KING PHARMACEUTICALS INC
Form 10-Q
May 10, 2004

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2004

OR

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

For the transition period from _____ to _____

Commission File No. 0-24425

King Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Tennessee	**54-1684963**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
501 Fifth Street, Bristol, TN	**37620**
(Address of principal executive offices)	(Zip Code)

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

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

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No o

Number of shares outstanding of Registrant s common stock as of May 7, 2004: 241,383,201

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PART I FINANCIAL INFORMATION

Item 1. *Financial Statements*

KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	March 31, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 161,326	$ 146,053
Restricted cash	147,410	133,969
Accounts receivable, net of allowance for doubtful accounts of $9,295 and $11,055	193,002	246,417
Inventories	251,193	260,886
Deferred income taxes	127,589	124,930
Prepaid expenses and other current assets	46,048	30,036
Assets related to discontinued operations	1,530	4,012
Total current assets	928,098	946,303
Property, plant and equipment, net	263,216	257,659
Goodwill	134,892	121,355
Intangible assets, net	1,484,708	1,552,492
Other assets (includes restricted cash of $660 and $30,265)	45,988	76,117
Deferred income taxes	62,215	19,307
Assets related to discontinued operations	30,469	204,501
Total assets	$2,949,586	$3,177,734
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 49,306	$ 83,078
Accrued expenses	480,589	506,033
Income taxes payable	51,530	79,641
Notes payable	7,437	
Current portion of long-term debt	4	97
Total current liabilities	588,866	668,849
Long-term debt	345,000	345,000
Other liabilities	83,585	121,705
Total liabilities	1,017,451	1,135,554
Commitments and contingencies (Note 9)		
Shareholders equity	1,932,135	2,042,180
Total liabilities and shareholders equity	$2,949,586	$3,177,734

See accompanying notes.

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KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31,	
	2004	**2003**
Revenues:		
Net sales	$ 273,887	$322,997
Royalty revenue	16,757	15,424
Total revenues	290,644	338,421
Operating costs and expenses:		
Cost of revenues, exclusive of depreciation shown below	87,714	79,441
Selling, general and administrative, exclusive of co-promotion fees	86,602	44,115
Co-promotion fees	27,504	61,700
Total selling, general and administrative expenses	114,106	105,815
Research and development	16,023	9,636
Research and development-in process upon acquisition		18,000
Total research and development	16,023	27,636
Depreciation and amortization	39,318	17,637
Intangible asset impairment	34,936	110,970
Gain on sale of intangible assets	(858)	
Total operating costs and expenses	291,239	341,499
Operating loss	(595)	(3,078)
Other income (expense):		
Interest income	1,054	2,494
Interest expense	(3,105)	(3,034)
Valuation (charge) benefit convertible notes receivable	(49)	7,967
Other, net	(703)	(83)
Total other (expense) income	(2,803)	7,344
(Loss) income from continuing operations before income taxes	(3,398)	4,266
Income tax (benefit) expense	(1,048)	8,676
Loss from continuing operations	(2,350)	(4,410)
Discontinued operations:		
	(171,242)	(4,382)

Loss from discontinued operations, including expected loss on disposal		
Income tax benefit	(62,532)	(1,599)
Total loss from discontinued operations	(108,710)	(2,783)
Net loss	$ (111,060)	$ (7,193)
Loss per common share:		
Basic:		
Loss from continuing operations	$ (0.01)	$ (0.02)
Total loss from discontinued operations	(0.45)	(0.01)
Net loss	$ (0.46)	$ (0.03)
Diluted:		
Loss from continuing operations	$ (0.01)	$ (0.02)
Total loss from discontinued operations	(0.45)	(0.01)
Net loss	$ (0.46)	$ (0.03)

See accompanying notes.

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KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

AND OTHER COMPREHENSIVE INCOME
(Unaudited)
(In thousands, except share data)

	Common Stock		Retained Earnings	Accumulated Other Comprehensive Income	Total
	Shares	Amount			
Balance at December 31, 2002	240,624,751	$1,201,897	$ 729,241	$ 45	$1,931,183
Comprehensive income:					
Net loss			(7,193)		(7,193)
Net unrealized gain on marketable securities, net of tax of $137				254	254
Foreign currency translation, net of tax of $(28)				(52)	(52)
Total comprehensive loss					(6,991)
Stock option activity	266,319	1,883			1,883
Balance at March 31, 2003	240,891,070	$1,203,780	$ 722,048	$ 247	$1,926,075
Balance at December 31, 2003	241,190,852	$1,205,970	$ 835,097	$1,113	$2,042,180
Comprehensive income:					
Net loss			(111,060)		(111,060)
Net unrealized loss on marketable securities, net of tax of $(16)				(30)	(30)
Foreign currency translation, net of tax of $56				99	99
Total comprehensive loss					(110,991)
Stock option activity	177,792	946			946
Balance at March 31, 2004	241,368,644	$1,206,916	$ 724,037	$1,182	$1,932,135

See accompanying notes.

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KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2004	**2003**
Cash flows from operating activities of continuing operations	$ 60,318	$ 79,425
Cash flows from investing activities of continuing operations:		
Transfer to restricted cash	(351)	
Purchases of marketable securities		(25,903)
Proceeds from sale of marketable securities		253,097
Proceeds from loan receivable	248	3,711
Purchases of property, plant and equipment	(12,585)	(12,842)
Proceeds from sale of property and equipment		12
Payment of contingent consideration	(36,000)	
Investment in Meridian Medical Technologies, Inc., net of cash acquired		(237,682)
Purchases of product rights		(9,000)
Net cash used in investing activities of continuing operations	(48,688)	(28,607)
Cash flows from financing activities of continuing operations:		
Proceeds from exercise of stock options, net	946	1,864
Payments on other long-term debt and capital lease obligations	(93)	(50)
Debt issuance costs		(214)
Net cash provided by financing activities of continuing operations	853	1,600
Net cash provided by (used in) discontinued operations	2,790	(1,738)
Increase in cash and cash equivalents	15,273	50,680
Cash and cash equivalents, beginning of period	146,053	588,225
Cash and cash equivalents, end of period	$161,326	$ 638,905

See accompanying notes.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2004 and 2003
(Unaudited)
(In thousands)

1. General

The accompanying unaudited interim condensed consolidated financial statements of King Pharmaceuticals, Inc. (King or the Company) have been prepared by the Company in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X, and accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of items of a normal recurring nature) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. These consolidated statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2003. The year-end condensed balance sheet was derived from the audited consolidated financial statements but does not include all disclosures required by generally accepted accounting principles.

