KING PHARMACEUTICALS INC
Form 10-Q
August 09, 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 June 30, 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 August 5, 2004: 241,559,586

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PART I FINANCIAL INFORMATION

Item 1. *Financial Statements*

KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)
(In thousands)

	June 30, 2004	December 31, 2003
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 106,807	$ 146,053
Restricted cash	129,738	133,969
Accounts receivable, net of allowance for doubtful accounts of $9,455 and $11,055	255,697	246,417
Inventories	236,855	260,886
Deferred income taxes	179,283	124,930
Prepaid expenses and other current assets	64,534	30,036
Assets related to discontinued operations	1,031	4,012
Total current assets	973,945	946,303
Property, plant and equipment, net	273,468	257,659
Goodwill	134,892	121,355
Intangible assets, net	1,447,109	1,552,492
Other assets (includes restricted cash of $660 and $30,265)	45,926	76,117
Deferred income taxes	57,585	19,307
Assets related to discontinued operations	30,469	204,501
Total assets	$2,963,394	$3,177,734
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 61,125	$ 83,078
Accrued expenses	580,155	506,033
Income taxes payable	26,182	79,641
Current portion of long-term debt		97
Total current liabilities	667,462	668,849
Long-term debt	345,000	345,000
Other liabilities	81,032	121,705
Total liabilities	1,093,494	1,135,554
Commitments and contingencies (Note 9)		
Shareholders equity	1,869,900	2,042,180

Total liabilities and shareholders equity	$2,963,394	$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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Net sales	$254,021	$350,839	$ 527,909	$673,836
Royalty revenue	21,119	16,176	37,875	31,600
Total revenues	275,140	367,015	565,784	705,436
Operating costs and expenses:				
Cost of revenues, exclusive of depreciation shown below	85,411	91,644	173,125	171,085
Selling, general and administrative, exclusive of co-promotion fees	104,125	72,949	190,727	117,064
Co-promotion fees	20,823	55,241	48,327	116,941
Total selling, general and administrative expense	124,948	128,190	239,054	234,005
Research and development	17,478	11,093	33,501	20,729
Research and development-in process upon acquisition		175,000		193,000
Total research and development	17,478	186,093	33,501	213,729
Depreciation and amortization	38,466	20,637	77,784	38,274
Intangible asset impairment			34,936	110,970
Medicaid related charge (Note 9)	65,000		65,000	
Merger related costs (Note 12)	3,126		3,126	
Restructuring charges (Note 11)	6,153		6,153	
Gain on sale of products (Note 6)	(3,421)		(4,279)	
Total operating costs and expenses	337,161	426,564	628,400	768,063
Operating loss	(62,021)	(59,549)	(62,616)	(62,627)
Other income (expense):				
Interest income	1,081	2,199	2,135	4,693
Interest expense	(3,266)	(3,435)	(6,371)	(6,469)
Valuation (charge) benefit convertible notes receivable	(2,438)	7,647	(2,487)	15,614
Other, net	1,168	(15)	465	(98)
Total other (expense) income	(3,455)	6,396	(6,258)	13,740
Loss from continuing operations before income taxes	(65,476)	(53,153)	(68,874)	(48,887)
Income tax expense (benefit)	152	(16,653)	(896)	(7,977)

Loss from continuing operations	(65,628)	(36,500)	(67,978)	(40,910)
Discontinued operations (Note 8):				
Income (loss) from discontinued operations, including expected loss on disposal	3,332	2,338	(167,910)	(2,044)
Income tax expense (benefit)	1,243	853	(61,289)	(746)
Total income (loss) from discontinued operations	2,089	1,485	(106,621)	(1,298)
Net loss	$ (63,539)	$ (35,015)	$ (174,599)	$ (42,208)
(Loss) income per common share:				
Basic:				
Loss from continuing operations	$ (0.27)	$ (0.15)	$ (0.28)	$ (0.17)
Total gain (loss) from discontinued operations	0.01		(0.44)	(0.01)
Net loss	$ (0.26)	$ (0.15)	$ (0.72)	$ (0.18)
Diluted:				
Loss from continuing operations	$ (0.27)	$ (0.15)	$ (0.28)	$ (0.17)
Total gain (loss) from discontinued operations	0.01		(0.44)	(0.01)
Net loss	$ (0.26)	$ (0.15)	$ (0.72)	$ (0.18)

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	Accumulated Other Comprehensive	
	Shares	Amount	Earnings	Income	Total
Balance at December 31, 2002	240,624,751	$1,201,897	$ 729,241	$ 45	$1,931,183
Comprehensive loss:					
Net loss			(42,208)		(42,208)
Net unrealized gain on marketable securities, net of tax of $400				742	742
Foreign currency translation, net of tax of $45				83	83
Total comprehensive loss					(41,383)
Stock option activity	404,701	2,785			2,785
Balance at June 30, 2003	241,029,452	$1,204,682	$ 687,033	$ 870	$1,892,585
Balance at December 31, 2003	241,190,852	$1,205,970	$ 835,097	$1,113	$2,042,180
Comprehensive loss:					
Net loss			(174,599)		(174,599)
Net unrealized loss on marketable securities, net of tax of $28				(53)	(53)
Foreign currency translation, net of tax of $26				48	48
Total comprehensive loss					(174,604)
Stock option activity	221,659	2,324			2,324
Balance at June 30, 2004	241,412,511	$1,208,294	$ 660,498	$1,108	$1,869,900

See accompanying notes.

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KING PHARMACEUTICALS, INC.

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

	Six Months Ended June 30,	
	2004	**2003**
Cash flows from operating activities of continuing operations	$ 15,948	$ 202,800
Cash flows from investing activities of continuing operations:		
Transfer from restricted cash	806	
Purchases of marketable securities		(25,903)
Proceeds from sale of marketable securities		253,097
Proceeds from loan receivable		6,187
Purchases of property, plant and equipment	(28,462)	(24,774)
Proceeds from sale of assets	113	241
Acquisition of primary care business of Elan	(36,000)	(760,212)
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	(63,543)	(798,046)
Cash flows from financing activities of continuing operations:		
Proceeds from exercise of stock options, net	2,324	2,765
Payments on other long-term debt and capital lease obligations	(97)	(96)
Proceeds from revolving credit facility		125,000
Debt issuance costs		(214)
Net cash provided by financing activities of continuing operations	2,227	127,455
Net cash provided by discontinued operations	6,122	3,308
Decrease in cash and cash equivalents	(39,246)	(464,483)
Cash and cash equivalents, beginning of period	146,053	588,225
Cash and cash equivalents, end of period	$ 106,807	$ 123,742

See accompanying notes.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 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 and six months ended June 30, 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, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. 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 loss and diluted loss per common share would have increased to the following pro forma amounts:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss:				
As reported	$(63,539)	$(35,015)	$(174,599)	$(42,208)
Compensation costs for options granted	(2,377)	(142)	(3,568)	(299)
Pro forma	$(65,916)	$(35,157)	$(178,167)	$(42,507)
Diluted loss per common share:				
Net loss:				
As reported	$ (0.26)	$ (0.15)	$ (0.72)	$ (0.18)
Pro forma	$ (0.27)	$ (0.15)	$ (0.74)	$ (0.18)

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 June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Basic loss per common share:				
Weighted average common shares	241,383	240,954	241,341	240,866
Diluted loss per common share:				
Weighted average common shares	241,383	240,954	241,341	240,866
Effect of stock options				
Weighted average common shares	241,383	240,954	241,341	240,866

For the three months ended June 30, 2004 and June 30, 2003, options to purchase 817 and 1,178 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. For the six months ended June 30, 2004 and June 30, 2003, options to purchase 866 and 1,292 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:

	June 30, 2004	December 31, 2003
Raw materials	$131,419	$139,675
Work-in-process	14,899	11,508
Finished goods (including $18,731 and $18,252 of sample inventory in 2004 and 2003, respectively)	157,817	140,307
	304,135	291,490
Inventory valuation allowance	(67,280)	(30,604)
	$236,855	$260,886

During the second quarter of 2004, the Company initiated a voluntary recall of certain batches of Levoxyl®. A charge in the amount of $4,459 related to this recall is included in cost of revenues in the accompanying financial statements.

5. Property, Plant and Equipment

In June 2004, the U.S. Food and Drug Administration (FDA) approved supplemental New Drug Applications (sNDA) which provide that Unithroid® (levothyroxine sodium tablets, USP) and Levo-T® (levothyroxine sodium tablets, USP) are bioequivalent and therapeutically equivalent (AB-Rated) to Levoxyl® (levothyroxine sodium tablets, USP). Similarly, in July 2004, the FDA approved a supplemental Abbreviated New Drug Application (sANDA) which provides that Mylan Laboratories Inc. s (Mylan) previously approved generic for Unithroid® is AB-Rated to Levoxyl®. Accordingly, some prescriptions for Levoxyl® are being filled with AB-Rated product instead of Levoxyl®. As a result, sales of Levoxyl® are likely to be materially adversely affected in future periods. The Company does not have any intangible assets recorded on its balance sheet related to Levoxyl®. However, the St. Petersburg facility manufactures Levoxyl®

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

exclusively. At June 30, 2004, the net carrying value of the property, plant and equipment at the St. Petersburg facility was $14,818. Management currently believes that these assets are not impaired based on estimated undiscounted future cash flows.

The Company s Rochester, Michigan facility manufactures products for the Company and various third parties. As of June 30, 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 $85,747 and $26,922, 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 at other facilities or by third parties. As an example, prior to May 2004, the Company relied solely on third parties to manufacture Brevital®. As of May 2004 the Rochester facility is qualified in accordance with FDA guidance as a manufacturing, testing and packaging site for Brevital® and the Company is currently distributing Brevital® that is produced at this site. These transfers should increase production and cash flow at the Rochester facility. Management currently believes that these long-term assets associated with the Rochester facility are not impaired based on estimated undiscounted future cash flows. However, if production volumes continue to decline or if the Company is not successful in transferring additional production to Rochester, the Company may have to write off a portion of the property, plant, equipment and intangible assets associated with this facility.

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 and six months ended June 30, 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 June 30, 2003	Six Months Ended June 30, 2003
Total revenues from continuing operations	$430,924	$822,201
Net income (loss)	$ 88,572	$ (32,704)
Basic income (loss) per common share	$ 0.37	$ (0.14)
Diluted income (loss) per common share	$ 0.37	$ (0.14)

On June 30, 2004, the Company sold the Anusol-HC® and Proctocort® product lines to Salix Pharmaceuticals, Inc. (Salix) for $13,000. In addition, the Company sold inventory of Anusol-HC® and Proctocort® to Salix for $337. The assets sold included related product assets, intangible property, advertising and promotional materials, and labeling and packaging materials. As part of the transaction, the Company will contract manufacture the Anusol-HC® and Proctocort® product lines for two years. The Company recorded a $3,421 gain on the sale of the Anusol-HC® and Proctocort® product lines, which is included as a reduction in total operating costs and expenses in the accompanying financial statements.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. Intangible Assets and Goodwill

The following table reflects the components of intangible assets as of June 30, 2004:

	Gross Carrying Amount	Accumulated Amortization	Net Intangible Assets
Trademarks and product rights	$1,481,212	$195,972	$1,285,240
Patents	260,068	99,793	160,275
Other intangibles	9,986	8,392	1,594
Total intangible assets	$1,751,266	$304,157	$1,447,109

Amortization expense for the three months ended June 30, 2004 and 2003 was $31,904 and $19,131, respectively. Estimated annual amortization expense as of June 30, 2004 for each of the five succeeding fiscal years is as follows:

Fiscal Year Ended December 31:	Amount
2004	$132,881
2005	107,126
2006	87,797
2007	85,223
2008	78,196

During January 2003, the Company was notified of the approval by the FDA of a second generic fludrocortisone acetate, USP, a product that represents additional competition for the Company s Florinef® (fludrocortisone acetate, USP) product. The Company recorded an impairment charge in the amount of $110,970 in the first quarter of 2003 reflecting the reduction in the fair value of the Florinef® intangible assets. 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. 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.

