the funds in escrow. During 2003, \$67,751 of the deferred obligation was paid to Wyeth from funds in escrow. As of December 31, 2003, \$96,375 remains in escrow to satisfy the deferred obligation to Wyeth, \$66,770 of which represents a short-term obligation and is classified as restricted cash and \$29,605 of which represents a long-term obligation and is classified as other assets in the accompanying financial statements.

10. Lease Obligations

The Company leases certain office and manufacturing equipment and automobiles under non-cancelable operating leases with terms from one to five years. Estimated future minimum lease payments as of December 31, 2003 for leases with initial or remaining terms in excess of one year are as follows:

2004	\$ 13,315
2005	13,580
2006	10,234
2007	9,518
2008	9,231
Thereafter	19,641

Lease expense for the years ended December 31, 2001, 2002 and 2003 was approximately \$7,846, \$10,189, and \$10,411, respectively.

11. Accrued Expenses

Accrued expenses consist of the following:

	2002	2003
Rebates (see Note 17)	\$ 140,949	\$ 232,472
Accrued co-promotion fees	68,295	53,925
Current portion of loss contract (see Note 8)	32,679	37,619
Product returns and chargebacks	22,611	50,131
Accrued interest	1,216	1,216
Product recall accrual	758	1,832
Contingent liabilities (see Note 7)		69,212
Other	31,020	59,626
	<u>\$ 297,528</u>	<u>\$ 506,033</u>

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Long-Term Debt

Long-term debt consists of the following:

	2002	2003
Convertible debentures(a)	\$ 345,000	\$ 345,000
Senior subordinated notes(b)	93	93
Senior secured revolving credit facility(c)		
Notes payable to former shareholders, due in equal annual installments of principal and interest (at a rate of 6%) of \$1,226 through December 2003	1,156	
Various capital leases with interest rates ranging from 8.3% to 12.7% and maturing at various times through 2003	144	4
	<u>346,393</u>	<u>345,097</u>
Less current portion	1,300	97
	<u>\$ 345,093</u>	<u>\$ 345,000</u>

- (a) During the fourth quarter of 2001, the Company issued \$345,000 of 2 3/4% Convertible Debentures due November 15, 2021. The debentures are unsecured unsubordinated obligations, and the payment of principal and interest is guaranteed by the Company's domestic subsidiaries on a joint and several basis. The debentures accrue interest at an initial rate of 2 3/4%, which will be reset (but not below 2 3/4% or above 4 1/4%) on May 15, 2006, May 15, 2011, and May 15, 2016. Interest is payable on May 15 and November 15 of each year.

On or after November 20, 2006, the Company may redeem for cash all or part of the debentures that have not previously been converted or repurchased at a price equal to 100% of the principal amount of the debentures plus accrued interest up to but not including the date of redemption. Holders may require the Company to repurchase for cash all or part of their debentures on November 15, 2006, November 15, 2011 or November 15, 2016 at a price equal to 100% of the principal amount of the debentures plus accrued interest up to but not including the date of repurchase. In addition, upon a change of control, each holder may require the Company to repurchase for cash all or a portion of the holder's debentures.

Holders may surrender their debentures for conversion into shares of King common stock at the conversion price (initially \$50.16 per share and subject to certain adjustments) if any of the following conditions are satisfied:

if the closing sale price of King common stock, for at least 20 trading days in the 30 trading day period ending on the trading day prior to the date of surrender, exceeds 110% of the conversion price per share of King common stock on that preceding trading day;

if we have called the debentures for redemption; or

upon the occurrence of specified corporate transactions.

The Company has reserved 6,877,990 shares of common stock in the event such debentures are converted into shares of the Company's common stock.

(b)

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

On March 3, 1999, the Company issued \$150,000 of 10 3/4% Senior Subordinated Notes due 2009. During 2000 and 2001, the Company redeemed \$53,618 and \$96,289, respectively, at a price of \$59,144 and \$114,299, respectively. The Company redeemed the remaining Senior Subordinated Notes of \$93 during the first quarter of 2004.

- (c) On April 23, 2002, the Company established a \$400,000 five year Senior Secured Revolving Credit Facility. The facility has been collateralized in general by all real estate with a value of \$5,000 or

F-22

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

more and all personal property of the Company and its significant subsidiaries. The Company's obligations under the Senior Secured Revolving Credit Facility are unconditionally guaranteed on a senior basis by significant subsidiaries. The Senior Secured Revolving Credit Facility accrues interest at the Company's option, at either (a) the base rate (which is based on the greater of (1) the prime rate or (2) the federal funds rate plus one-half of 1%) plus an applicable spread ranging from 0.0% to 0.75% (based on a leverage ratio) or (b) the applicable LIBOR rate plus an applicable spread ranging from 1.0% to 1.75% (based on a leverage ratio). In addition, the lenders under the Senior Secured Revolving Credit Facility are entitled to customary facility fees based on (a) unused commitments under the Senior Secured Revolving Credit Facility and (b) letters of credit outstanding. As of December 31, 2003, there were no outstanding borrowings under this facility, however, the Company had \$11,600 of letters of credit outstanding under this facility.

To establish the Senior Secured Revolving Credit Facility, the Company incurred \$5,067 of deferred financing costs that are being amortized over five years, the life of the Senior Secured Revolving Credit Facility.

The Senior Secured Revolving Credit Facility requires the Company to maintain a minimum net worth of no less than \$1.2 billion plus 50% of the Company's consolidated net income for each fiscal quarter after April 23, 2002, excluding any fiscal quarter for which consolidated income is negative; an EBITDA to interest expense ratio of no less than 3.00 to 1.00; and a funded debt to EBITDA ratio of no greater than 3.50 to 1.00 prior to April 24, 2004 and of no greater than 3.00 to 1.00 on or after April 24, 2004. As of December 31, 2003, the Company has complied with these covenants.

During 2001, as a result of terminating its Senior Credit Facility and redemption, through a tender offer of \$96,300, of the Company's 10 3/4% Senior Subordinated Notes prior to maturity, the Company recorded a charge of \$22,903, resulting from the write-off of deferred financing costs and the payment of an early redemption premium which is classified as other expense in the accompanying financial statements.

For the years ended December 31, 2001, 2002 and 2003, the Company capitalized interest of approximately \$1,256, \$1,127, and \$1,180 respectively.

The aggregate maturities of long-term debt (including capital lease obligations) at December 31, 2003 are as follows:

2004	\$ 97
2005	
2006	345,000
2007	
2008	
	<hr/>
	\$ 345,097
	<hr/>

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. Other Liabilities

Other liabilities consist of the following:

	2002	2003
Contingent milestone liabilities (Note 7)	\$	\$ 39,302
Deferred revenue from co-promotion revenue fees	52,876	34,694
Contingent escrow liabilities (Note 7)		29,605
Long-term portion of loss contract (Note 8)	17,198	16,121
Other	750	1,983
	<u>\$70,824</u>	<u>\$121,705</u>

14. Financial Instruments

The following disclosures of the estimated fair values of financial instruments are made in accordance with the requirements of SFAS No. 107, Disclosures About Fair Value of Financial Instruments. The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies.

Cash and Cash Equivalents, Accounts Receivable and Accounts Payable. The carrying amounts of these items are a reasonable estimate of their fair values.

Marketable Securities. The fair value of marketable securities was based primarily on quoted market prices (Note 4). If quoted market prices are not readily available, fair values are based on quoted market prices of comparable instruments.

Convertible Senior Notes Receivable from Novavax. At December 31, 2002 and 2003, the carrying amount of the convertible notes receivable were at their estimated fair value based on the quoted market price of Novavax common stock on an as-if-converted basis.

Long-Term Debt. The fair value of the Company's long-term debt, including the current portion, at December 31, 2002 and 2003 is estimated to be approximately \$310,485 and \$322,674, respectively, using discounted cash flow analyses and based on the Company's incremental borrowing rates for similar types of borrowing arrangements.