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.

Certain amounts from prior consolidated financial statements have been reclassified to conform to the presentation in 2004.

2. Stock Compensation

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards (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 common share would have decreased to the following pro forma amounts:

	Three Months Ended March 31,	
	2004	**2003**
Net income:		
As reported	$(111,060)	$(7,193)
Compensation costs for options granted	(1,191)	(157)
Pro forma	$(112,251)	$(7,350)
Diluted income per common share:		
Net income:		
As reported	$ (0.46)	$ (0.03)
Pro forma	$ (0.47)	$ (0.03)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. Earnings Per Share

The basic and diluted income per common share was determined using the following share data:

	Three Months Ended March 31,	
	2004	**2003**
Basic loss per common share:		
Weighted average common shares	241,300	240,777
Diluted loss per common share:		
Weighted average common shares	241,300	240,777
Effect of stock options		
Weighted average common shares	241,300	240,777

For the three months ended March 31, 2004 and March 31, 2003, options to purchase 915 and 1,406 shares of common stock, respectively, were not included in the computation of diluted earnings per share because their inclusion would have been antidilutive and would have reduced the loss per share. The Company s convertible debentures could also be converted into 6,878 shares of common stock in the future, subject to certain contingencies outlined in the indenture. Because such contingencies were not fulfilled, the convertible debentures were not considered in the calculation of diluted income per common share.

4. Inventories

Inventories consist of the following:

	March 31, 2004	**December 31, 2003**
Raw materials	$139,706	$139,675
Work-in-process	18,431	11,508
Finished goods (including $17,654 and $18,252 of sample inventory, respectively)	153,682	140,307
	311,819	291,490
Inventory valuation allowance	(60,626)	(30,604)
	$251,193	$260,886

5. Property, Plant and Equipment

The Company s Rochester facility manufactures products for the Company and various third parties. At March 31, 2004, 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 $83,392 and $27,430, respectively. Overall production volume at this facility has been declining. The Company currently has plans to transfer to this facility the manufacture of certain products that are currently manufactured for the Company by third parties. This should increase production and cash flow 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.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. 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. On January 8, 2003, the Company completed its acquisition of Meridian Medical Technologies, Inc. (Meridian). 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 three months ended March 31, 2003 (including the effects of charges for in-process research and development). 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, nor are they indicative of future results.

	Three Months Ended March 31, 2003
Total revenues from continuing operations	$ 391,277
Net loss	$(121,275)
Basic loss per common share	$ (0.50)
Diluted loss per common share	$ (0.50)

7. Intangible Assets and Goodwill

The following table reflects the components of intangible assets as of March 31, 2004:

	Gross Carrying Amount	Accumulated Amortization
Trademarks and product rights	$1,488,925	$181,706
Patents	258,300	82,549
Other intangibles	9,470	7,732
Total intangible assets	$1,756,695	$271,987

Amortization expense for the three months ended March 31, 2004 and 2003 was $32,847 and $13,408, respectively. Estimated annual amortization expense as of March 31, 2004 for each of the five succeeding fiscal years is as follows:

Fiscal Year Ended December 31:	Amount
2004	$133,035

2005	107,435
2006	88,106
2007	85,532
2008	78,505

During the first quarter of 2004, the Company recorded intangible asset impairment charges totaling $34,936 primarily due to a greater than anticipated decline in prescriptions for Florinef® and Tapazole® as a result of the availability of generics for these products. 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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

value of the Florinef® intangible assets. The additional intangible asset impairment charge pertaining to Florinef® recorded in the first quarter of 2004 reflects a further reduction in the fair value of the Florinef intangible assets due to a decline in prescriptions for the product which is in excess of the Company s original estimate. The Company determined the fair value of the intangible assets associated with Florinef® and Tapazole® based on management s discounted cash flow projections for these products. Florinef® and Tapazole® are included in the Company s branded pharmaceuticals 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 March 31, 2004, the Company had net intangible assets related to Cortisporin® of $18,008. 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 Neosporin®, Septra®, and another small branded pharmaceutical product have continued to decline over the past two years. At March 31, 2004, these products have net intangible assets associated with them totaling $19,201. 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 these products.

During the first quarter of 2004, the Company performed its annual review of intangible asset lives for amortization purposes. As a result of this review, the Company reduced the lives of some of its branded pharmaceutical products, to reflect management s current view of such intangibles future utilization.

Goodwill at December 31, 2003 and March 31, 2004 is as follows:

	Branded Segment	Meridian Segment	Total
Goodwill at December 31, 2003	$12,742	$108,613	$121,355
Goodwill associated with Elan primary care business acquisition	13,537		13,537
Goodwill at March 31, 2004	$26,279	$108,613	$134,892

During the first quarter of 2004, the Company paid a $25,000 milestone payment to Elan relating to the continued exclusivity of Skelaxin® and an $11,000 milestone payment to Elan in connection with the development of new formulations of Sonata®. These milestone payments increased goodwill to the extent they were not accrued by the Company at the time of purchase.

8. Discontinued Operations

An ongoing clinical trial, the Women s Health Initiative, is being conducted by the National Institutes of Health. Data from the 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 markets including the Company s products Prefest® and Menest®. Prescriptions for some of the Company s other women s health products have also continued to decline over the past few years primarily due to the availability of generics. Accordingly, during the first quarter of 2004, the Company s Board of Directors approved management s decision to market for divestiture many of the Company s women s health products, including Prefest®, Nordette®, and Menest®. The Company is now actively marketing these assets to potential purchasers and plans to divest such assets within the next year.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Prefest® and Nordette® product rights held for sale have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities and have been classified as discontinued operations in the accompanying financial statements. The Company wrote down intangible assets by the amount of $169,591 to reduce the carrying value of the intangible assets associated with these products to their estimated fair value less costs to sell. The Company determined the fair value of these intangible assets based on management s discounted cash flow projections for the products less expected selling costs. Prefest® and Nordette® are included in the Company s branded pharmaceuticals segment.

The major classes of assets associated with discontinued operations in the accompanying financial statements are as follows:

	March 31, 2004	December 31, 2003
Inventories	$ 1,530	$ 4,012
Intangible assets, net	30,469	204,501
Total assets	$31,999	$208,513

Summarized financial information for the discontinued operations are as follows:

	Three Months Ended	
	March 31, 2004	March 31, 2003
Total revenues	$ 6,998	$ 5,422
Operating loss, including expected loss on disposal	(171,242)	(4,382)
Net loss	(108,710)	(2,783)

9. 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.