Prescriptions for Intal® and Tilade® have declined over the past year. At June 30, 2004, the Company had net intangible assets related to Intal® and Tilade® of $113,381. Management currently believes that these assets are not impaired based on estimated undiscounted cash flows. If, however, prescription declines exceed current expectations, the Company may have to write off a portion or all of the intangible assets associated with these products.

In March 2003, the Company also became aware that an Abbreviated New Drug Application (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 June 30, 2004, the Company had net intangible assets related to Cortisporin® of $17,711. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows. If, however, prescription declines exceed current expectations, the Company may have to write off a portion or all of the intangible assets associated with this product.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Prescriptions for Corzide® have declined over the past year. At June 30, 2004, the Company had net intangible assets related to Corzide® of $53,051. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows. If, however, prescription declines exceed current expectations, the Company may have to write off a portion or all of the intangible assets associated with this product.

Goodwill at December 31, 2003 and June 30, 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 June 30, 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

Ongoing research, referred to as 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. 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 these assets within the next nine months.

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. During the first quarter of 2004, 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:

	June 30, 2004	December 31, 2003
Inventories	$ 1,031	$ 4,012
Intangible assets, net	30,469	204,501
Total assets	$31,500	$208,513

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Summarized financial information for the discontinued operations are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Total revenues	$4,268	$3,695	$ 11,266	$ 9,117
Operating income (loss), including expected loss on disposal	3,332	2,338	(167,910)	(2,044)
Net income (loss)	2,089	1,485	(106,621)	(1,298)

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

Jones denies any liability incident to the distribution of Obenix® or its generic phentermine product and intends to pursue all defenses available to it. Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. The manufacturers of fenfluramine and dexfenfluramine have settled many of these cases. In the event that Jones insurance coverage is

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

In March 2003, upon the recommendation of management and with the assistance of independent counsel and a forensic 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 it had underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002.

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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.

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.

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 related to the 2002 adjustment and $19,000 related to the 2003 adjustment).

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 SEC and other federal and state agencies. The Company expects that these discussions will include a detailed review of its calculations by the appropriate agencies, and it is possible that this review could result in material changes. The accruals described above relate solely to King s estimated underpayments and exclude any interest, fines, penalties or other amounts that might be owed in connection with the underpayments, which are discussed below.

As part of King s ongoing discussions with the governmental agencies, King has begun to discuss with some of the government representatives the possibility of settling the matters being investigated. Although King has not reached any agreements or understandings with respect to a possible settlement, in accordance with generally accepted accounting principles, King has determined that, solely for accounting purposes, it is probable, as this term is defined by SFAS No. 5, Accounting for Contingencies, that it will enter into a settlement with respect to the investigations.

Accordingly, King has accrued $65,000 for estimated settlement costs as an operating expense during the second quarter of 2004 to cover interest, costs, fines, penalties and all other amounts beyond the $65,400 that King has previously accrued for the Company s estimated underpayments to Medicaid and other government pricing programs. Although the Company has not entered into any agreements or understandings with respect to any settlement, these accruals represent King s current best estimate of the aggregate payment King would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and all other relevant state and federal agencies. There can be no assurance that King will be able to reach a settlement, whether on these terms or at all, and the ultimate amount that King will actually have to pay to resolve these matters could be materially more or less than the

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

total amount the Company has accrued for this purpose. This accrual does not apply to the related pending class actions and derivative suits, described below, as to which King is still unable to predict the outcome or reasonably estimate the range of loss, if any.

The governmental investigations of King described above are continuing. The SEC, the Office of Inspector General of the Department of Health and Human Services, and other federal and state agencies that are 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. Except to the limited extent reflected by the accrual for estimated settlement costs described above, 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.

On July 13, 2004, the United States Magistrate Judge issued a report recommendation on the defendants motions to dismiss in which he recommended that the motions be denied except as to two individual defendants as to whom he recommended that the motion be granted. Both plaintiffs and defendants have the right to object to the report and ask that it be reviewed de novo by the United States District Judge presiding over the case. The Company and those individual defendants affected by the recommended denials of the motion have objected to the report of the Magistrate Judge. The District Court Judge will review these objections and ultimately may accept all or part of the Magistrate Judge s recommendations, or reject them entirely. In the event that the District Judge denies the defendants motion to dismiss, the Company intends to vigorously defend the lawsuit but cannot predict the outcome of the case.

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 is 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 (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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company s 401(k) Retirement Savings Plan s participants and beneficiaries under ERISA. The allegations underlying each of these additional lawsuits are similar in many respects to those in the class action litigation described above. The Company filed a motion to dismiss the ERISA action on March 5, 2004; this motion to dismiss is currently pending.

The Company intends to defend all of these lawsuits vigorously but is unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

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

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 New Drug Application (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

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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 against the 128 and 102 patents alleging noninfringement and invalidity of those patents. Mutual has filed a Paragraph IV certification against the 102 patent alleging noninfringement and invalidity of that patent. The Company filed separate suits against Eon Labs on January 2, 2003; CorePharma on March 7, 2003; and Mutual on March 12, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suits against CorePharma and Eon provides the Company with an automatic stay of FDA approval of Eon s ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of CorePharma 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. The Company filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information about food effect studies from generic labels. King concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated the Company s Citizen Petition. CorePharma responded to the Company s Citizen Petition on April 30, 2004.

On March 12, 2004, the FDA sent a letter to the Company explaining that King s proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, the Company submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of the Company s proposed labeling revision until the FDA has fully evaluated and ruled upon the Company s Citizen Petition, as well as all comments submitted in response to that petition. The Company submitted a response in opposition to Mutual s request on May 13, 2004. Mutual supplemented its original petition on May 17, 2004. The Company replied to both CorePharma s response and Mutual s supplement on July 21, 2004.

If the Company s 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. At June 30, 2004, the Company had net intangible assets related to Skelaxin® of $228,354. While the Company is amortizing the intangible assets related to the patent over only a two year period ending June 30, 2005, if a generic version of Skelaxin® enters the market, the Company may have to write off a portion of the patent intangible assets and the other intangible assets associated with this product.

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

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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. See Note 12 regarding Mylan.

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®, was issued on April 28, 1992 and United States Patent No. 5,382,573 (the 573 patent), a utility patent with pharmaceutical preparation claims relating to Prefest®, was issued on January 17, 1995. The 995 patent and the 573 patent are both listed in the FDA s Orange Book. The 995 patent does not expire until April 28, 2009, and the 573 patent does not expire until January 17, 2012. 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.

On June 8, 2004, the U.S. Patent and Trademark Office issued United States Patent No. 6,747,019 (the 019 patent). The 019 patent relates to pharmaceutical preparations, pharmaceutical packages and methods of treating a female in need of hormone replacement therapy by administering a specific dose combination of estrogen and progestin. The Company has certified that the 019 patent covers the Prefest® product and, therefore the patent has been listed in the Orange Book. On June 30, 2004, the Company received a Notice Letter from Barr concerning its amended Paragraph IV Certification to its ANDA for Prefest®. The Notice Letter outlines Barr s assertions of invalidity and noninfringement of the 019 patent. On July 9, 2004, the Company filed a complaint in the Southern District of New York for infringement of the 019 patent. The Company intends to vigorously enforce its rights under the 995, 573, and 019 patents. At June 30, 2004, the Company had net intangible assets related to Prefest® of $15,656. If a generic version enters the market, the Company may have to write off a portion of the intangible assets associated with this product.

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. 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: 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 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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

biotechnology companies. Royalties include revenues the Company derives from pharmaceutical products after the Company has transferred the manufacturing or marketing rights to third parties in exchange for licensing fees or royalty payments.

The Company primarily evaluates its segments based on gross profit. Reportable segments were separately identified based on revenues, gross profit (excluding depreciation) and total assets. Revenues among the segments are presented in the individual segments and removed through eliminations in the information below. Substantially all of the eliminations relate to sales from the contract manufacturing segment to the branded pharmaceuticals segment.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Total revenues:				
Branded pharmaceuticals	$ 219,587	$308,969	$ 452,796	$ 599,932
Meridian Medical Technologies	27,681	34,298	62,182	59,938
Royalties	21,119	16,176	37,875	31,600
Contract manufacturing and other	152,540	64,908	285,431	157,170
Eliminations	(145,787)	(57,336)	(272,500)	(143,204)
Consolidated total net revenues	$ 275,140	$367,015	$ 565,784	$ 705,436
Segment profit:				
Branded pharmaceuticals	$ 160,847	$248,267	$ 331,879	$ 485,977
Meridian Medical Technologies	14,001	15,325	33,454	23,273
Royalties	17,978	13,714	32,155	26,130
Contract manufacturing and other	(3,097)	(1,935)	(4,829)	(1,029)
Consolidated segment profit, excluding depreciation	$ 189,729	$275,371	$ 392,659	$ 534,351
Other operating costs and expense	251,750	334,920	455,275	596,978
Operating loss	$ (62,021)	$ (59,549)	$ (62,616)	$ (62,627)

The three and six months ended June 30, 2003 segment profit amounts reflect reclassifications of $2,332 and $7,497, respectively, 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 June 30, 2004	As of December 31, 2003
Total assets:		
Branded pharmaceuticals	$2,921,614	$3,151,045
Meridian Medical Technologies	261,427	250,935

Royalties	22,943	20,032
Contract manufacturing and other	92,690	91,002
Eliminations	(335,280)	(335,280)
Consolidated total assets	$2,963,394	$3,177,734

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following represents branded pharmaceutical revenues by therapeutic area:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Total revenues:				
Cardiovascular	$ 70,454	$152,719	$150,319	$309,536
Anti-infective	10,030	29,621	19,959	61,299
Critical care	38,602	36,161	78,104	71,524
Endocrinology/women s health	33,733	37,260	67,736	85,765
Respiratory	780	3,227	9,908	15,305
Neuroscience	63,057	45,994	125,486	45,994
Other branded	2,931	3,987	1,284	10,509
Consolidated branded pharmaceutical revenues	$219,587	$308,969	$452,796	$599,932

11. Restructuring

During the second quarter of 2004 the Company incurred restructuring charges of $6,248, as a result of separation agreements with several executives and the relocation of the Company s sales and marketing operations from Bristol, Tennessee to Princeton, New Jersey. A summary of the types of costs accrued and incurred are summarized below:

	Income Statement Impact	Payments	Accrued Balance at June 30, 2004
Employee separation payments	$5,772	$2,373	$3,399
Employee relocation	476	136	340
Reversal of amounts previously accrued	(95)		
	$6,153	$2,509	$3,739

It is anticipated that the relocation of key sales and marketing employees to New Jersey will be completed within the next year and will require additional costs, which in accordance with FAS 146, Accounting for Costs Associated with Exit or Disposal Activities, have not yet been accrued. All of the accrued restructuring charges relate to the branded pharmaceutical segment, except for $374 related to contract manufacturing which has not yet been paid but which was accrued at June 30, 2004.