15. Income Taxes

The net income tax expense (benefit) is summarized as follows:

	2001	2002	2003
Current			
Federal	\$ 99,534	\$ 154,347	\$ 189,057
State	14,743	8,857	12,800
	<u>\$114,277</u>	<u>\$163,204</u>	<u>\$201,857</u>
Deferred			

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Federal	\$ 13,147	\$ (71,158)	\$ (126,150)
State	2,062	(6,903)	(4,474)
	<u> </u>	<u> </u>	<u> </u>
Total deferred	\$ 15,209	\$ (78,061)	\$ (130,624)
	<u> </u>	<u> </u>	<u> </u>
Total expense	\$ 129,486	\$ 85,143	\$ 71,233
	<u> </u>	<u> </u>	<u> </u>

F-24

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A reconciliation of the difference between the federal statutory tax rate and the effective income tax rate as a percentage of income before income taxes and extraordinary item is as follows:

	2001	2002	2003
Federal statutory tax rate	35.0%	35.0%	35.0%
State income taxes, net of federal benefit	3.0	0.7	4.3
Charitable donations	(0.4)	(2.7)	(3.5)
In-process research and development			3.8
Other	(0.4)	(1.2)	0.6
Effective tax rate	37.2%	31.8%	40.2%

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities are as follows:

	2002	2003
Accrued expenses and reserves	\$ 105,395	\$ 136,822
Net operating losses		4,008
Intangible assets		42,111
Other	923	2,032
Total deferred tax assets	106,318	184,973
Valuation allowance		(6,525)
Net deferred tax assets	106,318	178,448
Property, plant and equipment	(13,998)	(16,188)
Intangible assets	(8,521)	
Other	(11,227)	(18,023)
Total deferred tax liabilities	(33,746)	(34,211)
Net deferred tax asset	\$ 72,572	\$ 144,237

The Company has \$11.1 million of foreign operating loss carryforwards which may be carried forward indefinitely; a valuation allowance has been provided as it is more likely than not that the deferred tax assets relating to those loss carryforwards will not be fully realized. Additionally, a valuation allowance has been provided against certain state deferred tax assets where it is more likely than not that the deferred tax asset will not be realized.

16. Benefit Plans

The Company sponsors a defined contribution employee retirement savings 401(k) plan that covers all employees over 21 years of age. The plan allows for employees' contributions, which are matched by the Company up to a specific amount under provisions of the plan. Company contributions during the years ended December 31, 2001, 2002 and 2003 were \$2,134, \$2,412, and \$3,860, respectively. The plan also provides for discretionary profit-sharing contributions by the Company. There were no discretionary profit-sharing contributions during the years ended

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

December 31, 2001, 2002 and 2003. The increase during 2003 is primarily due to an increase in the number of employees and an increase in the Company's matching percentage.

F-25

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. Commitments and Contingencies

Fen/Phen Litigation

Many distributors, marketers and manufacturers of anorexigenic drugs have been subject to claims relating to the use of these drugs. Generally, the lawsuits allege that the defendants (1) misled users of the products with respect to the dangers associated with them, (2) failed to adequately test the products and (3) knew or should have known about the negative effects of the drugs, and should have informed the public about the risks of such negative effects. The actions generally have been brought by individuals in their own right and have been filed in various state and federal jurisdictions throughout the United States. They seek, among other things, compensatory and punitive damages and/or court supervised medical monitoring of persons who have ingested the product. The Company is one of many defendants in no more than 10 lawsuits that claim damages for personal injury arising from the Company's production of the anorexigenic drug phentermine under contract for GlaxoSmithKline. The Company expects to be named in additional lawsuits related to the Company's production of the anorexigenic drug under contract for GlaxoSmithKline.

While the Company cannot predict the outcome of these suits, the Company believes that the claims against it are without merit and intends to vigorously pursue all defenses available to it. The Company is being indemnified in all of these suits by GlaxoSmithKline for which the Company manufactured the anorexigenic product, provided that neither the lawsuits nor the associated liabilities are based upon the independent negligence or intentional acts of the Company, and intends to submit a claim for all unreimbursed costs to the Company's product liability insurance carrier. However, in the event that GlaxoSmithKline is unable to satisfy or fulfill its obligations under the indemnity, the Company would have to defend the lawsuits and be responsible for damages, if any, that are awarded against it or for amounts in excess of the Company's product liability coverage. A reasonable estimate of possible losses related to these suits cannot be made.

In addition, Jones Pharma, Incorporated (Jones), a wholly owned subsidiary of the Company, is a defendant in approximately 926 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine. These suits have been filed in various jurisdictions throughout the United States, and in each of these suits Jones is one of many defendants, including manufacturers and other distributors of these drugs. Although Jones has not at any time manufactured dexfenfluramine, fenfluramine, or phentermine, Jones was a distributor of a generic phentermine product and, after the acquisition of Abana Pharmaceuticals, was a distributor of Obenix®, its branded phentermine product. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs and are seeking compensatory and punitive damages as well as medical care and court supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to, product liability, strict liability, negligence, breach of warranty, and misrepresentation.

Jones denies any liability incident to the distribution of Obenix® or its generic phentermine product and intends to pursue all defenses available to it. Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. The manufacturers of fenfluramine and dexfenfluramine have settled many of these cases. In the event that Jones' insurance coverage is inadequate to satisfy any resulting liability, Jones will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

While the Company cannot predict the outcome of these suits, management believes that the claims against Jones are without merit and intends to vigorously pursue all defenses available. The Company is unable to disclose an aggregate dollar amount of damages claimed because many of these complaints are multi-party suits and do not state specific damage amounts. Rather, these claims typically state damages

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

as may be determined by the court or similar language and state no specific amount of damages against Jones. Additionally, the Company cannot reasonably estimate possible losses related to the lawsuits.

Thimerosal/Vaccine Related Litigation

King and Parkedale Pharmaceuticals, Inc. (Parkedale), a wholly owned subsidiary of King, have been named as defendants in California, Illinois and Mississippi, along with Abbott Laboratories, Wyeth, Aventis Pharmaceuticals, and other pharmaceutical companies that have manufactured or sold products containing the mercury-based preservative, thimerosal.

In these cases, the plaintiffs attempt to link the receipt of the mercury-based products to neurological defects. The plaintiffs claim unfair business practices, fraudulent misrepresentations, negligent misrepresentations, and breach of implied warranty, which are all arguments premised on the idea that the defendants promoted products without any reference to the toxic hazards and potential public health ramifications resulting from the mercury-containing preservative. The plaintiffs also allege that the defendants knew of the dangerous propensities of thimerosal in their products.

The Company's product liability insurance carrier has been given proper notice of all of these matters and defense counsel is vigorously defending the Company's interests. The Company intends to file a motion to be dismissed from the litigation due, among other things, to lack of product identity in the plaintiffs' complaints. In 2001, the Company was dismissed on this basis in a similar case. The Company intends to defend these lawsuits vigorously but is unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

Governmental Investigations and Securities and ERISA Litigation

As previously reported, in March 2003 the SEC initiated a formal investigation of King. The Company received SEC subpoenas relating to, among other topics, sales of King's products to VitaRx and Prison Health Services, the Company's best price lists, the pricing of the Company's pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., the Company's calculations related to Medicaid rebates, and the Audit Committee's internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, the Company received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to the Company's sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®.

In March 2003, upon the recommendation of management and with the assistance of independent counsel and an independent accounting firm, the Audit Committee of the Company's Board of Directors initiated an assessment and internal review of issues raised by the SEC investigation. In connection with the internal review, King estimated that it had underpaid amounts due under Medicaid and other governmental pricing programs, and recorded an adjustment of \$46,500 to net sales and accrued expenses in the fourth quarter of 2002. This amount represented the Company's best estimate as of July 2003 of the extent to which we had underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002.

The July 2003 estimate was based upon an extensive sample of available data supporting the calculation of Medicaid rebates paid from 1998 to 2002, and was generated with the assistance of outside consultants. Since that time, King's outside consultants have undertaken a comprehensive audit to determine the actual amount of underpayments under Medicaid during the period from 1998 to 2002. As a result of that recently completed audit, King has determined that its accrual for estimated amounts due under Medicaid and other governmental pricing programs through December 31, 2002, should be increased

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

by \$18,000. In addition, based on the results of the comprehensive audit for the period from 1998 through 2002, the Company estimates that it underpaid amounts due Medicaid by \$900 during the period from 1994 through 1997. Accordingly, results for the fourth quarter of 2003 include an adjustment of \$18,900 to net sales and accrued expenses.

Following the accrual adjustment recorded in the fourth quarter of 2002, the Company recovered on a pre-tax basis approximately \$9,500 in fees it previously paid under its Co-Promotion Agreement for Altace® and has recognized this amount in the fourth quarter of 2003. In addition, fees under the Company's Co-Promotion Agreement for Altace® in the fourth quarter of 2003 were reduced on a pre-tax basis by approximately \$5,700 as a result of the accrual adjustment recorded in that quarter.

Under generally accepted accounting principles, the \$18,000 adjustment in the Company's accrual for Medicaid rebates for the period from 1998 through 2002 constitutes a change in an accounting estimate effective as of December 31, 2003. The change resulted principally from two factors. First, the recently completed Medicaid audit included additional data that was used to refine the July 2003 estimate. Second, the Company received legal advice that, in calculating amounts payable under Medicaid, it should revise the methodology it had previously been advised to use for calculating "best price" in respect of a complex issue concerning rebates to pharmacy benefit managers. The \$900 adjustment in the Company's accrual for Medicaid rebates for the period from 1994 through 1997 reflects the correction of immaterial errors that occurred during that period.