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 potential 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 861 multi-defendant lawsuits involving the manufacture and sale of dexfen-

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

fluramine, 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 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 potential 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 has filed motions to dismiss 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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. Subsequent to that time, King s outside consultants conducted a comprehensive audit to determine the actual amount of underpayments under Medicaid during the period from 1998 to 2002. As a result of that audit, King determined that its accrual for estimated amounts due under Medicaid and other governmental pricing programs through December 31, 2002, should be increased by $18,000. In addition, based on the results of the comprehensive audit for the period from 1998 through 2002, the Company estimated that it underpaid amounts due Medicaid by $900 during the period from 1994 through 1997. Accordingly, results for the fourth quarter of 2003 included 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 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 constituted a change in an accounting estimate effective as of December 31, 2003. The change resulted principally from two factors. First, the 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 reflected 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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 its 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).

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 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.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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. In March 2004, Cobalt stipulated to infringement of the 722 patent. Should the court find in favor of a Cobalt summary judgment motion on the validity of 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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, capricious, and inconsistent with the FDA s previous position on this issue. On March 18, 2004, the Company filed a Citizen s Petition with the FDA requesting reinstatement of the FDA s previous policy on this issue and a requirement that all ANDA applicants include this use in their product labeling. If the Company s Citizen s Petition is rejected, 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. The Company does not believe that unfavorable outcomes as a result of these routine legal proceedings will have a material adverse effect on its financial position, results of operations and cash flows.

10. Accounting Developments

In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46). In December 2003, the FASB revised FIN 46 to

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

discuss certain FIN 46 implementation issues. The revised provisions are applicable no later than the first reporting period ending after March 15, 2004. 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 has evaluated its relationship with Novavax and determined that Novavax is not currently a variable interest entity that is required to be consolidated in the Company s financial statements under FIN 46.

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. Following regulatory approval, 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 Estrasorb™ was approved by the U.S. Food and Drug Administration during October 2003. King owns approximately 0.9% of Novavax common stock. The Company s estimate of maximum exposure to loss as a result of its contractual relationships with Novavax is $32,309.

Novavax is a fully-integrated specialty biopharmaceutical company focused on research, development and commercialization of products utilizing its drug delivery and vaccine technologies for large and growing markets, concentrating on the areas of women s health and infectious diseases. At December 31, 2003, Novavax reported total assets of $84.2 million, total liabilities of $48.2 million, revenues for the year ended December 31, 2003 of $11.8 million, and a net loss of $17.3 million for the year ended December 31, 2003.

11. 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 seven therapeutic areas, including cardiovascular, endocrinology/women s health, neuroscience, critical care, anti-infective, respiratory, and other. Such branded prescription products have been aggregated because of the similarity in regulatory environment, manufacturing processes, methods of distribution, and the types of customer. The Meridian Medical Technologies segment was added as 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 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.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following represents selected information for the Company s reportable segments for the periods indicated:

	Three Months Ended March 31,	
	2004	**2003**
Total revenues:		
Branded pharmaceuticals	$ 233,208	$290,963
Meridian Medical Technologies	34,501	25,640
Royalties	16,757	15,424
Contract manufacturing	132,892	92,262
Eliminations	(126,714)	(85,868)
Consolidated total net revenues	$ 290,644	$338,421
Segment profit:		
Branded pharmaceuticals	$ 171,031	$237,710
Meridian Medical Technologies	19,454	7,948
Royalties	14,177	12,416
Contract manufacturing	(1,732)	906
Consolidated segment profit, excluding depreciation	$ 202,930	$258,980
Other operating costs and expense	203,525	262,058
Operating loss	$ (595)	$ (3,078)

The March 31, 2003 segment profit amounts reflect a reclassification of $5,165, decreasing the branded pharmaceuticals segment profit and increasing the contract manufacturing segment profit, from amounts previously reported as a result of the reclassification of certain expenses.

	As of March 31, 2004	As of December 31, 2003
Total assets:		
Branded pharmaceuticals	$2,659,962	$2,897,137
Meridian Medical Technologies	260,344	250,935
Royalties	17,734	20,032
Contract manufacturing	92,908	90,992
All other	10	10
Eliminations	(81,372)	(81,372)
Consolidated total assets	$2,949,586	$3,177,734

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following represents branded pharmaceutical revenues by therapeutic area:

	Three Months Ended March 31,	
	2004	**2003**
Total revenues:		
Cardiovascular	$ 79,865	$156,817
Anti-infective	9,929	31,678
Critical care	39,502	35,363
Endocrinology/women s health	34,003	48,505
Respiratory	9,128	11,633
Neuroscience	62,429	
Other branded	(1,648)	6,967
Consolidated branded pharmaceutical revenues	$233,208	$290,963

12. 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.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING BALANCE SHEETS

	March 31, 2004						
	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	$ 151,433	$ 7,854	$	$ 159,287	$ 2,039	$	$ 161,326
Restricted cash	67,331	80,079		147,410			147,410
Accounts receivable, net	6,028	185,580		191,608	1,394		193,002
Inventories	209,109	41,810		250,919	274		251,193
Deferred income tax assets	38,731	88,858		127,589			127,589
Prepaid expenses and other current assets	17,396	28,652		46,048			46,048
Assets related to discontinued operations	1,530			1,530			1,530
Total current assets	491,558	432,833		924,391	3,707		928,098
Property, plant, and equipment, net	115,142	148,074		263,216			263,216
Goodwill		134,892		134,892			134,892
Intangible assets, net	6,181	1,471,131		1,477,312	7,396		1,484,708
Other assets	45,988			45,988			45,988
Deferred income tax assets	(4,395)	66,610		62,215			62,215
Investment in subsidiaries	2,183,214		(2,177,697)	5,517		(5,517)	
Assets related to discontinued operations		30,469		30,469			30,469
Total assets	$2,837,688	$2,284,009	$(2,177,697)	$2,944,000	$11,103	$(5,517)	$2,949,586
LIABILITIES AND SHAREHOLDERS EQUITY							
Current liabilities:							
Accounts payable	$ 20,116	$ 28,363	$	$ 48,479	$ 827	$	$ 49,306
Accrued expenses	(7,074)	487,663		480,589			480,589
Income taxes payable	55,251	(3,915)		51,336	194		51,530
Notes payable	7,437			7,437			7,437
Current portion of long-term debt	4			4			4
Total current liabilities	75,734	512,111		587,845	1,021		588,866