12. Subsequent Events

On July 26, 2004, the Company entered into a merger agreement with Mylan and a wholly-owned subsidiary of Mylan (Merger Sub) pursuant to which Mylan will acquire King in a stock-for-stock transaction. Under the merger agreement, Mylan has agreed to issue 0.9 shares of its common stock in exchange for each outstanding share of common stock of the Company. Subject to the terms and conditions of the merger agreement, upon the closing of the merger, Merger Sub will be merged with and into the Company, the separate corporate existence of Merger

Sub will cease, and the Company will continue as a wholly-owned subsidiary of Mylan. The merger agreement has been approved by each of the Boards of Directors of the Company and Mylan. The transaction is anticipated to close by the end of calendar year 2004 and be tax-free to shareholders of the Company and Mylan. The closing of the transaction is subject to regulatory approvals, the declaration of effectiveness of the Form S-4 registration statement to be filed by Mylan with the SEC, approval by the shareholders of the Company and Mylan and other customary closing conditions. The Company incurred merger related costs of $3,126 for professional fees and expenses related to

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this agreement. In connection with the planned merger, the Company expects to continue to incur professional fees that could be material to cash flows and results of operations.

On July 19, 2004, the Company and Novavax, Inc. (Novavax) mutually agreed to end their co-promotion and license agreements regarding Estrasorb™. As part of this transaction, Novavax reacquired all rights to Estrasorb™ as well as all rights to other women s health products that Novavax may successfully develop utilizing its micellar nanoparticle technology. Additionally, Novavax repurchased all of its convertible notes held by King, acquired a portion of King s women s health field sales force, and received approximately $8,000 from the Company to provide support for marketing and promotion. In return, Novavax paid King $22,000 and issued approximately 3,776 shares of Novavax common stock to King. This transaction will result in an immaterial net gain in the third quarter of 2004. As a result of this transaction, King now owns approximately 4,101 shares of common stock of Novavax that the Company will account for as available for sale securities. Such shares are currently restricted and are required to be held by the Company until July 2005.

13. Related Party Transactions

The Company periodically makes contributions to charitable and not-for-profit organizations in communities where its facilities are located. In April 2004, the Company made a three-year pledge totaling $900 to Sullins Academy, a private school offering education in grades K-8. The Company recorded the pledge during the second quarter of 2004. During the fourth quarter of 2003 and the first quarter of 2004, the Company made a contribution to Sullins Academy of $150. At certain times during this period, children of some Company employees, including the Company s former Chief Executive Officer and the former President, attended Sullins Academy and the former President and the spouse of the former Chief Executive Officer served as volunteer members of the Sullins Academy board of directors.

14. Recent Accounting Pronouncements

On July 1, 2004, the Emerging Issues Task Force (EITF) reached a tentative consensus on earnings per share calculation for issuers of contingently convertible bonds. In EITF Issue 04-8, Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effects on Diluted Earnings per Share, the EITF has proposed that the potential earnings per share (EPS) dilution from contingently convertible bonds should be considered and included in the EPS calculation from the date of issue. Currently, the Company does not consider the EPS dilution of the Convertible Debentures until the closing price of our common stock reaches the threshold to permit conversion of Debentures at the option of holders of the Convertible Debentures of $55.18 per share (110% of the conversion price of $50.16 per share) for at least 20 trading days during 30 consecutive trading days. If all of the Convertible Debentures were converted, the Company would currently be required to issue approximately 6,878 shares.

15. 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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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING BALANCE SHEETS
(In thousands, except per share data)

	June 30, 2004				
	King	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminating Entries	King Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	$ 98,859	$ 6,150	$ 1,798	$	$ 106,807
Restricted cash	65,980	63,758			129,738
Accounts receivable, net	6,061	248,080	1,556		255,697
Inventories	197,241	39,332	282		236,855
Deferred income tax assets	40,775	138,508			179,283
Prepaid expenses and other current assets	28,004	36,530			64,534
Assets related to discontinued operations		1,031			1,031
Total current assets	436,920	533,389	3,636		973,945
Property, plant, and equipment, net	115,913	157,553	2		273,468
Goodwill		134,892			134,892
Intangible assets, net	5,408	1,434,411	7,290		1,447,109
Other assets	45,636	290			45,926
Deferred income tax assets	(6,493)	64,078			57,585
Investment in subsidiaries	2,185,905			(2,185,905)	
Assets related to discontinued operations		30,469			30,469
Total assets	$2,783,289	$2,355,082	$10,928	$(2,185,905)	$2,963,394
LIABILITIES AND SHAREHOLDERS EQUITY					
Current liabilities:					
Accounts payable	$ 30,832	$ 29,445	$ 848	$	$ 61,125
Accrued expenses	114,294	465,861			580,155
Income taxes payable	28,969	(2,640)	(147)		26,182
Current portion of long-term debt					
Total current liabilities	174,095	492,666	701		667,462
Long-term debt	345,000				345,000
Other liabilities	48,746	32,286			81,032
Intercompany (receivable) payable	345,548	(349,478)	3,930		
Total liabilities	913,389	175,474	4,631		1,093,494
Shareholders equity	1,869,900	2,179,608	6,297	(2,185,905)	1,869,900
Total liabilities and shareholders equity	$2,783,289	$2,355,082	$10,928	$(2,185,905)	$2,963,394

[Additional columns below]

[Continued from above table, first column(s) repeated]

	June 30, 2004				December 31,2003
	King	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminating Entries	King Consolidated
ASSETS					
Current assets:					
Cash and cash equivalents	$ 140,617	$ 3,641	$ 1,795	$	$ 146,053
Restricted cash	67,199	66,770			133,969
Accounts receivable, net	4,529	240,574	1,314		246,417
Inventories	224,081	36,554	251		260,886
Deferred income tax assets	16,428	108,502			124,930
Prepaid expenses and other current assets	5,249	24,787			30,036
Assets related to discontinued operations	4,012				4,012
Total current assets	462,115	480,828	3,360		946,303
Property, plant, and equipment, net	115,442	142,217			257,659
Goodwill		121,355			121,355
Intangible assets, net	6,955	1,538,035	7,502		1,552,492
Other assets	45,410	30,707			76,117
Deferred income tax assets	14,831	4,476			19,307
Investment in subsidiaries	2,308,924			(2,308,924)	
Assets related to discontinued operations		204,501			204,501
Total assets	$2,953,677	$2,522,119	$10,862	$(2,308,924)	$3,177,734
LIABILITIES AND SHAREHOLDERS EQUITY					
Current liabilities:					
Accounts payable	$ 51,924	$ 31,135	$ 19	$	$ 83,078
Accrued expenses	$ 55,764	450,269			506,033
Income taxes payable	78,363	838	440		79,641
Current portion of long-term debt	97				97
Total current liabilities	186,148	482,242	459		668,849
Long-term debt	345,000				345,000
Other liabilities	50,953	70,752			121,705
Intercompany (receivable) payable	329,396	(333,103)	3,707		
Total liabilities	911,497	219,891	4,166		1,135,554
Shareholders equity	2,042,180	2,302,228	6,696	(2,308,924)	2,042,180
Total liabilities and shareholders equity	$2,953,677	$2,522,119	$10,862	$(2,308,924)	$3,177,734

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GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF INCOME

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

	Three Months Ended June 30, 2004					Three Months Ended June 30, 2003				
	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Revenues:										
Net sales	$121,767	$253,563	$ 465	$(121,774)	$254,021	$ 34,803	$349,013	$1,603	$(34,580)	$350,839
Royalty revenue		21,119			21,119		16,176			16,176
Total revenues	121,767	274,682	465	(121,774)	275,140	34,803	365,189	1,603	(34,580)	367,015
Operating costs and expenses:										
Costs of revenues	35,167	171,881	137	(121,774)	85,411	10,584	115,208	432	(34,580)	91,644
Selling, general and administrative	48,692	76,165	91		124,948	20,117	107,993	80		128,190
Depreciation and amortization	4,312	34,048	106		38,466	2,055	18,508	74		20,637
Research and development	146	17,332			17,478	225	185,868			186,093
Medicaid related charge	65,000				65,000					
Transaction costs	3,126				3,126					
Gain on sale of product lines		(3,421)			(3,421)					
Restructuring charges	6,247	(94)			6,153					
Intangible asset impairment										
Total operating costs and expenses	162,690	295,911	334	(121,774)	337,161	32,981	427,577	586	(34,580)	426,564
Operating (loss) income	(40,923)	(21,229)	131		(62,021)	1,822	(62,388)	1,017		(59,549)
Other income (expense):										
Interest income	917	164			1,081	2,136	63			2,199
Interest expense	(3,266)				(3,266)	(3,435)				(3,435)
Valuation change convertible notes receivable	(2,438)				(2,438)	7,647				7,647
Other, net	(162)	1,375	(45)		1,168	(4)	(11)			(15)
Equity in loss of subsidiaries	1,919			(1,919)		(49,578)			49,578	
Intercompany interest income (expense)	(8,164)	8,164				4,902	(4,902)			
Total other income (expense)	(11,194)	9,703	(45)	(1,919)	(3,455)	(38,332)	(4,850)		49,578	6,396

(Loss) income from continuing operations before income taxes	(52,117)	(11,526)	86	(1,919)	(65,476)	(36,510)	(67,238)	1,017	49,578	(53,153)
Income tax expense (benefit)	11,422	(11,300)	30		152	(1,495)	(15,538)	380		(16,653)
Loss from continuing operations	(63,539)	(226)	56	(1,919)	(65,628)	(35,015)	(51,700)	637	49,578	(36,500)
Discontinued operations:										
Income from discontinued operations		3,332			3,332		2,338			2,338
Income tax expense		1,243			1,243		853			853
Net (loss) income	$ (63,539)	$ 1,863	$ 56	$ (1,919)	$ (63,539)	$ (35,015)	$ (50,215)	$ 637	$ 49,578	$ (35,015)

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GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF INCOME