The Medicaid audit did not result in any changes to the Company's accruals for programs other than Medicaid. King is currently in the process of conducting detailed audits of its compliance with the requirements of several other governmental pricing programs, but its obligations under these programs are substantially smaller than its obligations under Medicaid, and the Company does not expect the audits to result in material adjustments to its accruals.

Although the amounts described above constitute the Company's best estimate of amounts owed in respect of Medicaid and other governmental pricing programs, its calculations are subject to review and challenge by the applicable government agencies. In connection with the pending governmental investigations, the Company has continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, and the Public Health Service. The Company expects that these discussions will include a detailed review of its calculations by the appropriate agencies, and it is possible that this review could result in material changes. The accruals described above relate solely to King's estimated underpayments and exclude any interest, fines, penalties or other amounts that might be owed in connection with the underpayments, as the Company cannot predict or reasonably estimate their likelihood or magnitude at this time.

Pending determination of the precise amount of our obligations, the Company has placed a total of \$65,500 in an interest-bearing escrow account (\$46,500 during 2003 and \$19,000 during 2004). In addition, since the first quarter of 2003, the Company voluntarily has been making its Medicaid payments on a basis that it believes represents an overpayment of amounts actually due, and King would expect to offset these payments against the amounts ultimately determined to be due in respect of prior years. Based on the results of the Medicaid audit, the Company estimates that these overpayments total approximately \$18,579 as of December 31, 2003.

The governmental investigations of King described above are continuing. The SEC, the Office of Inspector General of the Department of Health and Human Services, the Department of Justice, the Department of Veterans Affairs, the Public Health Service, the Centers for Medicare and Medicaid Services and other governmental agencies that might be investigating or might commence an investigation of King could impose, based on a claim of a violation of fraud and false claims laws or otherwise, civil

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. The Company cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of the Company's securities against the Company, its directors, former directors, executive officers, former executive officers, a Company subsidiary, and a former director of the subsidiary in the United States District Court for the Eastern District of Tennessee, alleging violations of the Securities Act of 1933 and/or the Securities Exchange Act of 1934. These 22 complaints have been consolidated in the United States District Court for the Eastern District of Tennessee. In addition, holders of the Company's securities filed two class action complaints alleging violations of the Securities Act of 1933 in Tennessee state court. The Company removed these two cases to the United States District Court for the Eastern District of Tennessee, where these two cases were consolidated with the other class actions. Plaintiffs in these actions unsuccessfully moved to remand these two cases back to Tennessee state court. These two actions therefore remain part of the consolidated action. The district court has appointed lead plaintiffs in the consolidated action, and those lead plaintiffs filed a consolidated amended complaint on October 21, 2003 alleging that King, through some of its executive officers, former executive officers, directors and former directors, made false or misleading statements concerning its business, financial condition and results of operations during periods beginning February 16, 1999 and continuing until March 10, 2003. Plaintiffs in the consolidated action have also named the underwriters of King's November 2001 public offering as defendants. The Company and other defendants have filed motions to dismiss the consolidated amended complaint, and those motions are currently pending.

Seven purported shareholder derivative complaints have also been filed in federal and state courts in Tennessee alleging a breach of fiduciary duty, among other things, by some of the Company's officers and directors. The derivative cases in state court were consolidated and are currently stayed. The stay will remain in place at least until the motion to dismiss the federal securities class action are decided. The derivative case in federal court are stayed until there is a decision on the merits in the state court derivative suits. Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act (ERISA). As amended, the complaint alleges that the Company and certain of its executive officers, former executive officers, directors, former directors and an employee of the Company violated fiduciary duties that they allegedly owed the Company's 401(k) Retirement Savings Plan's participants and beneficiaries under ERISA. The allegations underlying each of these additional lawsuits are similar in many respects to those in the class action litigation described above. The Company filed a motion to dismiss the ERISA action on March 5, 2004; this motion to dismiss is currently pending. The Company intends to defend all of these lawsuits vigorously but is unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

If any governmental sanctions are imposed, or if the Company were not to prevail in the pending litigation, neither of which the Company can predict or reasonably estimate at this time, the Company's business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the government investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending King in the pending litigation has resulted, and is expected to continue to result, in a significant diversion of management's attention and resources and an increase in professional fees.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Other Legal Proceedings

The Rochester facility was one of six facilities owned by Pfizer subject to a Consent Decree of Permanent Injunction issued August 1993 in *United States of America v. Warner-Lambert Company and Melvin R. Goodes and Lodewijk J.R. DeVink* (U.S. Dist. Ct., Dist. of N.J.) (the Consent Decree). The Company acquired the Rochester facility in February 1998. The Rochester facility is currently manufacturing pharmaceutical products subject to the Consent Decree that prohibits the manufacture and delivery of specified drug products unless, among other things, the products conform to current good manufacturing practices and are produced in accordance with an approved ANDA or NDA. The Company intends, when appropriate, to petition for relief from the Consent Decree.

Cobalt Pharmaceuticals, Inc. (Cobalt), a generic drug manufacturer located in Mississauga, Ontario, Canada, has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book): U.S. Patent Nos. 4,587,258 (the 258 patent) and 5,061,722 (the 722 patent), two composition of matter patents related to Altace®, and U.S. Patent No. 5,403,856 (the 856 patent), a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the FDA's Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and the Company filed suit on March 14, 2003 to enforce its rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides the Company an automatic stay of FDA approval of Cobalt's ANDA for 30 months from no earlier than February 5, 2003. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, the Company would not receive the full benefit of that 30 month stay. Subsequent to filing its original complaint, the Company amended its complaint to add an allegation of infringement of the 856 patent. In its answer to the amended complaint, Cobalt denied infringement and alleged that the 856 patent is invalid. Pursuant to FDA regulations, however, Cobalt is not required to certify against the 856 patent. The Company intends to vigorously enforce its rights under the 722 and 856 patents. Regardless of the outcome of the lawsuit involving the 722 and 856 patents, however, Cobalt has not challenged the validity of the 258 patent and, therefore, cannot market a generic version of Altace® prior to the expiration of that patent in January 2005.

Eon Labs, Inc. (Eon Labs), CorePharma, LLC (CorePharma) and Mutual Pharmaceutical Co., Inc. (Mutual) have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin®. United States Patent Nos. 6,407,128 (the 128 patent) and 6,683,102 (the 102 patent) two method-of-use patents relating to Skelaxin®, are listed in the FDA's Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 and 102 patents. Mutual has filed a Paragraph IV certification alleging noninfringement and invalidity of the 102 patent. The Company filed separate suits against Eon Labs on January 2, 2003 and CorePharma on March 7, 2003 and is currently assessing its right to bring suit against Mutual. Pursuant to the Hatch-Waxman Act, the filing of the suits against Core and Eon provides the Company with an automatic stay of FDA approval of Eon's ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of Core's ANDA for 30 months from no earlier than January 24, 2003. The Company intends to vigorously enforce its rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, the Company received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA's Orange Book for the 128 patent may be deleted from the ANDA applicants' product labeling. The Company believes that this decision is arbitrary,

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

capricious, and inconsistent with the FDA's previous position on this issue. The Company is currently assessing its legal options and may request the FDA to reinstate its previous policy on this issue and reject any ANDAs that delete such use from their product labeling. If the Company is unable to persuade the FDA to reinstate its previous policy, however, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected.

Mylan Pharmaceuticals, Inc. (Mylan) and KV Pharmaceutical Company (KV) have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. United States Patent No. 6,555,581 (the 581 patent), a utility patent with formulation claims relating to Levoxyl®, was issued to the Company on April 29, 2003. The 581 patent is listed in the FDA's Orange Book and does not expire until February 15, 2022. No earlier than April 30, 2003, the Company received notice of Mylan's Paragraph IV certification, which alleges noninfringement of the 581 patent. The Company filed suit against Mylan on June 13, 2003 in the Eastern District of Pennsylvania and on June 16, 2003 in the Northern District of West Virginia; these suits have been consolidated in the Northern District of West Virginia and trial is currently scheduled in June 2005. Pursuant to the Hatch-Waxman Act, the filing of the suits against Mylan provides the Company with an automatic stay of FDA approval of Mylan's ANDA for 30 months from no earlier than April 30, 2003. On June 24, 2003, the Company received notice of KV's Paragraph IV certification, which alleges noninfringement and invalidity of the 581 patent. The Company filed suit against KV on August 7, 2003 and the trial is currently scheduled to begin on December 6, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suit against KV provides the Company with an automatic stay of FDA approval of KV's ANDA for 30 months from no earlier than June 24, 2003. The Company intends to vigorously enforce its rights under the 581 patent to the full extent of the law.