Long-term debt	345,000			345,000			345,000
Other liabilities	51,049	32,536		83,585			83,585
Intercompany (receivable) payable	434,592	(438,434)		(3,842)	3,842		
Total liabilities	906,375	106,213		1,012,588	4,863		1,017,451
Shareholders equity	1,931,313	2,177,796	(2,177,697)	1,931,412	6,240	(5,517)	1,932,135
Total liabilities and shareholders equity	$2,837,688	$2,284,009	$(2,177,697)	$2,944,000	$11,103	$(5,517)	$2,949,586

[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
Restricted cash	67,199	66,770		133,969			133,969
Accounts receivable, net	4,529	240,574		245,103	1,314		246,417
Inventories	224,081	36,554		260,635	251		260,886
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
Assets related to discontinued operations	4,012			4,012			4,012
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	1,538,035		1,544,990	7,502		1,552,492
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)	
Assets related to discontinued operations		204,501		204,501			204,501
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
Notes payable							

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
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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF INCOME

(Unaudited)
(In thousands, except per share data)

	Three Months Ended March 31, 2004						Three Months Ended March 31, 2003					
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland Limited	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated with Guarantor Subsidiaries	Ireland	King Consolidated
Revenues:												
Net sales	$ 106,502	$ 273,347	$(106,380)	$ 273,469	$ 418	$ 273,887	$ 66,018	$322,804	$(66,018)	$322,804	$193	$322,997
Royalty revenue		16,757		16,757		16,757		15,424		15,424		15,424
Total revenues	106,502	290,104	(106,380)	290,226	418	290,644	66,018	338,228	(66,018)	338,228	193	338,421
Operating costs and expenses:												
Costs of revenues	31,997	161,980	(106,380)	87,597	117	87,714	24,588	120,822	(66,018)	79,392	49	79,441
Selling, general and administrative	36,695	76,560		113,255	851	114,106	5,161	100,653		105,814	1	105,815
Depreciation and amortization	4,340	34,872		39,212	106	39,318	1,904	15,659		17,563	74	17,637
Research and development	110	15,913		16,023		16,023	225	27,411		27,636		27,636
Intangible asset impairment		34,936		34,936		34,936		110,970		110,970		110,970
Gain on sale of product lines		(858)		(858)		(858)						
Total operating costs and expenses	73,142	323,403	(106,380)	290,165	1,074	291,239	31,878	375,515	(66,018)	341,375	124	341,499
Operating (loss) income	33,360	(33,299)		61	(656)	(595)	34,140	(37,287)		(3,147)	69	(3,078)
Other income (expense):												
Interest income	894	160		1,054		1,054	2,396	98		2,494		2,494
Interest expense	(3,100)	(5)		(3,105)		(3,105)	(3,032)	(2)		(3,034)		(3,034)

Valuation change convertible notes receivable	(49)			(49)		(49)	7,967			7,967		7,967
Other, net	(325)	(331)		(656)	(47)	(703)	(64)	(19)		(83)		(83)
Equity in loss of subsidiaries	(124,529)		124,529				(31,380)		31,380			
Intercompany interest income (expense)	(7,166)	7,166					1,391	(1,391)				
Total other income (expense)	(134,275)	6,990	124,529	(2,756)	(47)	(2,803)	(22,722)	(1,314)	31,380	7,344		7,344
(Loss) income from continuing operations before income taxes	(100,915)	(26,309)	124,529	(2,695)	(703)	(3,398)	11,418	(38,601)	31,380	4,197	69	4,266
Income tax expense (benefit)	9,688	(10,490)		(802)	(246)	(1,048)	18,680	(10,004)		8,676		8,676
Loss from continuing operations	(110,603)	(15,819)	124,529	(1,893)	(457)	(2,350)	(7,262)	(28,597)	31,380	(4,479)	69	(4,410)
Discontinued operations:												
Loss from discontinued operations		(171,242)		(171,242)		(171,242)		(4,382)		(4,382)		(4,382)
Income tax benefit		(62,532)		(62,532)		(62,532)		(1,599)		(1,599)		(1,599)
Net (loss) income	$(110,603)	$(124,529)	$ 124,529	$(110,603)	$ (457)	$(111,060)	$ (7,262)	$ (31,380)	$ 31,380	$ (7,262)	$ 69	$ (7,193)

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GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF CASH FLOWS

(Unaudited)
(In thousands)

	Three Months Ended March 31, 2004					Three Months Ended March 31, 2003				
	King	Guarantor Subsidiaries	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland Limited	King Consolidated	King	Guarantor Subsidiaries	King Consolidated with Guarantor Subsidiaries	Monarch Pharmaceuticals Ireland	King Consolidated
Cash flows from operating activities	$ (91,452)	151,661	60,209	109	$ 60,318	$ 50,540	28,885	79,425		$ 79,425
Cash flows from investing activities:										
Transfer to restricted cash		(351)	(351)		(351)					
Purchases of marketable securities						(25,903)		(25,903)		(25,903)
Proceeds from sale of marketable securities						253,097		253,097		253,097
Proceeds from loans receivable		248	248		248		3,711	3,711		3,711
Purchases of property, plant and equipment	(3,477)	(9,108)	(12,585)		(12,585)	(2,118)	(10,724)	(12,842)		(12,842)
Proceeds from sale of property and equipment						12		12		12
Acquisition of Primary Care from Elan		(36,000)	(36,000)		(36,000)					
Investment in Meridian						(253,092)	15,410	(237,682)		(237,682)
Purchases of product rights						(9,000)		(9,000)		(9,000)
Net cash used in investing activities	(3,477)	(45,211)	(48,688)		(48,688)	(37,004)	8,397	(28,607)		(28,607)
Cash flows from financing activities:										
Proceeds from exercise of stock options, net	946		946		946	1,864		1,864		1,864
Payments on other long-term debt	(93)		(93)		(93)	(50)		(50)		(50)
Other						(214)		(214)		(214)
Intercompany	104,892	(105,027)	(135)	135		37,187	(37,187)			
Net cash provided by (used in) financing activities	105,745	(105,027)	718	135	853	38,787	(37,187)	1,600		1,600

Net cash provided by (used in) discontinued operations		2,790	2,790		2,790		(1,738)	(1,738)		(1,738)
Increase (decrease) in cash and cash equivalents	10,816	4,213	15,029	244	15,273	52,323	(1,643)	50,680		50,680
Cash and cash equivalents, beginning of period	140,617	3,641	144,258	1,795	146,053	594,385	(6,160)	588,225		588,225
Cash and cash equivalents, end of period	$151,433	7,854	159,287	2,039	$161,326	$ 646,708	(7,803)	638,905		638,905

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PART I FINANCIAL INFORMATION

Item 2. *Management s Discussion and Analysis of Results of Operations and Financial Condition*

The following discussion contains certain forward-looking statements that reflect management s current views of future events and operations. This discussion should be read in conjunction with the following: (a) Risk Factors set out below and in our Annual Report on Form 10-K for the year ended December 31, 2003, which are supplemented by the discussion which follows; (b) our audited consolidated financial statements which are included in our Annual Report on Form 10-K for the year ended December 31, 2003; and (c) our unaudited consolidated financial statements and related notes which are included in this report on Form 10-Q. Please see the sections entitled Risk Factors and A Warning About Forward-Looking Statements for a discussion of the uncertainties, risks and assumptions associated with these statements.