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

	Six Months Ended June 30, 2004					Six Months Ended June 30, 2003				
	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Revenues:										
Net sales	$ 228,269	$ 526,911	$ 883	$ (228,154)	$ 527,909	$ 100,821	$ 671.817	$ 1,796	$ (100,598)	$ 673,836
Royalty revenue		37,875			37,875		31,600			31,600
Total revenues	228,269	564,786	883	(228,154)	565,784	100,821	703,417	1,796	(100,598)	705,436
Operating costs and expenses:										
Costs of revenues	67,164	333,861	254	(228,154)	173,125	35,172	236,030	481	(100,598)	171,085
Selling, general and administrative	85,387	152,725	942		239,054	25,278	208,646	81		234,005
Depreciation and amortization	8,652	68,920	212		77,784	3,959	34,167	148		38,274
Research and development	256	33,245			33,501	450	213,279			213,729
Medicaid related charge	65,000				65,000					
Transaction costs	3,126				3,126					
Gain on sale of product lines		(4,279)			(4,279)					
Restructuring charges	6,247	(94)			6,153					
Intangible asset impairment		34,936			34,936		110,970			110,970
Total operating costs and expenses	235,832	619,314	1,408	(228,154)	628,400	64,859	803,092	710	(100,598)	768,063
Operating (loss) income	(7,563)	(54,528)	(525)		(62,616)	35,962	(99,675)	1,086		(62,627)
Other income (expense):										
Interest income	1,811	324			2,135	4,532	161			4,693
Interest expense	(6,366)	(5)			(6,371)	(6,467)	(2)			(6,469)
Valuation change convertible notes receivable	(2,487)				(2,487)	15,614				15,614
Other, net	(487)	1,044	(92)		465	(68)	(30)			(98)
Equity in loss of subsidiaries	(123,067)			123,067		(80,889)			80,889	
Intercompany interest income (expense)	(15,330)	15,330				6,293	(6,293)			

Total other income (expense)	(145,926)	16,693	(92)	123,067	(6,258)	(60,985)	(6,164)		80,889	13,740
(Loss) income from continuing operations before income taxes	(153,489)	(37,835)	(617)	123,067	(68,874)	(25,023)	(105,839)	1,086	80,889	(48,887)
Income tax expense (benefit)	21,110	(21,790)	(216)		(896)	17,185	(25,542)	380		(7,977)
(Loss) income from continuing operations	(174,599)	(16,045)	(401)	123,067	(67,978)	(42,208)	(80,297)	706	80,889	(40,910)
Discontinued operations:										
Loss from discontinued operations		(167,910)			(167,910)		(2,044)			(2,044)
Income tax benefit		(61,289)			(61,289)		(746)			(746)
Net (loss) income	$(174,599)	$(122,666)	$ (401)	$ 123,067	$(174,599)	$ (42,208)	$ (81,595)	$ 706	$ 80,889	$ (42,208)

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GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF CASH FLOWS

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

	Six Months Ended June 30, 2004				Six Months Ended June 30, 2003			
	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	King Consolidated	King	Guarantor Subsidiaries	Non Guarantor Subsidiaries	King Consolidated
Cash flows from operating activities	$ (44,664)	$ 60,694	$ (82)	$ 15,948	$ 1,057	$ 201,743	$	$ 202,800
Cash flows from investing activities:								
Transfer from restricted cash	1,351	(545)		806				
Purchases of marketable securities					(25,903)			(25,903)
Proceeds from sale of marketable securities					253,097			253,097
Proceeds from loans receivable						6,187		6,187
Purchases of property, plant and equipment	(6,891)	(21,569)	(2)	(28,462)	(4,748)	(20,026)		(24,774)
Proceeds from sale of assets	113			113	12	229		241
Acquisition of Primary Care from Elan		(36,000)		(36,000)		(760,212)		(760,212)
Investment in Meridian					(253,092)	15,410		(237,682)
Purchases of product rights					(9,000)			(9,000)
Net cash used in investing activities	(5,427)	(58,114)	(2)	(63,543)	(39,634)	(758,412)		(798,046)
Cash flows from financing activities:								
Proceeds from exercise of stock options, net	2,324			2,324	2,765			2,765
Payments on other long-term debt	(97)			(97)	(96)			(96)
Proceeds from revolving credit facility					125,000			125,000
Debt issuance costs					(214)			(214)
Intercompany	6,106	(6,193)	87		(570,174)	570,174		
Net cash provided by (used in) financing activities	8,333	(6,193)	87	2,227	(442,719)	570,174		127,455
Net cash provided by discontinued operations		6,122		6,122		3,308		3,308
Increase (decrease) in cash and cash equivalents	(41,758)	2,509	3	(39,246)	(481,296)	16,813		(464,483)
Cash and cash equivalents, beginning of period	140,617	3,641	1,795	146,053	594,385	(6,160)		588,225
Cash and cash equivalents, end of period	$ 98,859	$ 6,150	$ 1,798	$ 106,807	$ 113,089	$ 10,653	$	$ 123,742

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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

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.

Strategic Developments

Mylan Merger

On July 26, 2004, we entered into a merger agreement with Mylan Laboratories Inc. and a wholly-owned subsidiary of Mylan, which we refer to as Merger Sub, pursuant to which Mylan will acquire King in a stock-for-stock transaction. Under the merger agreement, Mylan has agreed to issue 0.9 shares of its common stock in exchange for each outstanding share of common stock of King. Subject to the terms and conditions of the merger agreement, upon the closing of the merger, Merger Sub will be merged with and into King, the separate corporate existence of Merger Sub will cease, and King will continue as a wholly-owned subsidiary of Mylan. The merger agreement has been approved by each of the Boards of Directors of King and Mylan. The transaction is anticipated to close by the end of calendar year 2004 and be tax-free to shareholders of King and Mylan. The closing of the transaction is subject to regulatory approvals, the declaration of effectiveness of the Form S-4 registration statement to be filed by Mylan with the U.S. Securities and Exchange Commission, which we refer to as the SEC, approval by the shareholders of King and Mylan and other customary closing conditions.

Key Product Developments

Levoxyl®

On August 14, 1997, the U.S. Food and Drug Administration, which we refer to as the FDA, announced in the Federal Register (62 FR 43535) that orally administered levothyroxine sodium drug products are new drugs. The notice stated that manufacturers who wish to continue to market these products must submit applications as required by the FDC Act by August 14, 2000. On April 26, 2000, the FDA issued a second Federal Register notice extending the deadline for filing these applications until August 14, 2001. On May 25, 2001, the FDA approved our New Drug Application, which we refer to in this report as an NDA , for Levoxyl®, our levothyroxine sodium product.

During 2001 and 2002, we filed with the U.S. Patent and Trademark Office 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.

Mylan and KV Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. 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

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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.

We filed a Citizen Petition with the FDA on March 28, 2003 requesting that the FDA refrain from approving or accepting for filing any Abbreviated New Drug Application, which we refer to as ANDA, or supplemental Abbreviated New Drug Application, which we refer to as sANDA, 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 submitted similar and/or related comments to the FDA.

On June 23, 2004, the FDA denied our Citizen Petition and approved supplemental New Drug Applications, which we refer to as sNDA, filed by Alara Pharmaceuticals, Inc. and Jerome Stevens Pharmaceutical, Inc. under § 355(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355 *et seq.* seeking to market their currently approved products (Levo-T® and Unithroid®, respectively) as bioequivalent and therapeutically equivalent (*i.e.*, AB rated) to King s Levoxyl®. Neither Alara nor Jerome submitted a patent certification (under 21 U.S.C. §355(b)(2)(A)) against our 581 patent, despite its listing in the Orange Book as applicable to Levoxyl®. In response, we filed an action in the U.S. District Court for the District of Columbia against the FDA seeking preliminary and permanent injunctive relief in the form of an Order directing the FDA to withdraw its approval of the two sNDAs. Alara intervened in the action. In an Order dated July 8, 2004, however, the Court denied our request for a temporary restraining order and a preliminary injunction on the basis that we could not demonstrate a likelihood of success on the merits of our claim. We have yet to appeal that decision. Neither the FDA nor Alara has filed an Answer to our Complaint.

On July 14, 2004, the FDA approved an sANDA filed by Mylan under 21 U.S.C. § 355(j), seeking to market Mylan s currently approved levothyroxine sodium (LS) tablets as AB rated to Levoxyl®. The FDA did not require Mylan to certify against our 581 patent because Unithroid®, not Levoxyl®, is the listed drug referred to in Mylan s original ANDA. Presently, we have taken no action against the FDA in response to the Mylan approval. The pending patent infringement action discussed above against Mylan, however, will have no effect on the approval of the supplement (seeking AB rating to Levoxyl®) Mylan submitted to its earlier ANDA for Unithroid®. The FDA s decision to designate other levothyroxine sodium products as AB-Rated to Levoxyl® will adversely effect net sales of Levoxyl®, our results of operations and cash flows.

Levothyroxine sodium is a drug recognized to have a narrow toxic to therapeutic ratio with significant clinical consequences of excessive or inadequate treatment. The American Thyroid Association, The Endocrine Society, and the American Association of Clinical Endocrinologists have all raised concerns regarding patients being switched among a number of levothyroxine sodium preparations. Accordingly, these organizations have advised physicians caring for patients on levothyroxine sodium therapy to encourage their patients to ask to remain on their current levothyroxine sodium preparation. Nevertheless, sales of Levoxyl® may be materially adversely affected in future periods.

***Skelaxin*®**

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 against the 128 patent and the 102 patent alleging noninfringement and invalidity of these patents. Mutual has filed a Paragraph IV certification against the 102 patent alleging noninfringement and invalidity of that patent. We filed separate suits against Eon Labs on January 2, 2003; CorePharma on March 7, 2003; and Mutual on March 12, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suits against CorePharma and Eon provides us with an automatic stay of FDA

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approval of Eon s ANDA for 30 months from no earlier than November 18, 2002 and an automatic stay of FDA approval of CorePharma s ANDA for 30 months from no earlier than January 24, 2003. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. We filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information about food effect studies from generic labels. We concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated our Citizen Petition. CorePharma responded to our Citizen Petition on April 30, 2004.

On March 12, 2004, the FDA sent a letter to us explaining that our proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, we submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of our proposed labeling revision until the FDA has fully evaluated and ruled upon our Citizen Petition, as well as all comments submitted in response to that petition. We submitted a response in opposition to Mutual s request on May 13, 2004. Mutual supplemented its original petition on May 17, 2004. We replied to both CorePharma s response and Mutual s supplement on July 21, 2004.

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. At June 30, 2004, we had net intangible assets related to Skelaxin® of $228.4 million. While we are amortizing the patent intangibles over only a two-year period ending June 30, 2005, if a generic version of Skelaxin® enters the market, we may have to write off a portion of the patent intangible assets and the other intangible assets associated with this product.

We purchase metaxalone, the active ingredient in Skelaxin®, from two suppliers. We have a supply agreement with one of the suppliers. Both suppliers require firm purchase orders nine months prior to delivery. If sales of Skelaxin® decline, we may incur losses in connection with committed purchase orders under the supply agreement. In the event we incur losses in connection with the purchase orders, there may be a material adverse effect upon our results of operations and cash flows.