Barr Laboratories Inc. (Barr) has filed an ANDA, which included a Paragraph IV certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995 (the 995 patent), a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573 (the 573 patent), a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the FDA's Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 15, 2003, the Company received notice of Barr's Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. On November 26, 2003, the Company filed a Complaint against Barr in the Southern District of New York for infringement of the 995 and 573 patents. Pursuant to the Hatch-Waxman Act, the filing of that suit provides the Company an automatic stay of FDA approval of Barr's ANDA for 30 months from no earlier than October 15, 2003. The Company intends to vigorously enforce its rights under both patents.

The Company is involved in various routine legal proceedings incident to the ordinary course of its business.

KING PHARMACEUTICALS, INC.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Other Commitments and Contingencies*

The following summarizes the Company's unconditional purchase obligations at December 31, 2003:

2004	\$ 137,850
2005	119,279
2006	87,830
2007	88,399
2008	89,707
Thereafter	-0-
	<hr/>
Total	\$ 523,065
	<hr/>

The unconditional purchase obligations of the Company are primarily related to minimum purchase requirements under contracts with suppliers to purchase raw materials and finished goods related to the Company's branded pharmaceutical products.

The Company has a supply agreement with Aventis to produce ramipril, the active ingredient in Altace®. This supply agreement is reflected in the unconditional purchase obligations above. This supply agreement requires the Company to purchase certain minimum levels of ramipril as long as the Company maintains market exclusivity on Altace® in the United States. If sales of Altace® do not increase at the currently anticipated rates, if the Company is unable to maintain market exclusivity for Altace® in accordance with current expectations, if the Company's product life cycle management is not successful, or if the Company does not terminate the supply agreement at an optimal time, the Company may incur losses in connection with the purchase commitments under the supply agreement. In the event the Company incurs losses in connection with the purchase commitments under the supply agreement, there may be a material adverse effect upon the Company's results of operations and cash flows.

The Company has a supply agreement with Eli Lilly to produce Lorabid® which is reflected in the unconditional purchase obligations above. This supply agreement requires the Company to purchase certain minimum levels of inventory of Lorabid® through September 1, 2005. Based on changes in estimated prescription trends, the Company believes the minimum purchase commitments under the supply agreement are greater than that which the Company will be able to sell to its customers. As a result, the Company recorded charges of \$49,877 during 2002 and \$29,959 during the fourth quarter of 2003 related to the liability associated with the amount of its purchase commitments in excess of expected demand.

18. Segment Information

The Company's business is classified into five reportable segments: branded pharmaceuticals, Meridian Medical Technologies, royalties, contract manufacturing and all other. Branded pharmaceuticals include a variety of branded prescription products over eight therapeutic areas, including cardiovascular, endocrinology/women's health, orthopedic, critical care, neurology/central nervous system, anti-infective, respiratory, and other. These branded prescription products have been aggregated because of the similarity in regulatory environment, manufacturing processes, methods of distribution, and types of customer. The Meridian Medical Technologies segment is a new segment during 2003 as a result of the acquisition of Meridian on January 8, 2003. Meridian develops, manufactures, and sells auto-injector pharmaceutical products to both commercial and government markets. The principal source of revenues in the commercial market is the EpiPen® product line marketed by Dey L.P., which is primarily prescribed for the treatment of severe allergic reactions. Government revenues are principally derived from the sale of nerve agent antidotes and other emergency medicine auto-injector products marketed to the U.S. Department of Defense and other federal, state and local agencies, particularly those involved in homeland security, as well as to approved foreign governments. Contract manufacturing includes pharmaceutical manufacturing

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

services the Company provides to third-party pharmaceutical and biotechnology companies. Royalties include revenues the Company derives from pharmaceutical products after the Company has transferred the manufacturing or marketing rights to third parties in exchange for licensing fees or royalty payments.

The Company primarily evaluates its segments based on gross profit. Reportable segments were separately identified based on revenues, gross profit (excluding depreciation) and total assets. Revenues among the segments are presented in the individual segments and removed through eliminations in the information below. Substantially all of the eliminations relate to sales from the contract manufacturing segment to the branded pharmaceuticals segment.

The following represents selected information for the Company's reportable segments for the periods indicated:

	For the years ended December 31,		
	2001	2002	2003
Total revenues:			
Branded pharmaceuticals(1)	\$ 794,261	\$ 1,032,831	\$ 1,300,948
Meridian Medical Technologies			124,157
Royalties	46,774	58,375	68,365
Contract manufacturing(2)	79,443	143,373	278,836
All other	2,265	1,193	628
Eliminations	(50,481)	(107,437)	(251,546)
Consolidated total revenues	\$ 872,262	\$ 1,128,335	\$ 1,521,388
Segment profit:			
Branded pharmaceuticals	\$ 654,331	\$ 793,361	\$ 1,033,515
Meridian Medical Technologies			57,954
Royalties	38,474	47,881	57,121
Contract manufacturing	(7,229)	(7,727)	(11,942)
All other	122	(156)	(23)
Consolidated segment profit	\$ 685,698	\$ 833,359	\$ 1,136,625
Other operating costs and expenses	319,432	539,159	970,511
Operating income	\$ 366,266	\$ 294,200	\$ 166,114

- (1) Results for 2002 reflect (a) a \$22,113 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2001, (b) a \$12,399 charge for corrections of immaterial errors related to underpayments of amounts due under Medicaid and other governmental pricing programs related to 2002 and recorded in the fourth quarter of 2002, and (c) an \$11,970 charge arising from changes in accounting estimates related to Medicaid and other governmental pricing programs. Results for 2003 reflect an \$18,000 charge for changes in accounting estimates related to Medicaid for the years 1998 to 2002 and a \$900 charge for corrections of immaterial errors related to Medicaid for the years 1994 to 1997. For additional information regarding these charges, see Note 17.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- (2) Contract manufacturing revenues include \$49,763, \$107,437, and \$251,546 of intercompany sales for the years ended December 31, 2001, 2002 and 2003, respectively.

	As of December 31,	
	2002	2003
Total assets:		
Branded pharmaceuticals	\$2,642,380	\$2,897,137
Meridian Medical Technologies		250,935
Royalties	18,738	20,032
Contract manufacturing	98,404	90,992
All other	11	10
Eliminations	(8,873)	(81,372)
Consolidated total assets	\$2,750,660	\$3,177,734

The following represents branded pharmaceutical revenues by therapeutic area:

	For the years ended December 31,		
	2001	2002	2003
Total revenues:			
Cardiovascular	\$308,502	\$483,052	\$562,386
Anti-infective	140,661	116,133	85,834
Critical care	84,136	104,885	148,426
Endocrinology/women's health	231,358	296,107	196,421
Neuroscience			251,664
Respiratory	3,866	1,993	42,250
Other branded	25,738	30,661	13,967
Consolidated branded pharmaceutical revenues	\$794,261	\$1,032,831	\$1,300,948

Capital expenditures of \$40,167, \$73,587, and \$51,201 for the years ended December 31, 2001, 2002 and 2003, respectively, are substantially related to the branded pharmaceuticals and contract manufacturing segments.

19. Related Party Transactions

The Benevolent Fund is a nonprofit corporation organized under the laws of the Commonwealth of Virginia and is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code. The Benevolent Fund obtains pharmaceutical products either as gifts-in-kind from manufacturers or by purchase from third-party distributors or wholesalers. The Benevolent Fund donates the pharmaceutical products purchased or received as gifts-in-kind to medical missions in the United States and in foreign countries to advance its humanitarian aid efforts. The Benevolent Fund was founded in 1994 by John M. Gregory, who also founded King and was its Chairman of the Board until June 28, 2002 and its Chief Executive Officer until January 1, 2002. John M. Gregory owned more than 5% of the Company's common stock until May 6, 2002. John M. Gregory, who serves as President of the Board of Directors of the Benevolent Fund, is the brother of Jefferson J. Gregory, who became the Company's Chief Executive Officer on January 1, 2002 and the Company's Chairman of the Board on June 28, 2002, and James E. Gregory, a former director of the Company. In addition, Mary Ann Blessing, a sister of Jefferson J. Gregory, John M. Gregory and James E. Gregory,

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

served as the Chief Operating Officer of the Benevolent Fund until approximately January 2001 and presently serves as a director and Treasurer of the Board of the Directors of the Benevolent Fund. Carol Shrader, mother of Brian Shrader, Chief Financial Officer of the Company until September 2000, is presently a director of the Benevolent Fund.