Overview of Financial Results

We are a vertically integrated pharmaceutical company that develops, manufactures, markets and sells branded prescription pharmaceutical products. We seek to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products in attractive markets and the strategic acquisition of branded products that can benefit from focused promotion and marketing and product life-cycle management.

General

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

	For the Three Months Ended March 31,	
	2004	**2003**
Branded pharmaceuticals	$233,208	$290,963
Meridian Medical Technologies	34,501	25,640
Royalties	16,757	15,424
Contract manufacturing	6,178	6,394
Total	$290,644	$338,421

Results of Operations

Three Months Ended March 31, 2004 and 2003

Revenues

Total net revenue decreased $47.8 million, or 14.1%, to $290.6 million in 2004 from $338.4 million in 2003, primarily due to dramatically lower net sales from our branded pharmaceuticals segment during 2004, partially offset by increased revenues from our Meridian Medical Technologies segment during the same period. Due to our decision to market Prefest® and Nordette® for divestiture as discussed more fully below, net sales associated with these products are classified as part of discontinued operations and are not included in total revenues for the periods presented.

Net sales from branded pharmaceutical products decreased $57.8 million, or 19.9%, to $233.2 million in 2004 from $291.0 million in 2003. This decrease was primarily the result of wholesale channel inventory reductions of some of our branded pharmaceutical products during 2004 which occurred while we were actively negotiating inventory management agreements with our three key wholesale customers, partially offset by net sales of Skelaxin® and Sonata® which we acquired in June 2003. Accordingly, net sales of our branded pharmaceutical products during 2004 were well below the level that prescription demand for such products would indicate. Prescription demand estimates are inherently imprecise and rely on third-party information which itself is subject to uncertainties and limitations. Net sales of Altace® were particularly negatively affected during 2004, as wholesale channel inventories of this product were reduced well over one

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month of current prescription demand for this product. Returns of branded pharmaceuticals increased significantly in the first quarter of 2004, reflecting high levels of returns primarily by wholesalers that purchased in excess of prescription demand, as well as reduced prescriptions for certain products due to competition. Additionally, we believe our announced plans to enter into inventory management agreements with certain wholesalers has also contributed to the increase in returns of products. Under the agreements, we expect to, among other things, reduce the amount of inventory in the wholesale pipeline and reduce the variability of customer ordering patterns. While we believe the first quarter rate of returns is not indicative of future returns, we are closely monitoring returns. As a result of the unusually high return levels in the first quarter of 2004, we supplemented our normal returns reserve to address specific products with higher levels of returns and/or declining sales. The impact of returns on net sales increased from $12.9 million in the first quarter of 2003 to $41.3 million in the first quarter of 2004, $7.2 million of which was due to the supplemental reserve.

On March 9, 2004, we received a copy of a letter from the FDA that was addressed to all applicants that have filed an abbreviated new drug application, which we refer to as an ANDA , in order to obtain permission to market a generic version of Skelaxin®. The letter stated that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. This FDA decision may explain some of the wholesale inventory reduction that negatively affected net sales of Skelaxin® during 2004. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. On March 18, 2004, the Company filed a Citizen Petition with the FDA requesting reinstatement of the FDA s previous policy on this issue and a requirement that all ANDA applicants include this use in their product labeling. If our Citizen Petition is rejected, 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.

Since the conclusion of the first quarter ended March 31, 2004, we have entered into an inventory management agreement with each of our three key wholesale customers in order to facilitate improved management of wholesale channel inventory levels of all of our branded pharmaceutical products. Accordingly, although we believe net sales of our branded products, particularly including but not limited to Altace®, will be significantly adversely affected by wholesale inventory reductions during the second quarter of 2004. We anticipate that net sales of our branded pharmaceuticals during the remainder of fiscal year 2004 should begin to return to levels that are more consistent with prescription demand for such products.

An ongoing clinical trial, the Women s Health Initiative, is being conducted by the National Institutes of Health. Data from the 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 markets including our products Prefest® and Menest®. Prescriptions for some of our other women s health products have also continued to decline over the past few years primarily due to the availability of generics. Accordingly, during the first quarter of 2004, our Board of Directors approved management s decision to market many of our women s health products, including Prefest®, Nordette®, and Menest®, for divestiture. We are now actively marketing such assets to potential purchasers.

Revenues from Meridian Medical Technologies increased $8.9 million, or 34.8%, to $34.5 million in 2004 from $25.6 million in 2003 primarily due to increased unit sales of EpiPen® under our supply agreement with Dey L.P. who markets the product. 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. The increase in the first quarter of 2004 is not necessarily indicative of future results.

Revenues from royalties is derived from payments we receive based on sales of Adenoscan® and Adenocard®. Revenue from royalties increased $1.4 million, or 9.1%, to $16.8 million in 2004 from $15.4 million in 2003 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 Adenoscan® and Adenocard® and, thus, are not able to predict whether growth will continue, if at all, at the rate experienced in the first quarter of 2004.

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Net revenues from contract manufacturing were $6.2 million in 2004 compared to $6.4 million in 2003.

Operating Costs and Expenses

Total operating costs and expenses decreased $50.3 million, or 14.7%, to $291.2 million in 2004 from $341.5 million in 2003. The decrease was primarily due to a $89.3 million reduction in the net charge associated with special items included in total operating costs and expenses during 2004 compared to 2003. Other variables which affected total operating costs and expenses during 2004 and 2003 are discussed in more detail below.

Special items are those particular income or expense items that our management believes are not related to our ongoing, underlying business, are non-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 extinguishment of debt; asset impairment charges; expenses of drug recalls; revenues and expenses associated with discontinued operations; 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 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 item involves judgments by us.