Research and Development Update

Altace® Product Life-Cycle Projects

We recently began our clinical development program for an Altace®-chlorthalidone combination product. Altace® is our patented angiotensin converting enzyme (ACE) inhibitor, indicated for the treatment of hypertension and chlorthalidone is a long-acting diuretic. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) states that data from hypertension trials and the standard clinical care of hypertensive patients demonstrate that most patients will require two or more antihypertensive medications to achieve their blood pressure goals. The combination product of Altace® and chlorthalidone would give physicians treatment options, while simplifying a patient s antihypertensive drug regimen.

We recently commenced the first of two planned bioavailability studies evaluating our Altace®-chlorthalidone product. The pivotal efficacy trial is expected to commence by mid 2005, with a possible NDA submission for the combination product in 2007. The clinical development program for the proposed combination tablet is designed to demonstrate that ramipril and chlorthalidone may be combined in a single dosage form with each component making a contribution to the claimed antihypertensive effect. We plan to discontinue our development of a modified-release formulation of Altace®.

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Other Developments

Wholesale Inventory Reductions

During the six months ended June 30, 2004, net sales of some of our branded pharmaceutical products have been significantly affected by wholesale inventory reductions. In order to facilitate improved management of wholesale inventory levels of all of our branded pharmaceutical products, we entered into inventory management agreements with each of our three key wholesale customers in April 2004. As we previously disclosed, we anticipated that sales of our branded pharmaceutical products would be significantly adversely affected during the second quarter of 2004 as we effectively reduced wholesale inventory levels of our branded pharmaceutical products. As of June 30, 2004, the wholesale inventory levels of our key branded pharmaceutical products, Altace®, Skelaxin®, Sonata® and Levoxyl®, based on data obtained through our inventory management agreements with our three largest customers and IMS America prescription data, were on average at an acceptable level of approximately 2.4 months of prescription demand. Accordingly, with the possible exception of Levoxyl® due to the recent entry of generic competition as discussed above, we anticipate that future quarterly net sales of our key branded products should more closely reflect demand-based sales.

Divestitures

Ongoing research, referred to as 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. 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®. At June 30, 2004, we had net intangible assets related to Prefest®, Menest®, and Nordette® of $34.3 million. If we are unable to sell these products at or above net book value, we may have to write off a portion of the intangible assets associated with these products.

As an extension of our strategic decision to divest many of our women s health products, in July 2004 we terminated our co-promotion and license agreements with Novavax, Inc. regarding Estrasorb™. As part of the transaction, Novavax reacquired all rights to Estrasorb™ as well as all rights to other women s health products that Novavax may successfully develop utilizing its micellar nanoparticle technology. Additionally, Novavax repurchased all of its convertible notes which we held, acquired a portion of our women s health field sales force, and received approximately $8.0 million from us to provide support for marketing and promotion. In return, Novavax paid us $22.0 million and issued us approximately 3.8 million shares of Novavax common stock. This transaction will result in an immaterial net gain in the third quarter of 2004. As a result of this transaction, we own approximately 4.1 million shares of Novavax common stock, representing approximately 10% of the outstanding common stock of Novavax. Such shares are currently restricted and are required to be held by King until July 2005.

In June 2004, we divested our Anusol-HC® and Proctocort® product lines to Salix Pharmaceuticals, Inc. for $13.0 million. As part of this transaction, we will contract manufacture the Anusol-HC® and Proctocort® product lines for two years. Additionally, in July 2004, we sold our rights to Derma Cidol®, Derma Scrub®, Derma Soothe®, Derma Stat® and Panthoderm® for approximately $0.4 million in cash, plus royalties and potential milestones based on future product sales. These divestitures are part of our strategy to divest some of our smaller, non-core products and use the proceeds from such divestitures to focus more extensively on the strategic acquisition and in-licensing of products in late-stage development.

Brevital®

Prior to May 2004, we relied solely on third parties to manufacture Brevital® who were unable to consistently supply the product. As of May 2004 the Rochester facility is qualified in accordance with FDA

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guidance as a manufacturing, testing and packaging site for Brevital® and we are currently distributing Brevital® that is produced at this site. This qualification is part of our plan to transfer the manufacture of some of our pharmaceutical products to our Rochester facility.

Key Personnel

In May 2004, Jefferson J. Gregory resigned from his position as Chief Executive Officer and from his position as Chairman and as a member of our Board of Directors. We previously announced Mr. Gregory s intention to retire in February 2004. Also in May 2004, Kyle P. Macione left his position as President.

Our Board of Directors appointed Ted G. Wood as Non-Executive Chairman of the Board in May 2004. On July 16, 2004, our Board appointed Brian A. Markison as our President and Chief Executive Officer and also appointed him to our Board.

General Review of Financial Results

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2004	2003	2004	2003
Branded pharmaceuticals	$219,587	$308,969	$452,796	$599,932
Meridian Medical Technologies	27,681	34,298	62,182	59,938
Royalties	21,119	16,176	37,875	31,600
Contract manufacturing	6,753	7,572	12,931	13,966
Total	$275,140	$367,015	$565,784	$705,436

Results of Operations

Three Months Ended June 30, 2004 and 2003

Revenues

Total net revenues decreased $91.9 million, or 25.0%, to $275.1 million in 2004 from $367.0 million in 2003 primarily due to dramatically lower net sales from our branded pharmaceuticals segment during 2004.

Net sales from branded pharmaceutical products decreased $89.1 million, or 28.8%, to $219.9 million in 2004 from $309.0 million in 2003. This decrease was primarily the result of wholesale inventory reductions of some of our branded pharmaceutical products during 2004 partially offset by an increase in net sales of Skelaxin®, which we acquired in June 2003. Net sales of Altace®, Skelaxin®, Levoxyl® and Sonata® during 2004 were well below the level that prescription demand for such products would indicate. Prescription demand estimates are imprecise and rely on third-party information which itself is subject to uncertainties and limitations.

Returns of branded pharmaceuticals increased significantly in 2004, primarily reflecting high levels of returns by wholesalers, as well as reduced prescriptions for some products due to the entry of generic competition. Additionally, we believe our inventory management agreements that we entered into with our three key wholesalers during the second quarter of 2004 have also contributed to the increase in returns of our branded pharmaceutical products. While we believe the rate of returns during 2004 is not indicative of future returns, we are closely monitoring this matter. As a result of the unusually high level of returns in 2004, we supplemented our normal returns reserve to address specific products with higher levels of returns and/or declining sales. Levoxyl® required the most significant supplemental reserve of all of our products during 2004 due to the FDA s decision to designate other available products as AB-Rated to Levoxyl® as discussed above in the section entitled Key Product Development under the subsection Levoxyl® . Returns reduced our net sales $20.4 million in 2003 and $56.0 million in 2004. As of June 30, 2004, the total return reserve was $61.9 million.

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Revenues from Meridian Medical Technologies decreased $6.6 million, or 19.2%, to $27.7 million in 2004 from $34.3 million in 2003 primarily due to a decrease in sales to the U.S. military partially offset by an increase in sales of Epipen® under our supply agreement with Dey, L.P. which markets the product.

Revenues from royalties are derived primarily from payments we receive based on sales of Adenoscan®. Revenue from royalties increased $4.9 million, or 30.5%, to $21.1 million in 2004 from $16.2 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 are not able to predict whether growth will continue, if at all, at the rate experienced in the second quarter of 2004.

Net revenues from contract manufacturing were $6.8 million in 2004 compared to $7.6 million in 2003.

Operating Costs and Expenses

Total operating costs and expenses decreased $89.4 million, or 21.0%, to $337.2 million in 2004 from $426.6 million in 2003. The decrease was primarily due to a substantially lower 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; litigation settlements, 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 decreased $6.2 million, or 6.8%, to $85.4 million in 2004 from $91.6 million in 2003. The decrease was primarily due to lower unit sales of our branded pharmaceutical products as a result of wholesale inventory reductions as discussed above, partially offset by a charge during the second quarter of 2004 in the amount of $10.4 million for the write-off of excess inventory associated with our branded pharmaceuticals segment which is to some extent attributable to reduced unit sales of branded pharmaceutical products during 2004. Special items affecting cost of revenues included a charge of $4.6 million and $1.5 million, respectively, in the second quarter of 2004 and 2003 which primarily related to the voluntary recall of some lots of Levoxyl®. As a percentage of total revenues, cost of revenues increased to 31.0% in 2004 from 25.0% in 2003 primarily due to lower net sales of our branded pharmaceutical products which on average have lower cost of revenues, as a percentage of revenues, and the write-off of excess inventory described above. 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 decreased $2.0 million, or 3.3%, to $58.7 million in 2004 from $60.7 million in 2003.

Cost of revenues from Meridian Medical Technologies decreased $5.3 million, or 27.9%, to $13.7 million in 2004 from $19.0 million in 2003 primarily due to a decrease in unit sales of lower margin products, partially offset by an increase in unit sales of higher margin products.

Cost of revenues from royalties increased $0.6 million to $3.1 million in 2004 from $2.5 million in 2003.

Cost of revenues associated with contract manufacturing was $9.9 million in 2004 compared to $9.5 million in 2003.

Total selling, general and administrative expenses decreased $3.3 million, or 2.6%, to $124.9 million in 2004 from $128.2 million in 2003. This decrease was primarily attributable to a decrease in co-promotion fees paid under our Co-Promotion Agreement with Wyeth Pharmaceuticals due to lower sales of Altace® during

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2004, as compared to 2003, for the reasons discussed above, offset by increased operating expenses primarily associated with the expansion of our field sales force and increased marketing expenses associated with the creation and/or launch of new marketing campaigns for some of our products. Selling, general and administrative expenses included a special item resulting in a net charge of $5.0 million and $14.3 million, respectively, in the second quarter of 2004 and 2003 for professional fees that were primarily related to the ongoing investigations of our company by the SEC and the Office of Inspector General of the Department of Health and Human Services. In connection with these investigations, we expect to continue to incur legal and professional fees that could materially affect our cash flows and results of operations.

As a percentage of total revenues, total selling, general, and administrative expenses increased to 45.4% in 2004 compared to 34.9% in 2003. The increase was primarily due to lower net sales of branded pharmaceutical products during 2004 for the reasons discussed above in the section entitled Other Developments in the subsection entitled Wholesale Inventory Reductions.

Depreciation and amortization expense increased $17.9 million, or 86.9%, to $38.5 million in 2004 from $20.6 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.

Prescriptions for Intal® and Tilade® have declined over the past year. At June 30, 2004, we had net intangible assets related to Intal® and Tilade® of $113.4 million. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows. However, if prescription declines exceed current expectations, we may have to write off a portion or all of the intangible assets associated with these products.

Prescriptions for Corzide® have declined over the past year. At June 30, 2004, we had net intangible assets related to Corzide® of $53.1 million. Management currently believes that this asset is not impaired based on estimated undiscounted cash flows. However, if prescription declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with this product.

Total research and development expense decreased $168.6 million, to $17.5 million in 2004 from $186.1 million in 2003. This decrease was primarily due to a special item that resulted in a charge of $175.0 million during 2003 due to acquired in-process research and development associated with our acquisition of Sonata® and Skelaxin® on June 12, 2003, offset by an increase in expenses associated with ongoing research and development programs that have progressed to later stages of clinical development.