F-34

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Jefferson J. Gregory and James E. Gregory were members of the Board of Directors of the Benevolent Fund in 1999, 2000, 2001 and 2002, but no longer hold those positions. In addition, Joseph R. Gregory, who was Vice Chairman of the Company's Board of Directors and President of the Company's wholly-owned subsidiary Monarch Pharmaceuticals, Inc. until February 2003, served as a director of the Benevolent Fund in 1999, 2000, 2001 and 2002, but no longer holds that position. Joseph R. Gregory is the brother of Jefferson J. Gregory, James E. Gregory, John M. Gregory and Mary Ann Blessing. Herschel Blessing, Executive Vice President of Logistics for King until July 1, 2002, is the husband of Mary Ann Blessing and a director of the Benevolent Fund.

The Company occasionally donates its products to the Benevolent Fund. The Company donated inventory with a carrying value of \$4,107 in 2001, \$22,586 in 2002, and \$16,322 in 2003. In addition to receiving donations of products directly from pharmaceutical manufacturers, the Benevolent Fund also purchases pharmaceutical products, including those manufactured by King, from third-party distributors or wholesalers.

On December 26, 2002, the Company sold \$4,701 of Cortisporin®, Silvadene® and Tigan® to a third-party wholesaler, which in turn resold those products to the Benevolent Fund in January 2003. The Company is recognizing revenue associated with this transaction as the Benevolent Fund distributes the products to the beneficiaries of the Benevolent Fund's charitable donations. During 2003, the Company recognized \$4,270 of the deferred revenue.

During 2001, the Company donated \$103 to King College, which is located in Bristol, Tennessee. Gregory D. Jordan, a director of the Company, is the president of King College. Jefferson J. Gregory, the Company's Chairman and Chief Executive Officer, served as a member of the King College Board of Trustees from 1994 until 1998, as the Board's Vice Chairman from 1998 until 2001 and as its Chairman from 2001 until 2003.

During 2002, the Company paid \$73 to James E. Gregory, a former director of the Company, for consulting services. Of that amount, \$23 was paid in the form of personal use of the corporate aircraft.

During the years ended December 2001, 2002 and 2003, the Company paid \$5, \$171, and \$88 to the Wake Forest University School of Medicine, respectively, for research and development activities. R. Charles Moyer, a director of the Company, is the Dean Emeritus of the Babcock Graduate School of Management at Wake Forest University.

20. Stockholders' Equity

Preferred Shares

The Company is authorized to issue 15 million shares of blank-check preferred stock, the terms and conditions of which will be determined by the Board of Directors. As of December 31, 2002 and 2003, there were no shares issued or outstanding.

2001 Offerings

On November 7, 2001 and November 20, 2001, the Company completed the sale of 16,000,000 and 1,992,000, respectively, of newly issued shares of common stock for \$38.00 per share (\$36.67 per share net of commissions and expenses) resulting in net proceeds of \$659,767.

Stock Splits

On June 20, 2001, the Company's Board of Directors declared a four for three stock split for shareholders of record as of July 3, 2001, which was distributed July 19, 2001. The stock split has been reflected in all share data contained in these consolidated financial statements.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Repurchase Program

On May 13, 2002, the Company's Board of Directors authorized a plan to repurchase up to 7.5 million shares of the Company's common stock. Under the plan, the Company could repurchase shares of its common stock in the open-market from time to time, depending on market conditions, share price and other factors. During the year ended December 31, 2002, the Company completed the plan, repurchasing 7.5 million shares for a total purchase price of \$166,274.

Accumulated Other Comprehensive Income

Accumulated other comprehensive income consists of the following components:

	2002	2003
Net unrealized gains on marketable securities, net of tax	\$ 45	\$ 719
Foreign currency translation, net of tax		394
	<u>\$ 45</u>	<u>\$ 1,113</u>

Stock Option Plans

The Company has various incentive stock plans for executives and employees. In connection with the plans, options to purchase common stock are granted at option prices not less than the fair market values of the common stock at the time the options are granted and either vest immediately or ratably over a period of up to ten years from the grant date. As of December 31, 2003, options for 8,802,537 shares of common stock are available for future grant. A total of 4,648,646, 4,908,317 and 3,849,864 options to purchase common stock were outstanding under these plans as of December 31, 2001, 2002 and 2003, respectively, of which 3,276,934, 4,211,652, and 3,561,167, respectively, were exercisable.

Certain of the incentive stock plans allow for employee payment of option exercise prices in the form of either cash or previously held common stock of the Company. Shares tendered in payment of the option exercise price must be owned by the employee making the tender, for either six months or one year depending on how the shares were acquired, prior to the date of tender.

A summary of the status of the Company's plans as of December 31, 2003 and changes during the years ended December 31, 2001, 2002 and 2003 are presented in the table below:

	2001	2002	2003
Outstanding options, January 1	5,882,509	4,648,646	4,908,317
Exercised	(1,972,628)	(436,160)	(578,245)
Granted	915,712	895,750	101,000
Cancelled	(176,947)	(199,919)	(581,208)
Outstanding options, December 31	<u>4,648,646</u>	<u>4,908,317</u>	<u>3,849,864</u>
Weighted average price of options outstanding, January 1	\$ 15.45	\$ 20.83	\$ 21.27

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Weighted average price of options exercised	\$ 13.46	\$ 9.95	\$ 7.31
Weighted average price of options granted	\$ 38.39	\$ 19.69	\$ 13.95
Weighted average price of options cancelled	\$ 15.67	\$ 28.52	\$ 25.90
Weighted average price of options outstanding, December 31	\$ 20.83	\$ 21.27	\$ 22.48

F-36

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Options outstanding at December 31, 2003 have exercise prices between \$4.67 and \$44.26, with a weighted average exercise price of \$22.48 and a remaining contractual life of approximately 6.22 years.

Range of Exercise Prices per Share	Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life in Years
Outstanding:			
\$4.67-\$18.96	1,075,073	\$ 8.36	3.51
\$18.98-\$29.81	1,453,783	20.85	7.15
\$30.25-\$44.26	1,321,008	35.77	7.41
\$4.67-\$44.26	3,849,864	\$22.48	

Range of Exercise Prices per Share	Shares	Weighted Average Exercise Price per Share
Exercisable:		
\$4.67-\$18.96	959,818	\$ 7.77
\$18.98-\$29.81	1,281,091	20.92
\$30.25-\$44.26	1,320,258	35.77
\$4.67-\$44.26	3,561,167	\$22.88

During 2001, 2002 and 2003, the Company granted 53,332, 50,000 and 70,000 options, respectively, of common stock to its directors under the 1998 Stock Option Plan at an exercise price equal to market value at the date of grant. The options vested immediately upon grant for the 2001 and 2002 grants and after one year of service for the 2003 grant. Options totaling 304,965 issued under the 1998 Stock Option Plan were outstanding at December 31, 2003 of which 234,965 were fully vested. Options under the 1998 Stock Option Plan expire 10 years from the date of grant. These options are included in amounts reflected in the above tables.

21. Income per Common Share

The basic and diluted income per common share was determined based on the following share data:

	2001	2002	2003
Basic income per common share:			
Weighted average common shares	231,542,983	244,375,770	240,989,093
Diluted income per common share:			
Weighted average common shares	231,542,983	244,375,770	240,989,093
Effect of dilutive stock options	2,363,376	1,322,898	537,540

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Weighted average common shares	<u>233,906,359</u>	<u>245,698,668</u>	<u>241,526,633</u>
--------------------------------	--------------------	--------------------	--------------------

The weighted average stock options that were anti-dilutive at December 31, 2001, 2002 and 2003 were 220,431, 1,669,922, and 3,034,318 shares, respectively. The convertible debentures could also be converted into 6,877,990 shares of common stock in the future, subject to certain contingencies outlined in the indenture (Note 12). Because such contingencies were not fulfilled, the convertible debentures were not considered in the calculation of diluted income per common share.

F-37

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

22. Recently Adopted Accounting Pronouncements

In the first quarter of 2002, the Company adopted SFAS No. 141, Business Combinations, and SFAS No. 142 Goodwill and Other Intangible Assets. SFAS No. 141 requires all business combinations to be accounted for under the purchase method of accounting. SFAS No. 141 was effective for all business combinations initiated after June 30, 2001. SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment.

SFAS No. 142 also required an additional impairment test for existing goodwill (\$12,742) and for the indefinite-lived intangible assets (\$19,192) that existed at the time SFAS No. 142 was adopted to determine whether any write-down was required as of the beginning of 2002. Upon completion of such testing, management determined that no write-down to the carrying value of these assets was required.