Cost of revenues increased $8.3 million, or 10.5%, to $87.7 million in 2004 from $79.4 million in 2003. This increase was primarily due to a charge during 2004 in the amount of $17.2 million for the write-off of excess inventory associated with our branded pharmaceuticals segment which is to some extent attributable to dramatically reduced net sales of branded pharmaceutical products during 2004 for the reasons discussed above, partially offset by a reduction in cost of revenues due to lower unit sales of our pharmaceutical products during the same period. Additionally, cost of revenue in 2004 includes a special item resulting in a charge of $4.2 million which represents that portion of our remaining minimum purchase commitments under our supply agreement for Procanbid® that exceeds our expected demand for the product. Accordingly, as a percentage of total revenues, cost of revenues increased to 30.2% in 2004 from 23.5% in 2003. During the remainder of calendar year 2004, we anticipate that cost of revenues as a percentage of total revenues should return to a level that is more consistent with that which we experienced in 2003.

Cost of revenues from branded pharmaceutical products increased $8.9 million, or 16.7%, to $62.2 million in 2004 from $53.3 million in 2003. This increase was primarily due to a charge in the amount of $17.2 million for the write-off of excess branded pharmaceutical products inventory discussed above and a special item resulting in a charge of $4.2 million which represents that portion of our remaining minimum purchase commitments under our supply agreement for Procanbid® that exceeds our expected demand for the product. Due to our decision to market Prefest® and Nordette® for divestiture, cost of revenues associated with these products is classified as part of discontinued operations and is not included in cost of revenues from branded pharmaceutical products for the periods presented.

Cost of revenues from Meridian Medical Technologies decreased $2.7 million, or 15.3%, to $15.0 million in 2004 from $17.7 million in 2003 primarily due to a special item consisting of a one-time inventory valuation adjustment in 2003 associated with our acquisition of Meridian on January 8, 2003, resulting in a charge of $2.2 million, and the mix of products sold in the respective periods.

Cost of revenues from royalties decreased $0.4 million to $2.6 million in 2004 from $3.0 million in 2003.

Cost of revenues associated with contract manufacturing increased $2.4 million, or 43.6%, to $7.9 million in 2004 from $5.5 million in 2003 primarily due to an increase in fixed overhead costs.

Total selling, general and administrative expenses increased $8.3 million, or 7.8%, to $114.1 million in 2004 from $105.8 million in 2003. This increase was primarily attributable to operating expenses associated with the expansion of our sales force, special items resulting in a charge equaling $5.7 million for professional fees that are primarily related to the ongoing investigations of our company by the Securities and Exchange Commission and the Office of Inspector General of the Department of Health and Human Services offset by

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decreases in co-promotion fees paid under our Co-Promotion Agreement with Wyeth Pharmaceuticals due to lower sales of Altace® during 2004, as compared to 2003, for the reasons discussed above. As a percentage of total revenues, total selling, general, and administrative expenses increased to 39.3% in 2004 compared to 31.3% in 2003. We anticipate that total selling, general and administrative expense, as a percentage of total revenues, should be less than the percentage experienced in the first quarter of 2004. Due to our decision to market Prefest® and Nordette® for divestiture as discussed more fully below, selling, general and administrative expense associated with these products is classified as part of discontinued operations and is not included in total selling, general and administrative expense for the periods presented.

Depreciation and amortization expense increased $21.7 million, or 123.3%, to $39.3 million in 2004 from $17.6 million in 2003. This increase was primarily attributable to the amortization of the intangible assets associated with our acquisitions of Sonata® and Skelaxin® on June 12, 2003. For more information regarding estimated future amortization expense, please see Note 7 to our condensed consolidated financial statements included in this report. Due to our decision to market Prefest® and Nordette® for divesture, amortization expense associated with these products is classified as part of discontinued operations and is not included in depreciation and amortization expense for the periods presented.

Other special items that also affected operating costs and expenses during 2004 resulted in a net intangible asset impairment charge totaling $34.9 million which is primarily related to a greater than expected decline in prescriptions for Florinef® and Tapazole® due to availability of generics for these products. These special items were recorded in order to adjust the carrying value of the intangible assets on our balance sheet associated with these products so as to reflect the estimated fair value of such assets. During January 2003, we were notified of the approval by the FDA of a second generic fludrocortisone acetate, USP, a product that represents additional competition for our Florinef® (fludrocortisone acetate, USP) product. We recorded an impairment charge in the amount of $111.0 million during 2003 reflecting the reduction in the fair value of the Florinef® intangible assets. The additional intangible asset impairment charge pertaining to Florinef® recorded in 2004 reflects a further reduction in the fair value of the intangible assets associated with this product due to a decline in prescriptions for the product that is in excess of our original estimate. We determined the fair value of the intangible assets associated with Florinef® and Tapazole® based on our estimated discounted cash flows for these products.

Prescriptions for Neosporin®, Septra® and another small pharmaceutical product have continued to decline over the past two years. At March 31, 2004, these products have net intangible assets associated with them totaling $19.2 million. We currently believe 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.

Total research and development expense decreased $11.6 million, to $16.0 million in 2004 from $27.6 million in 2003. This decrease was primarily due to a special item that resulted in a charge of $18.0 million during 2003 due to acquired in-process research and development associated with our acquisition of Meridian, offset by an increase in expenses associated with ongoing research and development programs that have progressed to later stages of clinical development and an expansion in the number of these programs.

Operating Loss

Due to the factors discussed above, we had an operating loss equaling $0.6 million during 2004 compared to an operating loss of $3.1 million in 2003.

Other Income (Expense)

Interest income decreased $1.4 million to $1.1 million in 2004 from $2.5 million in 2003 primarily due to reduced cash balances in 2004.

Interest expense was $3.1 million in 2004 compared to $3.0 million in 2003.

Special items affecting other income (expense) include a charge in the amount of $49 thousand during 2004 to reflect an increase in the valuation allowance for the convertible notes receivable from Novavax, Inc.

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compared to income in the amount of $8.0 million during 2003 to reflect a decrease in the valuation allowance for the convertible notes receivable from Novavax. Statement of Financial Accounting Standards, which we refer to as SFAS, No. 114, Accounting by Creditors for Impairment of a Loan an amendment of FASB Statements No. 5 and 15 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. We will adjust the amount of the valuation allowance in future periods until the loan is no longer considered to be impaired. If the Novavax common stock price declines, we may incur additional charges related to the investment in the convertible notes.