In addition to the special items related to cost of revenues, selling, general and administrative expense and research and development described above, we incurred other special items affecting operating costs and expenses during 2004 resulting in a net charge totaling $70.9 million during the second quarter of 2004. These other special items include the following:

As part of our ongoing discussions with the Office of Inspector General of the Department of Health and Human Services, the U.S. Securities and Exchange Commission, which we refer to as the SEC, and other state and federal agencies, we have begun to discuss with some of the government representatives the possibility of settling the matters being investigated. We have accrued $65.0 million for estimated settlement costs as an operating expense during the second quarter of 2004 to cover interest, costs, fines, penalties and all other amounts in addition to the $65.4 million that we have previously accrued for estimated underpayments to Medicaid and other government pricing programs. Although we have not entered into any agreements or understandings with respect to a possible settlement, these accruals represent our current best estimate of the aggregate payment we would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and other federal and state agencies. For additional information, please see Governmental Investigations and Securities Litigation in Liquidity and Capital Resources.

A restructuring charge in the amount of $6.2 million during 2004 primarily due to separation agreements with several executives and the relocation of our sales and marketing operations from

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Bristol, Tennessee to Princeton, New Jersey. It is anticipated that the relocation of key sales and marketing employees to New Jersey will be completed within the next year and will require additional costs. All of the restructuring charges relate to the branded pharmaceutical segment, except for any related to contract manufacturing.

Income in the amount of $3.4 million due to a gain on the sale of our Anusol-HC® and Proctocort® product lines.

A charge of $3.1 million for professional fees and expenses related to our merger agreement with Mylan. In connection with the planned merger, we expect to continue to incur professional fees that could be material to our cash flows and results of operations.

Operating Loss

Due to the factors discussed above, we had an operating loss of $62.0 million during 2004 compared to an operating loss of $59.5 million in 2003.

Other Income (Expense)

Interest income decreased $1.1 million to $1.1 million in 2004 from $2.2 million in 2003 primarily due to lower cash balances in 2004.

Interest expense was $3.3 million in 2004 compared to $3.4 million in 2003.

Special items affecting other income (expense) include a charge in the amount of $2.4 million during 2004 to reflect an increase in the valuation allowance for the convertible notes of Novavax compared to income in the amount of $7.6 million during 2003 to reflect a decrease in the valuation allowance. As discussed above, Novavax repurchased the convertible notes from us in July 2004.

Discontinued Operations

As discussed above, we are actively marketing the Prefest® and Nordette® product rights to potential purchasers. These 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 during 2004 and 2003 include income from discontinued operations in the amount of $3.3 million and $2.3 million, or $2.1 million and $1.5 million net of tax expense, respectively.

Income Tax Expense (Benefit)

During 2004, we had a tax expense of $0.2 million, which excludes any tax benefit related to the Medicaid related charge discussed above. During 2003, we had an income tax benefit of $16.7 million, which reflects a reduction of $5.8 million in the tax benefit due to the establishment of a valuation allowance against state deferred tax assets generated by the write-off of acquired in-process research and development. Accordingly, our effective tax rate for 2003 of 31.3% was lower than the federal statutory rate of 35%.

Net Loss

Due to the factors discussed above, we had a net loss of $63.5 million during 2004 compared to a net loss of $35.0 million in 2003.

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Six Months Ended June 30, 2004 and 2003

Revenues

Total net revenue decreased $139.7 million, or 19.8%, to $565.8 million in 2004 from $705.4 million in 2003, primarily due to lower net sales from our branded pharmaceuticals segment during 2004 as a result of wholesale inventory reductions as discussed above in the section entitled Other Developments in the subsection entitled Wholesale Inventory Reductions.

Net sales from branded pharmaceutical products decreased $147.1 million, or 24.5%, to $452.8 million in 2004 from $599.9 million in 2003. This decrease was primarily the result of wholesale inventory reductions of some of our branded pharmaceutical products during 2004, partially offset by increases in net sales of Skelaxin® and Sonata® which we acquired in June 2003. Net sales of Altace®, Skelaxin®, and Sonata® during 2004 were well below the level that prescription demand for such products would indicate. Prescription demand estimates are imprecise and rely on third-party information which itself is subject to uncertainties and limitations.

Returns of branded pharmaceuticals increased significantly during 2004 primarily reflecting high levels of returns by wholesalers as well as reduced prescriptions for some products due to the entry of generic competition. Additionally, we believe our inventory management agreements that we entered into with our three key wholesalers have also contributed to the increase in returns of our branded pharmaceutical products. While we believe the rate of returns during 2004 is not indicative of future returns, we are closely monitoring this matter. As a result of the unusually high return levels in 2004, we supplemented our normal returns reserve to address specific products with higher levels of returns and/or declining sales. Levoxyl® required the most significant supplemental reserve of all of our products in 2004 due to the FDA s decision to designate other available products as AB-Rated to Levoxyl® as discussed above. Returns reduced our net sales by $33.3 million in 2003 and by $97.3 million in the first half of 2004.

Revenues from Meridian Medical Technologies increased $2.3 million, or 3.7%, to $62.2 million in 2004 from $59.9 million in 2003 primarily due to increased unit sales of EpiPen® under our supply agreement with Dey, L.P., which markets the product partially offset by a decrease in sales to the U.S. military.

Revenues from royalties are primarily derived from payments we receive based on sales of Adenoscan®. Revenue from royalties increased $6.3 million, or 19.9%, to $37.9 million in 2004 from $31.6 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 are not able to predict whether growth will continue, if at all, at the rate experienced in the first half of 2004.

Net revenues from contract manufacturing were $12.9 million in 2004 compared to $14.0 million in 2003.

Operating Costs and Expenses

Total operating costs and expenses decreased $139.7 million, or 18.2%, to $628.4 million in 2004 from $768.1 million in 2003. The decrease was primarily due to a $199.7 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.

Cost of revenues increased $2.0 million, or 1.2%, to $173.1 million in 2004 from $171.1 million in 2003. This increase was primarily due to a charge during 2004 in the amount of $31.4 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, 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 and a special item resulting in a $4.6 million charge primarily related to the recall of some lots of Levoxyl®. Cost of revenue in

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2003 includes special items resulting in a $5.8 million charge relating to the recall of some lots of Levoxyl® and our acquisition of Meridian. Accordingly, as a percentage of total revenues, cost of revenues increased to 30.6% in 2004 from 24.3% 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 $6.9 million, or 6.1%, to $120.9 million in 2004 from $114.0 million in 2003. This increase was primarily due to a charge in the amount of $31.4 million for the write-off of excess branded pharmaceutical products inventory discussed above and an increase in special items. During 2004, we incurred 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 and a special item resulting in a charge of $4.6 million primarily related to the recall of some lots of Levoxyl®. During 2003, cost of revenues from branded pharmaceutical products included a special item resulting in a charge in the amount of $3.6 million which was primarily related to our recall of some lots of Levoxyl®.

Cost of revenues from Meridian Medical Technologies decreased $8.0 million, or 21.8%, to $28.7 million in 2004 from $36.7 million in 2003 partially 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 increased $0.2 million to $5.7 million in 2004 from $5.5 million in 2003.

Cost of revenues associated with contract manufacturing increased $2.8 million, or 18.7%, to $17.8 million in 2004 from $15.0 million in 2003 primarily due to an increase in fixed overhead costs.

Total selling, general and administrative expenses increased $5.1 million, or 2.2%, to $239.1 million in 2004 from $234.0 million in 2003. This increase was primarily attributable to operating expenses associated with the expansion of our sales force offset by 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. We incurred special items of $10.7 million and $14.3 million, respectively, in 2004 and 2003 for professional fees that were primarily related to the ongoing investigations of our company by the SEC and the Office of Inspector General of the Department of Health and Human Services. In connection with these investigations, we expect to continue to incur legal and professional fees that could be material to our cash flows and results of operations.

As a percentage of total revenues, total selling, general, and administrative expenses increased to 42.3% in 2004 compared to 33.2% in 2003. The increased percentage in 2004 was primarily due to lower net sales of branded pharmaceutical products during 2004 for the reasons discussed above in the section entitled Other Developments in the subsection entitled Wholesale Inventory Reduction.

Depreciation and amortization expense increased $39.5 million, or 103.1%, to $77.8 million in 2004 from $38.3 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.

Total research and development expense decreased $180.2 million, to $33.5 million in 2004 from $213.7 million in 2003. This decrease was primarily due to special items that resulted in a charge of $193.0 million during 2003 due to acquired in-process research and development associated with our acquisition of Sonata® and Skelaxin® on June 12, 2003 and our acquisition of Meridian on January 8, 2003, offset by an increase in expenses associated with ongoing research and development programs that have progressed to later stages of clinical development.

In addition to the special items related to cost of revenues of branded pharmaceutical products, selling, general and administrative, and research and development described above, we incurred other special items

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affecting operating costs and expenses resulting in a net charge totaling $104.9 million during 2004 and $111.0 during 2003. These other special items included the following:

An intangible asset impairment charge in the first half of 2004 of $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 fludrocoritsone acetate, USP, a product that represents additional competition for our Florinef® (fludrocoritsone 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 that fair value of the intangible assets associated with Florinef® and Tapazole® based on our estimated discounted cash flows for these products.

As part of our ongoing discussions with the Office of Inspector General of the Department of Health and Human Services, the SEC, and other state and federal agencies, we have begun to discuss with some of the government representatives the possibility of settling the matters being investigated. We have accrued $65.0 million for estimated settlement costs as an operating expense to cover interest, costs, fines, penalties and all other amounts in addition to the $65.4 million that we have previously accrued for estimated underpayments to Medicaid and other government pricing programs. Although we have not entered into any agreements or understandings with respect to a possible settlement, these accruals represent our current best estimate of the aggregate payment we would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and other federal and state agencies. For additional information, please see the section entitled Governmental Investigations and Securities Litigation in Liquidity and Capital Resources.

Restructuring charges in the amount of $6.2 million in the second quarter of 2004 as a result of separation agreements with several of our executives and the relocation of our sales and marketing operations from Bristol, Tennessee to Princeton, New Jersey. It is anticipated that the relocation of key sales and marketing employees to New Jersey will be completed within the next year and will require additional costs. All of the restructuring charges relate to the branded pharmaceutical segment, except for any related to contract manufacturing.

Income of $4.3 million in 2004 primarily due to a gain on the sale of our Anusol-HC® and Proctocort® product lines.

A charge of $3.1 million for professional fees and expenses related to the merger with Mylan. In connection with the planned merger, we expect to continue to incur professional fees that could be material to our cash flows and results of operations.

Operating Loss

Due to the factors discussed above, we had an operating loss of $62.6 million during 2004 and an operating loss of $62.6 million in 2003.

Other Income (Expense)

Interest income decreased $2.6 million to $2.1 million in 2004 from $4.7 million in 2003 primarily due to reduced cash balances in 2004.

Interest expense was $6.4 million in 2004 compared to $6.5 million in 2003.