The following table reflects consolidated results adjusted as though the adoption of SFAS No. 142 occurred as of January 1, 2001:

	For the Year Ended December 31,		
	2001	2002	2003
Net income:			
As reported:	\$ 217,936	\$ 182,520	\$ 105,856
Goodwill amortization	408		
Indefinite-life intangibles amortization	595		
As adjusted	\$ 218,939	\$ 182,520	\$ 105,856
Basic income per common share:			
As reported:	\$ 0.94	\$ 0.75	\$ 0.44
Goodwill amortization	0.01		
Indefinite-life intangibles amortization	0.01		
As adjusted	\$ 0.95	\$ 0.75	\$ 0.44
Diluted income per common share:			
As reported:	\$ 0.93	\$ 0.74	\$ 0.44
Goodwill amortization	0.01		
Indefinite-life intangibles amortization	0.01		
As adjusted	\$ 0.94	\$ 0.74	\$ 0.44

In May 2002, the Financial Accounting Standards Board issued SFAS No. 145, Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections as of April 2002. SFAS No. 145 was effective for fiscal periods beginning after May 15, 2002. The primary impact on the Company of adopting SFAS No. 145 was that gains and losses incurred upon the extinguishment of debt will no longer qualify for extraordinary item treatment in the income statement but will normally be presented as a non-operating gain or loss. Accordingly, the Company reclassified the loss incurred upon the extinguishment of debt during the year ended December 31, 2001 to other expense.

23. Restructuring Activities and Executive Retirements

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

During 2002, the Company consolidated the international division into the Company's operations in Bristol, Tennessee, decided to sell the veterinary business, and decided to terminate production at one of its facilities. These activities eliminated approximately 35 employee positions of which approximately 16 were hourly and 19 were salaried. Also during 2002, two executives retired and were paid \$4,325.

F-38

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Accordingly, the Company incurred a charge of \$5,911 during the year ended December 31, 2002. The Company had \$2,216 accrued relating to these activities as of December 31, 2002, which was paid during 2003.

24. Quarterly Financial Information (unaudited)

The following table sets forth summary financial information for the years ended December 31, 2002 and 2003:

2002 By Quarter	First	Second	Third	Fourth
Total revenues	\$258,065	\$282,533	\$315,705	\$272,032
Gross profit	209,957	227,305	252,143	143,954
Operating income (loss)	112,261	117,424	129,967	(65,451)
Net income (loss)	71,320	58,398	84,245	(31,442)
Basic income (loss) per common share(1):				
Net income (loss)	\$ 0.29	\$ 0.24	\$ 0.35	\$ (0.13)
Diluted income (loss) per common share(1):				
Net income (loss)	\$ 0.29	\$ 0.24	\$ 0.35	\$ (0.13)
2003 By Quarter	First	Second	Third	Fourth
Total revenues	\$343,843	\$370,710	\$424,204	\$382,631
Gross profit	263,803	278,601	333,783	260,438
Operating income (loss)	(7,460)	(57,211)	160,406	70,379
Net income (loss)	(7,193)	(35,015)	106,087	41,977
Basic (loss) income per common share(1):				
Net (loss) income	\$ (0.03)	\$ (0.15)	\$ 0.44	\$ 0.17
Diluted (loss) income per common share(1):				
Net (loss) income	\$ (0.03)	\$ (0.15)	\$ 0.44	\$ 0.17

(1) Quarterly amounts do not total to annual amounts due to the effect of rounding on a quarterly basis.

The information shown above for the fourth quarter of 2002 reflects significant charges consisting of a \$46.5 million adjustment to the Company's accrual for estimated amounts due under Medicaid and other governmental pricing programs. Included in the \$46.5 million adjustment are amounts representing corrections of immaterial errors. The impact of these immaterial errors in each of the three quarters prior to the fourth quarter of 2002 on revenues is \$5,495, \$2,831, and \$2,070, respectively, and on diluted income per common share is \$0.02, \$0.01, and \$0.01, respectively.

The information shown above for the fourth quarter 2003 reflects

an \$18,000 adjustment reducing total revenues for estimated amounts due under Medicaid for the period from 1998 to 2002,

a \$900 adjustment reducing total revenues for estimated amounts due under Medicaid for the period from 1994 to 1997,

a \$280 adjustment reducing royalty expense related to royalties due on the Company's Altace® product as a result of the Medicaid adjustment during 2003 described above,

a \$15,212 adjustment reducing the co-promotion fees paid to our Altace® co-promotion colleague as a result of the charges described above for amounts due under Medicaid and other governmental pricing programs for the years 1998 to 2002. Specifically (a) the Company

recovered on a pre-tax basis \$9,514 in fees which the Company previously accrued during the fourth quarter of 2002 and

F-39

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

has reduced the accrual for these fees by this amount in the fourth quarter of 2003 and (b) fees under the Co-Promotion Agreement for Altace® in the fourth quarter of 2003 were reduced on a pre-tax basis by an additional \$5,698 as a result of the Medicaid accrual adjustment recorded in that quarter.

25. Subsequent Events

On February 19, 2004, Jefferson J. Gregory announced his plan to retire as the Chief Executive Officer of the Company. The Company's Board of Directors has begun a search for a new Chief Executive Officer and Mr. Gregory intends to continue as Chief Executive Officer until a successor is appointed.

On February 19, 2004 the Company transferred an additional \$19,000 into escrow to cover the additional Medicaid accrual for the period from 1994 to 2002. This amount has been reflected as restricted cash in the accompanying financial statements.

26. Guarantor Financial Statements

Each of the Company's subsidiaries, except Monarch Pharmaceuticals Ireland Limited formed in January, 2003 (the Guarantor Subsidiaries), has guaranteed, on a full, unconditional and joint and several basis, the Company's performance under the \$345,000, 2 3/4% Convertible Debentures due 2021 and under the \$400,000 Senior Secured Revolving Credit Facility on a joint and several basis. There are no restrictions under the Company's financing arrangements on the ability of the Guarantor Subsidiaries to distribute funds to the Company in the form of cash dividends, loans or advances. The following combined financial data provides information regarding the financial position, results of operations and cash flows of the Guarantor Subsidiaries (condensed consolidating financial data). Separate financial statements and other disclosures concerning the Guarantor Subsidiaries are not presented because management has determined that such information would not be material to the holders of the debt.

KING PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING BALANCE SHEETS

December 31, 2002

	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 594,385	\$ (6,160)	\$	\$ 588,225
Marketable securities	227,263			227,263
Restricted cash				
Accounts receivable, net	17,352	151,469	(8,834)	159,987
Inventories	45,761	121,392		167,153
Deferred income tax assets	36,328	69,840		106,168
Prepaid expenses and other current assets	7,996	4,910		12,906
Total current assets	929,085	341,451	(8,834)	1,261,702
Property, plant, and equipment, net	51,587	165,527		217,114
Goodwill		12,742		12,742
Intangible assets, net	892,793	326,778		1,219,571
Other assets	25,254	14,277		39,531
Deferred income tax assets				
Investment in subsidiaries	1,126,245		(1,126,245)	
Total assets	\$ 3,024,964	\$ 860,775	\$ (1,135,079)	\$ 2,750,660
LIABILITIES AND SHAREHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$ 26,119	\$ 32,604	\$ (8,834)	\$ 49,889
Accrued expenses	42,542	254,986		297,528
Income taxes payable	18,870	2,377		21,247
Current portion of long-term debt	1,300			1,300
	88,831	289,967	(8,834)	369,964

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Total current liabilities				
Long-term debt	345,093			345,093
Deferred income tax liabilities	11,991	21,605		33,596
Other liabilities	70,074	750		70,824
Intercompany (receivable) payable	577,792	(577,792)		
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total liabilities	1,093,781	(265,470)	(8,834)	819,477
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Shareholders' equity	1,931,183	1,126,245	(1,126,245)	1,931,183
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total liabilities and shareholders' equity	\$ 3,024,964	\$ 860,775	\$ (1,135,079)	\$ 2,750,660
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

[Additional columns below]

[Continued from above table, first column(s) repeated]