Discontinued Operations

An ongoing clinical trial, the Women s Health Initiative, is being conducted by the National Institutes of Health. Data from the 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 markets including our products Prefest® and Menest®. Prescriptions for some of our other women s health products have also continued to decline over the past few years primarily due to the availability of generics. Accordingly, during the first quarter of 2004, our Board of Directors approved management s decision to market for divestiture many of our women s health products, including Prefest®, Nordette®, and Menest®. We are now actively marketing these assets to potential purchasers.

The Prefest® and Nordette® product rights held for sale have identifiable cash flows that are largely independent of the cash flows of other groups of assets and liabilities and have been classified as discontinued operations in the accompanying financial statements. Accordingly, all net sales, cost of revenues, selling, general and administrative costs and amortization associated with Prefest® and Nordette® are included in discontinued operations in 2004 and 2003.

Special items include a loss from discontinued operations in the amount of $171.2 million during 2004 or $108.7 million net of tax benefit primarily due to an intangible asset write-down to reduce the carrying value of the intangible assets associated with these products to their estimated fair value less anticipated costs to sell. We determined the fair value of these intangible assets based on management s discounted cash flow projections for the products. Prefest® and Nordette® are included in our branded pharmaceuticals segment. Special items during 2003 include a loss from discontinued operations in the amount of $4.4 million, or $2.8 million net of tax benefit.

Income Tax Benefit

The effective tax rate of 30.8% (benefit) in 2004 is less than the federal statutory rate of 35% (benefit) due primarily to certain permanent book-tax differences, state taxes, and a valuation allowance established against certain state deferred tax assets. The effective tax rate in 2003 was higher than the federal statutory rate due primarily to certain permanent book-tax differences, state income taxes, and non-deductible in-process research and development charges incurred with the acquisition of Meridian Medical Technologies.

Net Loss

Due to the factors discussed above, we had a net loss equaling $111.1 million during 2004 compared to a net loss of $7.2 million in 2003

Liquidity and Capital Resources

We believe that existing balances of cash, cash equivalents and marketable securities, cash generated from operations, our 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.

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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®,

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

pay for costs associated with the development of a 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 then owing under our $400.0 million senior secured revolving credit facility and have no outstanding balance owing under this facility as of March 31, 2004.

As additional consideration for Synercid®, an injectable antibiotic acquired on December 30, 2002, we agreed to potential milestone payments. We will potentially pay Aventis milestone payments totaling $39.6 million over the next two years, payable in annual installments of $21.2 million and $18.6 million 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. An additional $25.0 million milestone is payable to Aventis if Synercid® should receive FDA approval to treat methicillin resistant staphylococcus aureus, or we will pay Aventis a one-time payment of $5.0 million the first time during any twelve-month period net sales of Synercid® exceed $60.0 million, and a one-time payment of $20.0 million the first time during any twelve-month period net sales of Synercid® exceed $75.0 million

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®.

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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 in our 2003 Form 10-K.

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 a subsidiary, executive officers, former executive officers, a subsidiary, and 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.

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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.

Three Months Ended March 31, 2004

We generated net cash from continuing operations of $60.3 million for the three months ended March 31, 2004. Our net cash provided from operations was primarily the result of a $2.4 million net loss from continuing operations, adjusted for non-cash depreciation and amortization from continuing operations of $39.3 million, a decrease in accounts receivable of $52.9 million, a decrease in inventory from continuing operations of $12.2 million, a change in deferred taxes from continuing operations of $17.0 million, and an intangible asset impairment charge from continuing operations of $34.9 million. Primary uses of cash within operations included a decrease in accounts payable of $33.6 million, a decrease in accrued expenses of $23.8 million, and a decrease in other liabilities of $20.1 million.

Investing activities reduced cash flow by $48.7 million primarily due to milestone payments related to the acquisition of the primary care business of Elan of $36.0 million and the purchase of property, plant and equipment of $12.6 million.

Financing activities contributed $0.9 million to cash flow due to the exercise of employee stock options.

Discontinued operations provided $2.8 million in cash flows. This was primarily the result of a $108.7 total loss from discontinued operations, adjusted for non-cash depreciation and amortization of $4.4 million, a change in deferred taxes of $62.5 million, and an intangible asset impairment charge of $169.6 million.

Certain Indebtedness and Other Matters

As of March 31, 2004, we had $345.0 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 accrued 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

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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 March 31, 2004, 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.

As of March 31, 2004, 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 $12.6 million and $12.8 million for the three months ended March 31, 2004 and 2003, respectively. The principal capital expenditures during the three months ended March 31, 2004 included property and equipment purchases, new information technology system implementation costs and building improvements for facility upgrades and increased capacity.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board, which we refer to as FASB, issued Interpretation No. 46, Consolidation of Variable Interest Entities, which we refer to as FIN 46. In December 2003, FASB revised FIN 46 to discuss certain FIN 46 implementation issues. The revised provisions are applicable no later than the first reporting period ending after March 15, 2004. 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 have evaluated our relationship with Novavax and determined that Novavax is not currently a variable interest entity that is required to be consolidated in our financial statements under FIN 46.

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 Estrasorb™ and Androsorb™, following approval, except in the United States and Puerto Rico, where we and Novavax will co-market the products. Following regulatory approval, 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 Estrasorb™ was approved by the FDA during October 2003. As of March 31, 2004, we owned approximately 0.9% of Novavax common stock. Our estimate of maximum exposure to loss as a result of our contractual relationships with Novavax is $32.3 million.

Novavax is a fully-integrated specialty biopharmaceutical company focused on research, development and commercialization of products utilizing their drug delivery and vaccine technologies for large and growing markets, concentrating on the areas of women s health and infectious diseases. At December 31, 2003, Novavax reported total assets of $84.2 million, total liabilities of $48.2 million, revenues for the year ended December 31, 2003 of $11.8 million, and a net loss of $17.3 million for the year ended December 31, 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

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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, excess quantities 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 specific indentification 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. Product returns are accrued based on historical experience of product return rates and on our estimate of inventory in the wholesale and retail pipeline. When we identify decreases in demand for products, we further analyze these products for potential additional future returns due to pipeline contraction. We provide a supplemental reserve for these products when it is determined that the decrease in demand may result in higher than expected returns. 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

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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.

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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 unaudited consolidated financial statements and related notes. You should also consider the information contained in our annual report on Form 10-K for the year ended December 31, 2003, 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 or our annual report on Form 10-K for the year ended December 31, 2003 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 in our 2003 Form 10-K.