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Special items affecting other income (expense) include a charge in the amount of $2.5 million during 2004 to reflect an increase in the valuation allowance for the convertible notes receivable from Novavax, Inc. compared to income in the amount of $15.6 million during 2003 to reflect a decrease in the valuation allowance. As discussed above, Novavax repurchased the convertible notes from us in July 2004. The shares we received as a result of this transaction are restricted and are required to be held until July 2005.

Discontinued Operations

As discussed above, we are now actively marketing the Prefest® and Nordette® product lines to potential purchasers. These 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 $167.9 million during 2004 or $106.6 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 $2.0 million, or $1.3 million net of tax benefit.

Income Tax Benefit

For the six months ended June 30, 2004, we had an income tax benefit of $0.9 million, which excludes any tax benefit related to the Medicaid related charge discussed above and includes the establishment of a valuation allowance against state deferred tax assets. For the six months ended June 30, 2003, we had an income tax benefit of $8.0 million, which reflects a reduction of $5.8 million in the tax benefit due to the establishment of a valuation allowance against state deferred tax assets and permanent differences generated by the write-off of acquired in-process research and development.

Net Loss

Due to the factors discussed above, we had a net loss equaling $174.6 million during 2004 compared to a net loss of $42.2 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.

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. At June 30, 2004 we have $63.8 million in escrow to satisfy deferred obligations to Wyeth that we assumed as part of this acquisition. In addition to the initial purchase price, we paid $25.0 million during January 2004, as a milestone payment to Elan relating to the

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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®.

As additional consideration for Synercid®, an injectable antibiotic acquired on December 30, 2002, we agreed to potential milestone payments. We will 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, if there is 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.

Governmental Investigations and Securities Litigation

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

In connection with our determination that we have underpaid amounts due to Medicaid and other governmental pricing programs, we have continued to engage in discussions with representatives of the Office of Inspector General of the Department of Health and Human Services and other federal and state agencies. 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. As part of our ongoing discussions with the governmental agencies, we have begun to discuss with some of the government representatives the possibility of settling the matters being investigated. Although we have not reached any agreements or understandings with respect to a possible settlement, in accordance with generally accepted accounting principles, we have determined that, solely for accounting purposes, it is probable, as this term is defined by SFAS No. 5, Accounting for Contingencies, that we will enter into a settlement with respect to the investigations.

Accordingly, we have accrued $65.0 million for estimated settlement costs as an operating expense during the second quarter of 2004 to cover interest, costs, fines, penalties and all other amounts beyond the $65.4 million that we have previously accrued for our estimated underpayments to Medicaid and other government pricing programs. Although we have not entered into any agreements or understandings with respect to any settlement, these accruals represent our current best estimate of the aggregate payment we would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and other federal and state agencies. We cannot assure you that we will be able to reach a settlement, whether on these terms or at all, and the ultimate amount that we will actually have to pay to resolve these matters could be materially more or less than the total amount we have accrued for this purpose. This accrual does not apply to the related pending class actions and derivative

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suits, as to which we are still unable to predict the outcome or reasonably estimate the range of loss, if any. The SEC, the Office of Inspector General, and other federal and state 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. Except to the limit extent reflected by the accrual for estimated settlement costs, 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.

On July 13, 2004, the United States Magistrate Judge issued a report recommendation on the defendants motions to dismiss in which he recommended that the motions be denied except as to two individual defendants as to whom he recommended that the motion be granted. Both plaintiffs and defendants have the right to object to the report and ask that it be reviewed de novo by the United States District Judge presiding over the case. We and those individual defendants affected by the recommended denials of the motion have objected to the report of the Magistrate Judge. The District Court Judge will review these objections and ultimately may accept all or part of the Magistrate Judge s recommendations, or reject them entirely. In the event that the District Judge denies the defendants motion to dismiss, we intend to vigorously defend the lawsuit but cannot predict the outcome of the case.

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.

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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.

Six Months Ended June 30, 2004

We generated net cash from continuing operations of $15.9 million for the six months ended June 30, 2004. Our net cash provided from operations was primarily the result of a $68.0 million net loss from continuing operations, adjusted for non-cash depreciation and amortization from continuing operations of $77.8 million, intangible asset impairment charges from continuing operation of $34.9 million, a change in deferred taxes of $31.3 million and changes in working capital. Changes in working capital include an increase in inventory of $26.3 million, an increase in accrued expenses of $88.8 million, a decrease in accounts payable of $23.2 million, a decrease in income taxes payable of $53.5 million, an increase in accounts receivable of $10.2 million, and an increase in prepaid expenses of $13.8 million.

Investing activities reduced cash flow by $63.5 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 $28.5 million.

Financing activities contributed $2.2 million to cash flow due to the exercise of employee stock options.

Discontinued operations provided $6.1 million in cash flows. This was primarily the result of a $106.6 total loss from discontinued operations, adjusted for non-cash depreciation and amortization of $4.4 million, a change in deferred taxes of $61.3 million, and an intangible asset impairment charge of $169.6 million.

Certain Indebtedness and Other Matters

As of June 30, 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 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 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

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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 of June 30, 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 $28.5 million and $24.8 million for the six months ended June 30, 2004 and 2003, respectively. The principal capital expenditures during the six months ended June 30, 2004 included property and equipment purchases, new information technology system implementation costs and building improvements for facility upgrades and increased capacity.

Recent Accounting Pronouncements

On July 1, 2004, the Emerging Issues Task Force (EITF) reached a tentative consensus on earnings per share calculation for issuers of contingently convertible bonds. In EITF Issue 04-8, Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effects on Diluted Earnings per Share, the EITF has proposed that the potential earnings per share (EPS) dilution from contingently convertible bonds should be considered and included in the EPS calculation from the date of issue. Currently, we do not consider the EPS dilution of the Convertible Debentures until the closing price of our common stock reaches the threshold to permit conversion of Debentures at the option of holders of the Convertible Debentures of $55.18 per share (110% of the conversion price of $50.16 per share) for at least 20 trading days during 30 consecutive trading days. If all of the Convertible Debentures were converted, we would currently be required to issue approximately 6,878 shares.

Critical Accounting Policies

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

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

Inventories. Our inventories are valued at the lower of cost or market value. We evaluate all of our inventory for short dated, 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 identification 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, our current inventory levels, or purchase commitments 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

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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 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

Our proposed transaction with Mylan may adversely affect our results of operations whether or not the merger is completed, and the merger may not be completed on a timely basis or at all.

Uncertainty surrounding the proposed transaction may have an adverse effect on employee morale and retention. In addition, focus on the merger and related matters has resulted in, and may continue to result in, the diversion of management attention and resources. Furthermore, the market value of our common stock may vary prior to completion of the merger due to market assessments regarding the expected timing of consummation of the merger and the risk that the merger will not be consummated. Due to regulatory or other reasons, the merger may not be completed on the anticipated timetable, and it is possible that the merger will not be completed at all. If the merger is not completed, the price of our common stock may decline. In addition, our business may be harmed to the extent that our customers, strategic partners or others believe that we cannot effectively compete in the marketplace without the merger or there is customer and employee uncertainty surrounding the future direction of our strategy on a stand-alone basis. We also will be required to pay significant costs incurred in connection with the merger, including legal, accounting and financial advisory fees, whether or not the merger is completed. Moreover, under specified circumstances we may be required to pay Mylan a termination fee of $85.0 million in connection with the termination of the merger agreement.

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, the Public Health Service, the National Association of Medicaid Fraud Control Units, and other governmental agencies or authorities. 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.

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In addition, as part of these ongoing discussions, we have begun to discuss with some of the government representatives the possibility of settling the matters being investigated. Although we have not reached any agreements or understandings with respect to a possible settlement, in accordance with generally accepted accounting principles we have determined that, solely for accounting purposes, it is probable, as the term is defined in SFAS No. 5 Accounting for Contingencies, that we will enter into a settlement with respect to the investigations. Accordingly, we have accrued $65.0 million for estimated settlement costs as an operating expense during the second quarter of 2004, to cover interest, costs, fines, penalties and all other amounts beyond the $65.4 million that we have previously accrued for our estimated underpayments to Medicaid and other government pricing programs. Although we have not entered into any agreements or understandings with respect to any settlement, these accruals represent our current best estimate of the aggregate payment we would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and other federal and state agencies. We cannot assure you that we will be able to reach a settlement, whether on these terms or at all, and the ultimate amount that we will actually have to pay to resolve these matters could be materially more or less than the total amounts we have accrued for this purpose. The SEC, the Office of Inspector General, and other federal and state 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. Except to the limited extent reflected by the accrual for estimated settlement costs, 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 , the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations under the heading Governmental Investigations and Securities Litigation , 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.

On July 13, 2004, the United States Magistrate Judge issued a report recommendation on the defendants motions to dismiss in which he recommended that the motions be denied except as to two individual defendants as to whom he recommended that the motion be granted. Both plaintiffs and defendants have the right to object to the report and ask that it be reviewed de novo by the United States District Judge presiding over the case. We and those individual defendants affected by the recommended denials of the motion have objected to the report of the Magistrate Judge. The District Court Judge will review these objections and ultimately may accept all or part of the Magistrate Judge s recommendations, or reject them entirely. In the event that the District Judge denies the defendants motion to dismiss, we intend to vigorously defend the lawsuit but cannot predict the outcome of the case.

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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 we cannot successfully enforce our rights under the patents relating to three of our largest products, Altace®, Levoxyl® and Skelaxin®, our results of operations could be materially adversely affected.

Cobalt Pharmaceuticals, Inc., a generic drug manufacturer located in Mississauga, Ontario, Canada, has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA s Orange Book: United States Patent Nos. 4,587,258, the 258 patent, and 5,061,722, the 722 patent, two composition of matter patents related to Altace®, and United States Patent No. 5,403,856, the 856 patent, a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the Hatch-Waxman Act, any generic manufacturer may file an ANDA with a certification, known as a Paragraph IV certification , challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and we filed suit on March 14, 2003 to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt s ANDA for 30 months from no earlier than February 5, 2003. 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 against the 128 patent and the 102 patent alleging noninfringement and invalidity of these patents. Mutual has filed a Paragraph IV certification against the 102 patent alleging

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noninfringement and invalidity of that patent. We filed separate suits against Eon Labs on January 2, 2003; CorePharma on March 7, 2003; and Mutual on March 12, 2004. Pursuant to the Hatch-Waxman Act, the filing of the suits against CorePharma 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 CorePharma s ANDA for 30 months from no earlier than January 24, 2003. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law. On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. We filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information about food effect studies from generic labels. King concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated our Citizen Petition. CorePharma responded to our Citizen Petition on April 30, 2004.

On March 12, 2004, the FDA sent a letter to us explaining that our proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, we submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of our proposed labeling revision until the FDA has fully evaluated and ruled upon our Citizen Petition, as well as all comments submitted in response to that petition. We submitted a response in opposition to Mutual s request on May 13, 2004. Mutual supplemented its original petition on May 17, 2004. We replied to both CorePharma s response and Mutual s supplement on July 21, 2004.