December 31, 2003

	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland Limited	Eliminating Entries	King Consolidated
ASSETS							
Current assets:							
Cash and cash equivalents	\$ 140,617	\$ 3,641	\$	\$ 144,258	\$ 1,795	\$	\$ 146,053
Marketable securities							
Restricted cash	67,199	66,770		133,969			133,969
Accounts receivable, net	4,529	240,574		245,103	1,314		246,417
Inventories	228,093	36,554		264,647	251		264,898
Deferred income tax assets	16,428	108,502		124,930			124,930
Prepaid expenses and other current assets	5,249	24,787		30,036			30,036
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total current assets	462,115	480,828		942,943	3,360		946,303
Property, plant, and equipment, net	115,442	142,217		257,659			257,659
Goodwill		121,355		121,355			121,355
Intangible assets, net	6,955	1,742,536		1,749,491	7,502		1,756,993
Other assets	45,410	30,707		76,117			76,117
Deferred income tax assets	14,831	4,476		19,307			19,307
Investment in subsidiaries	2,307,745		(2,302,228)	5,517		(5,517)	
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Total assets	\$2,952,498	\$2,522,119	\$ (2,302,228)	\$3,172,389	\$ 10,862	\$ (5,517)	\$3,177,734
LIABILITIES AND SHAREHOLDERS EQUITY							
Current liabilities:							
Accounts payable	\$ 51,924	\$ 31,135	\$	\$ 83,059	\$ 19	\$	\$ 83,078
Accrued expenses	55,764	450,269		506,033			506,033
Income taxes payable	78,363	838		79,201	440		79,641
Current portion of long-term debt	97			97			97
Total current liabilities	186,148	482,242		668,390	459		668,849
Long-term debt	345,000			345,000			345,000
Deferred income tax liabilities							
Other liabilities	50,953	70,752		121,705			121,705
Intercompany (receivable) payable	329,396	(333,103)		(3,707)	3,707		
Total liabilities	911,497	219,891		1,131,388	4,166		1,135,554
Shareholders equity	2,041,001	2,302,228	(2,302,228)	2,041,001	6,696	(5,517)	2,042,180
Total liabilities and shareholders equity	\$2,952,498	\$2,522,119	\$ (2,302,228)	\$3,172,389	\$ 10,862	\$ (5,517)	\$3,177,734

F-41

GUARANTOR SUBSIDIARIES

CONSOLIDATING STATEMENTS OF OPERATIONS

	December 31, 2001				December 31, 2002			
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Revenues:								
Net sales	\$ 27,206	\$ 821,469	\$ (23,187)	\$ 825,488	\$ 235,154	\$ 1,067,981	\$ (233,175)	\$ 1,069,960
Royalty revenue		46,774		46,774		58,375		58,375
Total revenues	27,206	868,243	(23,187)	872,262	235,154	1,126,356	(233,175)	1,128,335
Operating costs and expenses:								
Costs of revenues	26,425	183,326	(23,187)	186,564	122,922	405,229	(233,175)	294,976
Selling, general and administrative	12,660	228,220		240,880	14,166	352,757		366,923
Depreciation and amortization	23,381	24,585		47,966	35,658	23,639		59,297
Research and development	8,199	18,308		26,507	12,676	27,508		40,184
Intangible asset impairment					66,844			66,844
Merger, restructuring and other nonrecurring charges	(361)	4,440		4,079		5,911		5,911
Gain on sale of intangible assets								
Total operating costs and expenses	70,304	458,879	(23,187)	505,996	252,266	815,044	(233,175)	834,135
Operating income	(43,098)	409,364		366,266	(17,112)	311,312		294,200
Other income (expense):								
Interest income	9,472	1,503		10,975	21,227	1,168		22,395
Interest expense	(13,398)	714		(12,684)	(12,400)	(19)		(12,419)
Valuation charge					(35,629)			(35,629)

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

convertible notes receivable								
Extinguishment of debt expense	(22,903)			(22,903)				
Other, net	8,593	(2,280)		6,313	(190)	(694)		(884)
Equity in earnings of subsidiaries	246,856		(246,856)		202,483		(202,483)	
Intercompany interest (expense)	16,147	(16,147)			8,916	(8,916)		
Total other income (expense)	244,767	(16,210)	(246,856)	(18,299)	184,407	(8,461)	(202,483)	(26,537)
Income before income taxes and cumulative effect of change in accounting principle	201,669	393,154	(246,856)	347,967	167,295	302,851	(202,483)	267,663
Income tax (expense) benefit	16,812	(146,298)		(129,486)	15,225	(100,368)		(85,143)
Income (loss) before cumulative effect of change in accounting principle	218,481	246,856	(246,856)	218,481	182,520	202,483	(202,483)	182,520
Cumulative effect of change in accounting principle	(545)			(545)				
Net income	\$ 217,936	\$ 246,856	\$ (246,856)	\$ 217,936	\$ 182,520	\$ 202,483	\$ (202,483)	\$ 182,520

[Additional columns below]

[Continued from above table, first column(s) repeated]

December 31, 2003

	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland Limited	King Consolidated
Revenues:						
Net sales	\$ 329,974	\$ 1,449,474	\$ (329,481)	\$ 1,449,967	\$ 3,056	\$ 1,453,023
Royalty revenue		68,365		68,365		68,365

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Total revenues	<u>329,974</u>	<u>1,517,839</u>	<u>(329,481)</u>	<u>1,518,332</u>	<u>3,056</u>	<u>1,521,388</u>
Operating costs and expenses:						
Costs of revenues	145,931	567,431	(329,481)	383,881	882	384,763
Selling, general and administrative	65,800	429,361		495,161	106	495,267
Depreciation and amortization	8,013	116,139		124,152	423	124,575
Research and development	900	237,178		238,078		238,078
Intangible asset impairment	7,425	117,191		124,616		124,616
Merger, restructuring and other nonrecurring charges						
Gain on sale of intangible assets	<u>(810)</u>	<u>(11,215)</u>	<u></u>	<u>(12,025)</u>	<u></u>	<u>(12,025)</u>
Total operating costs and expenses	<u>227,259</u>	<u>1,456,085</u>	<u>(329,481)</u>	<u>1,353,863</u>	<u>1,411</u>	<u>1,355,274</u>
Operating income	<u>102,715</u>	<u>61,754</u>	<u></u>	<u>164,469</u>	<u>1,645</u>	<u>166,114</u>
Other income (expense):						
Interest income	5,960	889		6,849		6,849
Interest expense	(13,391)	(5)		(13,396)		(13,396)
Valuation charge convertible notes receivable	18,151			18,151		18,151
Extinguishment of debt expense						
Other, net	(649)	(150)		(799)	170	(629)
Equity in earnings of subsidiaries	60,110		(60,110)			
Intercompany interest (expense)	<u>(9,567)</u>	<u>9,567</u>	<u></u>	<u></u>	<u></u>	<u></u>
Total other income (expense)	<u>60,614</u>	<u>10,301</u>	<u>(60,110)</u>	<u>10,805</u>	<u>170</u>	<u>10,975</u>
Income before income taxes and cumulative effect of change in accounting principle	163,329	72,055	(60,110)	175,274	1,815	177,089
Income tax (expense) benefit	<u>58,652</u>	<u>11,945</u>	<u></u>	<u>70,597</u>	<u>636</u>	<u>71,233</u>
Income (loss) before cumulative effect of change in accounting principle	104,677	60,110	(60,110)	104,677	1,179	105,856
Cumulative effect of change in accounting						

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

principle

Net income	<u>104,677</u>	<u>60,110</u>	<u>\$ (60,110)</u>	<u>\$ 104,677</u>	<u>\$1,179</u>	<u>\$ 105,856</u>
------------	----------------	---------------	--------------------	-------------------	----------------	-------------------

F-42

KING PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)
GUARANTOR SUBSIDIARIES
CONSOLIDATING STATEMENTS OF CASH FLOWS

	December 31, 2001				December 31, 2002			
	King	Subsidiaries	Eliminations	King Consolidated	King	Subsidiaries	Eliminations	King Consolidated
Cash flows from operating activities:								
Net income	\$ 217,936	\$ 246,856	\$(246,856)	\$ 217,936	\$ 182,520	\$ 202,483	\$(202,483)	\$ 182,520
Equity in earnings of subsidiaries	(246,856)		246,856		(202,483)		202,483	
Adjustments to reconcile net income to net cash provided by Operating activities:								
Depreciation and amortization	23,383	24,583		47,966	36,333	23,638		59,971
Amortization of deferred financing costs	1,040			1,040	2,898			2,898
Extinguishment of debt expense	22,902			22,902				
Cumulative effect of change in accounting principle	870			870				
Stock compensation charge	3,229			3,229				
Write-down of inventory						15,152		15,152
Deferred income taxes	14,957	252		15,209	(29,972)	(48,089)		(78,061)
Valuation charge on convertible notes receivable					35,443			35,443
Net unrealized gain on convertible senior notes	(8,546)			(8,546)				
Tax benefits of stock options exercised	12,430			12,430	2,206			2,206
Impairment of intangible assets					66,844			66,844
In-process research and development charges					12,000			12,000
Gain on sales of intangible assets								
Other non-cash items, net	(15)	2,963		2,948	(873)	5,398		4,525