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 a subsidiary, executive officers, former executive officers, a subsidiary, and 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

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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 three months ended March 31, 2004 accounted for 24.9%, 15.8%, 13.5%, 9.9%, 5.7% and 5.8% of our total revenues from continuing operations, respectively, or 75.6% 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

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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. In March 2004, Cobalt stipulated to infringement of the 722 patent. Should the court find in favor of a Cobalt summary judgment motion on the validity of the 722 patent, 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. On March 18, 2004, we filed a Citizen s Petition with the FDA requesting reinstatement of the FDA s previous policy on this issue and a requirement that all ANDA applicants include this use in their product labeling. If our Citizen s Petition is rejected, 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

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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.

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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 also an FDA-approved manufacturing and packaging site for Altace®. Aventis Pharma Deutscheland 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.

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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,

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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 NDA s for their levothyroxine sodium products. The FDA has announced that after August 14, 2001, it will not accept NDA s 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.

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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 March 31, 2004, we had $1.6 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. 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 and FDA-approved products from other companies.

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;

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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 any 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

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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 (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. 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 agreements. 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 48.3% of our revenues for the last

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twelve months ended March 31, 2004. 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 are in the process of negotiating with Wyeth to supply Bicillin® for an additional six-month period. This new agreement will increase our costs and substantially decrease our margins over the term of the agreement. In addition, 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 three months ended March 31, 2004, net sales of Bicillin® were $13.4 million representing 4.6% 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. 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.

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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.

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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 $30.8 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 entered into inventory management agreements with each of our three key wholesale customers during the second quarter of 2004. Accordingly, we have not yet received data pursuant to these agreements over a long enough period of time to

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implement inventory improvements. 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.

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. As of March 31, 2004, 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.

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 861 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 products 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).

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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.

In February 2002 we issued 2 3/4% Convertible Debentures due November 15, 2021 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.

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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

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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 in our 2003 Form 10-K and elsewhere in that 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. Subsequent to that time, our outside consultants conducted a comprehensive audit to determine the actual amount of underpayments under Medicaid during the period from 1998 to 2002. As a result of that audit, we 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 estimated 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.

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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 chemistry, 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.

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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 Drug Enforcement Agency, a division of the U.S. Department of Justice, which we refer to as 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 Environmental Protection Agency, which we refer to as 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 Veteran s

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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 Food, Drug and Cosmetic Act, or the Public Health Service Act or both. New drugs, as defined in the Food, Drug and Cosmetic Act, and new human biological drugs, as defined in the Public Health Service 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 interpretations, when and if promulgated, adopted or enacted, may have on our business in the future. These changes could, among other things, require modifications to our 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

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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 5.7% of gross sales for the last twelve months ended March 31, 2004. 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

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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, an ongoing clinical trial conducted by the National Institutes of Health, which released data in July 2002. This data 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™. 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. Additionally, potential write-offs of the intangible assets associated with the affected products could materially adversely affect our results of operations.

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

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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

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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.

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

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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 co in the Management s Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors 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;
- 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 development of product line extensions;
- 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

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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 3. ***Quantitative and Qualitative Disclosure 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.

As of March 31, 2004, there were no significant changes in our qualitative or quantitative market risk since the prior reporting period.

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 are affected by our stock price.

Item 4. ***Controls and Procedures***

(a) *Evaluation of Disclosure Controls and Procedures.* As of 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 as of March 31, 2004 to ensure that material information relating to us and our consolidated subsidiaries is made known to them by others within these entities, in order to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls.* In connection with the evaluation referred to above, there have been no changes in our internal controls that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

The information required by this Item is incorporated by reference to Note 9 to the condensed consolidated financial statements included elsewhere in this report.

Item 5. ***Other Information***

(b) Shareholders may recommend director candidates to the Nominating and Corporate Governance Committee of King s Board of Directors at any time by submitting a written recommendation to King s General Counsel, 501 Fifth Street, Bristol, Tennessee 37620. The General Counsel will direct all such correspondence to the Committee.

In order for a written shareholder recommendation to be evaluated by the Committee, it must include all information about the recommended person that would be required to be disclosed in a solicitation of proxies for election of directors pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended. The written recommendation must also be accompanied by the recommended person s written consent to be named in a proxy statement as a nominee, if so selected by the Committee and by the Board, and to serve as a director if appointed or elected. Additional information about the recommended person may be requested by the Committee from time to time, either from the recommended person or from the recommending shareholder.

The recommending shareholder must also disclose, with the written recommendation, the number of shares of King s common stock beneficially owned by the shareholder, the percentage of all outstanding common stock which the shares represent and the period of time the shareholder has beneficially owned the shares. If the shareholder is part of a group of shareholders that is making the recommendation, the shareholder must also disclose the names of the other members of the group and, for each member of the group, the number of shares of King s common stock beneficially owned by the member, the percentage of all outstanding common stock which the shares represent and the period of time the member has beneficially owned the shares.

A shareholder may also nominate a person for election to the Board at a meeting of shareholders by giving notice in the form and at the times required by King s bylaws.

Item 6. ***Exhibits and Reports on Form 8-K***

(a) Exhibits

31.1	Certification of Jefferson J. Gregory, Chairman and Chief Executive Officer of King Pharmaceuticals, Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Jefferson J. Gregory, the Chairman and Chief Executive Officer of King Pharmaceuticals, Inc., Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, Inc. Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

We filed the following Current Reports on Form 8-K during the quarter ended March 31, 2004:

(1) A Current Report on Form 8-K filed February 19, 2004 furnished under Item 12 our financial results for the quarter ended June 30, 2003.

(2) A Current Report on Form 8-K filed March 15, 2004 reporting under Item 5 issuance of a press release announcing the receipt of a letter from the U.S. Food and Drug Administration (FDA) to all Abbreviated New Drug Application (ANDA) applicants for a generic equivalent to King s approved

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product Skelaxin® 400 mg (metaxalone). The letter stated that ANDA applicants may delete the use listed in the FDA s publication entitled Approved Drug Products with Therapeutic Equivalent Evaluations (commonly known as the Orange Book) for U.S. Patent No. 6,407,128 from their product labeling. Skelaxin® is a muscle relaxant, indicated for the relief of discomforts associated with acute, painful musculoskeletal conditions. On March 12, 2004, King issued a press release regarding the announcement.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KING PHARMACEUTICALS, INC.

Date: May 10, 2004

By: /s/ JEFFERSON J. GREGORY

Jefferson J. Gregory
Chief Executive Officer

Date: May 10, 2004

By: /s/ JAMES R. LATTANZI

James R. Lattanzi
Chief Financial Officer