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Changes in operating assets and liabilities:								
Accounts receivable	(5,829)	(42,069)	3,784	(44,114)	(4,617)	(2,787)	3,691	(3,713)
Inventories	(14,827)	(31,662)		(46,489)	(27,078)	(43,649)		(70,727)
Prepaid expenses and other current assets	17,010	(17,494)		(484)	(6,330)	1,240		(5,090)
Other assets	(993)	4,129		3,136	3	(1,023)		(1,020)
Accounts payable	1,902	(7,840)	(3,784)	(9,722)	21,338	13,671	(3,691)	31,318
Accrued expenses and other liabilities	(4,667)	46,186		41,519	53,476	143,828		197,304
Deferred revenue	(9,247)			(9,247)	(9,090)			(9,090)
Income taxes	16,540	12,437		28,977	23,589	(10,060)		13,529
Net cash flows (used in) provided by operating activities	41,219	238,341		279,560	156,207	299,802		456,009
Cash flows from investing activities:								
Purchase of investment securities	(49,880)			(49,880)	(823,112)			(823,112)
Proceeds from maturity and sale of investment securities					645,798			645,798
Transfer (to)/from restricted cash								
Convertible senior note	(10,000)			(10,000)	(10,000)			(10,000)
Loans receivable		(15,000)		(15,000)				
Purchases of property, plant and equipment	(12,064)	(28,103)		(40,167)	(15,214)	(58,373)		(73,587)
Acquisition of primary care business of Elan								
Acquisition of Meridian								
Purchases of intangible assets	(286,500)			(286,500)	(322,100)			(322,100)
Proceeds from loan receivable		14,086		14,086		4,310		4,310
Proceeds from sale of intangible assets	3,332			3,332				
Other investing activities		1,446		1,446	28	4,360		4,388
Net cash used in investing activities	(355,112)	(27,571)		(382,683)	(524,600)	(49,703)		(574,303)
Cash flows from financing activities:								
Proceeds from revolving credit facility	75,000			75,000				
Payments on revolving credit	(75,000)			(75,000)				

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

facility								
Proceeds from issuance of common shares and exercise of stock options, net	684,435			684,435	4,402			4,402
Stock repurchases					(166,274)			(166,274)
Payment of senior subordinated debt	(115,098)			(115,098)				
Payments on other long-term debt	(1,460)	(29)		(1,489)	(1,348)	(13)		(1,361)
Proceeds from convertible debentures	345,000			345,000				
Debt issuance costs	(11,100)			(11,100)	(4,850)			(4,850)
Other	(418)			(418)				
Intercompany	212,609	(212,609)			248,457	(248,457)		
Net cash provided by (used in) financing activities	1,113,968	(212,638)		901,330	80,387	(248,470)		(168,083)
Increase (decrease) in cash and cash equivalents	800,075	(1,868)		798,207	(288,006)	1,629		(286,377)
Cash and cash equivalents, beginning of period	82,316	(5,921)		76,395	882,391	(7,789)		874,602
Cash and cash equivalents, end of period	\$ 882,391	\$ (7,789)	\$	\$ 874,602	\$ 594,385	\$ (6,160)	\$	\$ 588,225

[Additional columns below]

[Continued from above table, first column(s) repeated]

December 31, 2003

	King	Subsidiaries	Eliminations	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland Limited	King Consolidated
Cash flows from operating activities:						
Net income	\$ 104,677	\$ 60,110	\$(60,110)	\$ 104,677	1,179	105,856
Equity in earnings of subsidiaries	(60,110)		60,110			
Adjustments to reconcile net income to net cash provided by Operating activities:						
Depreciation and amortization	8,914	116,165		125,079	423	125,502
Amortization of deferred financing	3,160			3,160		3,160

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

costs						
Extinguishment of debt expense						
Cumulative effect of change in accounting principle						
Stock compensation charge						
Write-down of inventory						
Deferred income taxes	13,357	(143,950)		(130,593)		(130,593)
Valuation charge on convertible notes receivable	(18,151)			(18,151)		(18,151)
Net unrealized gain on convertible senior notes						
Tax benefits of stock options exercised						
Impairment of intangible assets	7,425	117,191		124,616		124,616
In-process research and development charges		194,000		194,000		194,000
Gain on sales of intangible assets	(805)	(11,215)		(12,020)		(12,020)
Other non-cash items, net	47	6,011		6,058		6,058
Changes in operating assets and liabilities:						
Accounts receivable	12,823	(86,861)	(8,834)	(82,872)	(1,314)	(84,186)
Inventories	(84,826)	32,095		(52,731)	411	(52,320)
Prepaid expenses and other current assets	1,189	26,118		27,307		27,307
Other assets	(2,570)	(8)		(2,578)		(2,578)
Accounts payable	(11,585)	37,440	8,834	34,689	19	34,708
Accrued expenses and other liabilities	11,853	56,286		68,139		68,139
Deferred revenue	(9,092)			(9,092)		(9,092)
Income taxes	97,062	(40,604)		56,458	440	56,898
Net cash flows (used in) provided by operating activities	73,368	362,778		436,146	1,158	437,304
Cash flows from investing activities:						
Purchase of investment securities	(25,903)			(25,903)		(25,903)

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Proceeds from maturity and sale of investment securities	253,097			253,097		253,097
Transfer (to)/from restricted cash	(67,743)			(67,743)		(67,743)
Convertible senior note						
Loans receivable						
Purchases of property, plant and equipment	(7,874)	(43,327)		(51,201)		(51,201)
Acquisition of primary care business of Elan		(761,745)		(761,745)		(761,745)
Acquisition of Meridian	(253,908)	15,410		(238,498)		(238,498)
Purchases of intangible assets	(9,000)	(10,300)		(19,300)		(19,300)
Proceeds from loan receivable		13,320		13,320		13,320
Proceeds from sale of intangible assets	14,460	1,199		15,659		15,659
Other investing activities	46	249		295		295
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Net cash used in investing activities	(96,825)	(785,194)		(882,019)		(882,019)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Cash flows from financing activities:						
Proceeds from revolving credit facility	125,000			125,000		125,000
Payments on revolving credit facility	(125,000)			(125,000)		(125,000)
Proceeds from issuance of common shares and exercise of stock options, net	4,053			4,053		4,053
Stock repurchases						
Payment of senior subordinated debt						
Payments on other long-term debt	(1,296)			(1,296)		(1,296)
Proceeds from convertible debentures						
Debt issuance costs	(214)			(214)		(214)
Other						
Intercompany	(432,854)	432,217		(637)	637	
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Net cash provided by (used in) financing activities	(430,311)	432,217		1,906	637	2,543
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Increase (decrease) in cash and cash equivalents	(453,768)	9,801		(443,967)	1,795	(442,172)

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

Cash and cash equivalents, beginning of period	594,385	(6,160)		588,225		588,225
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Cash and cash equivalents, end of period	\$ 140,617	\$ 3,641	\$	\$ 144,258	1,795	146,053
	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>

F-43

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-K

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

KING PHARMACEUTICALS, INC.

By: /s/ JEFFERSON J. GREGORY

Jefferson J. Gregory
Chairman and Chief Executive Officer

March 11, 2004

In accordance with the requirements of the Securities Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Signature	Capacity	Date
/s/ JEFFERSON J. GREGORY	Chairman and Chief Executive Officer	March 11, 2004
Jefferson J. Gregory		
/s/ JAMES R. LATTANZI	Chief Financial Officer (principal financial and accounting officer)	March 11, 2004
James R. Lattanzi		
/s/ EARNEST W. DEAVENPORT, JR.	Director	March 11, 2004
Earnest W. Deavenport, Jr.		
/s/ ELIZABETH M. GREETHAM	Director	March 11, 2004
Elizabeth M. Greetham		
/s/ GREGORY D. JORDAN	Director	March 11, 2004
Gregory D. Jordan		
/s/ R. CHARLES MOYER	Director	March 11, 2004
R. Charles Moyer		
/s/ PHILIP M. PFEFFER	Director	March 11, 2004
Philip M. Pfeffer		
/s/ D. GREG ROOKER	Director	March 11, 2004
D. Greg Rooker		
/s/ TED G. WOOD	Director	March 11, 2004
Ted G. Wood		

KING PHARMACEUTICALS, INC.
**Schedule II. Valuation and Qualifying Accounts
(In thousands)**

Column A	Column B	Column C Additions		Column D	Column E
Description	Balances at Beginning of Period	Charged to Cost and Expenses	Charged (Credited) to Other Accounts	Deductions(1)	Balance at End of Period
Allowance for doubtful accounts, deducted from accounts receivable in the balance sheet					
Year ended December 31, 2003	\$7,513	\$4,176	\$1,063	\$1,697	\$11,055
Year ended December 31, 2002	6,047	4,700	890	4,124	7,513
Year ended December 31, 2001	5,000	2,952		1,905	6,047
Valuation allowance for deferred tax assets, deducted from deferred income tax assets in the balance sheet					
Year ended December 31, 2003	\$	\$3,124	\$3,401	\$	\$ 6,525
Year ended December 31, 2002					
Year ended December 31, 2001					

(1) Amounts represent write-offs of accounts.

S-1