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.

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

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®, Sonata® and royalty revenues for the last twelve months ended June 30, 2004 accounted for 27.3%, 18.3%, 10.5%, 5.9% and 5.4% of our total revenues from continuing operations, respectively, or 67.4% 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.

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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.

Our sales of Levoxyl® and our ability to maintain effective patent protection for Levoxyl® (levothyroxine sodium tablets (USP)) are likely to be affected by recent actions of the FDA, approving other levothyroxine sodium products as bio-equivalent and therapeutically equivalent (AB-Rated).

On August 14, 1997, the FDA announced in the Federal Register (62 FR 43535) that orally administered levothyroxine sodium drug products are new drugs. The notice stated that manufacturers who wish to continue to market these products must submit applications as required by the FDC Act by August 14, 2000. On April 26, 2000, the FDA issued a second Federal Register notice extending the deadline for filing these applications until August 14, 2001. On May 25, 2001, the FDA approved our NDA for Levoxyl®, our levothyroxine sodium drug product.

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.

We filed a Citizen 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.

On June 23, 2004, the FDA denied our Citizen Petition and approved the sNDA filed by Alara and Jerome under § 355(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355 *et seq.* seeking to market their currently approved products (Levo-T® and Unithroid®, respectively) as bioequivalent and therapeutically equivalent (*i.e.*, AB rated) to our Levoxyl®. Neither Alara nor Jerome submitted a patent certification (under 21 U.S.C. § 355(b)(2)(A)) against our 581 patent, despite its listing in the Orange Book as applicable to Levoxyl®. In response, we filed an action in the U.S. District Court for the District of Columbia against FDA seeking preliminary and permanent injunctive relief in the form of an Order directing the FDA to withdraw its approval of the two sNDAs. Alara intervened into the action. In an Order dated July 8, 2004, however, the Court denied our request for a temporary restraining order and a preliminary

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injunction on the basis that we could not demonstrate a likelihood of success on the merits of its claim. We have yet to appeal that decision. Neither the FDA nor Alara has filed an Answer to our Complaint.

On July 14, 2004, the FDA approved an sANDA filed by Mylan under 21 U.S.C. § 355(j), seeking to market Mylan s currently approved levothyroxine sodium (LS) tablets as AB rated to Levoxyl®. The FDA did not require Mylan to certify against our 581 patent because Unithroid®, not Levoxyl®, is the listed drug referred to in Mylan s original ANDA. Presently, we have taken no action against the FDA in response to the Mylan approval. Currently pending, however, is our lawsuit against Mylan for infringement of the 581 patent based on Mylan s submission of a second ANDA, which seeks approval to a market generic version of Levoxyl®. The pending infringement action against Mylan, however, will have no effect on the approval of the supplement (seeking AB rating to Levoxyl®) Mylan submitted to its earlier ANDA for Unithroid®. The FDA s decision to designate other levothyroxine sodium products as AB-Rated to Levoxyl® will adversely effect net sales of Levoxyl®, our results of operations and cash flows.

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

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

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

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

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

Our Bristol facility is an FDA-approved manufacturing and packaging site for Altace®. Aventis (USA) in Kansas City, Missouri, is 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

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receiving the finished product or raw material used for the future production of Altace® or the failure to maintain our Bristol facility and the Aventis (USA) facility as FDA-approved manufacturing and packaging sites for Altace® could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

If another company were to acquire, directly or indirectly, over 50% of the combined voting power of Wyeth s voting securities or more than half of its total assets, then Wyeth could assign its rights and obligations under the Altace® Co-Promotion Agreement to a successor without our prior consent. However, a successor would be required to first assume in writing the obligations of Wyeth under the Co-Promotion

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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.

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 June 30, 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, acquisitions, development and in-licensing, our business or 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 or in-licensing of products in development and FDA-approved products, 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 or licensing products in development and FDA-approved products from other companies.

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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®;
- 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 for which the FDA has issued an approvable letter;
- engaged in the development of an Altace®/chlorthalidone combination product; and
- engaged in the development of a diazepam-filled auto-injector.

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. The inability to effect acquisitions or licenses 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. 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.

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

The integration of acquisitions into our business requires significant management attention and may require the further expansion of our 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

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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.

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

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

Due to recent statutory changes, the FDA may approve generic substitutes of branded pharmaceutical products in a shorter period of time. Previously, the FDA required that generic applicants claiming patent invalidity or non-infringement give us notice each time either an ANDA was submitted or amended to claim invalidity or non-infringement of newly listed patents. If we filed a patent infringement suit against the generic applicant within 45 days of receiving such notice, the FDA was barred (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

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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 47.2% of our revenues for the last twelve months ended June 30, 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. 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.

We anticipate that sales of Levoxyl® will decline significantly as a result of the FDA s recent rulings described above concerning AB ratings to Levoxyl® of certain levothyroxine sodium product competitors.

King has begun construction of facilities to produce Bicillin® at its Rochester manufacturing facility in anticipation of the closing by a third party manufacturer (Wyeth) of its plant that currently produces Bicillin®. In anticipation of the closing of Wyeth s manufacturing facility and the time it will take to obtain regulatory approval of our Rochester Bicillin® production facilities, on July 6, 2004, we executed a Toll Manufacturing Agreement providing for Wyeth to increase production of Bicillin® for a six to eight month period. This agreement is currently being held in escrow pending resolution of certain conditions prior to Wyeth s execution of the agreement. We cannot assure you that these conditions will be satisfied or that Wyeth will enter into the Toll Manufacturing Agreement. The terms of this agreement are less favorable than the prior supply agreement with Wyeth, and there are no guarantees that the production of Bicillin® under the Toll

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Agreement, if executed with Wyeth, will be sufficient to supply the demand for the product prior to receiving regulatory approval and successful production of Bicillin® at our Rochester facility. If we are unable to obtain sufficient inventory of Bicillin® to sustain demand during such period, or if we experience delays in obtaining regulatory authorizations or experience production difficulties at our Rochester manufacturing facility, sales of this product may be reduced or the market for the product may be permanently diminished, either of which could have a material adverse affect on our business, financial condition, results of operations and cash flows. For the last twelve months ended June 30, 2004, net sales of Bicillin® were $23.3 million representing 1.7% 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. Some of the contracts we have for the supply of raw materials have short terms, and there is no assurance that we will be able to secure extension of the terms of such agreements. However, if we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to distribute our products as planned.

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

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

We develop products and product line extensions through research and development and through contractual relationships with third parties that develop new products, including new product formulations, on our behalf. Our reliance on third parties for the development of some of our products exposes us to risks which could cause delays in the development of new products or reformulated products or could cause other problems beyond our control. These third-party developers

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

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

may otherwise breach or terminate their agreements with us.

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

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

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

The Rochester facility was inspected by the FDA in February/ March 2003 and by an FDA Team Biologics inspector in August 2003. When an FDA inspector completes an authorized inspection of a manufacturing facility, the inspector typically provides the owner/operator of the facility with a written report listing the inspector s observations of objectionable conditions and practices. This written report is known as an FDA Form 483 or simply as a 483. The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a

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

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

We may not be successful in securing or maintaining proprietary patent protection for our products or products and technologies we develop or license. In addition, our competitors may develop products, including generic products, similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our sales. Some of our major branded pharmaceutical products have proprietary patent protection. All of these patents are listed in the FDA s Orange Book. A challenge to these patents can be subject to expensive litigation.

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 $30.9 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.

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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 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. 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.

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 745 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. We understand that a new competitive product manufactured by Hollister-Stier Laboratories LLC received FDA approval over one year ago but has yet to enter the market. 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 SEC and other federal and state agencies. 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. As part of our ongoing discussions with these agencies, we have begun to discuss with some of the government representatives the possibility of settling the matters being investigated. Although we have not reached any agreements or understandings with respect to a possible settlement, in accordance with generally accepted accounting principles, we have determined that, solely for accounting purposes, it is probable, as this term is defined by SFAS No. 5 Accounting for Contingencies, that we will enter into a settlement with respect to the investigations. Accordingly, we have accrued $65.0 million for estimated settlement costs as an operating expense during the second quarter of 2004 representing interest, costs, fines, penalties and all other amounts beyond the $65.4 million that we have previously accrued for our estimated underpayments to Medicaid and other government pricing programs. Although we have not entered into any agreements or understandings with respect to any settlement, these accruals represent our current best estimate of the aggregate payment we would have to make pursuant to a comprehensive settlement with the Office of Inspector General of the Department of Health and Human Services, the SEC and other federal and state agencies. We cannot assure you that we will be able to reach a settlement, whether on these terms or at all, and the ultimate amount that we will actually have to pay to resolve these matters could be materially more or less than the total amount we have accrued for this purpose. In addition, these agencies and other governmental agencies that might be investigating or might commence

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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. Except to the limited extent reflected by the accrual for estimated settlement costs, we cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time.

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

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

Under government regulations, chlorofluorocarbon compounds are being phased out because of environmental concerns. Our products Intal® and Tilade® currently use these compounds as propellants. The FDA has issued an approvable letter with respect to the NDA covering a new inhaler for Intal® using the alternative propellant hydrofluoroalkane, or HFA . The approvable letter provides that final approval of the NDA for Intal® HFA is subject to addressing certain FDA comments solely pertaining to the 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 which is located in Bristol, Tennessee. An interruption in operations at this facility 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. 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.

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.

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

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

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

variations in our results of operations;

perceived risks and uncertainties concerning our business;

announcements of earnings;

developments in the governmental investigations or securities and ERISA litigation;

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

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

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

comments or recommendations made by securities analysts;

general market conditions;

perceptions about market conditions in the pharmaceutical industry;

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

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

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

announcements concerning regulatory compliance and government agency reviews.

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

Risks Related to Our Industry

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

Virtually all aspects of our activities are regulated by federal and state statutes and government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution and advertising of our products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies, including the FDA, the 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

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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 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.

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

We face an inherent business risk of exposure to product liability claims in the event that the use of our technologies or products are alleged to have resulted in adverse effects. These risks will exist for those products in clinical development and with respect to those products that receive regulatory approval for commercial sale. While we have taken, and will continue to take, what we believe are appropriate precautions, we may not be able to avoid significant product liability exposure. We currently have product liability insurance in the amount of $80.0 million for aggregate annual claims including a $20.0 million self-insured retention; however, we cannot assure you that the level or breadth of any insurance coverage will be sufficient to cover fully all potential claims. Also, adequate insurance coverage might not be available in the future at acceptable costs, if at all. For example, we are now 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 could 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 7.9% of gross sales for the last twelve months ended June 30, 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

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the anti-kickback statutes. We seek to comply with the safe harbors. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of our practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly (in the civil context), or knowingly and willfully (in the criminal context), presenting, or causing to be presented for payment to third-party payors (including Medicaid and Medicare) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products are currently a subject of the Office of Inspector General s investigation, and as such they are likely to be subject to scrutiny under these laws. As discussed in this Risk Factors section under the heading The investigations by the SEC and Office of Inspector General of the Department of Health and Human Services, other possible governmental investigations, and securities and ERISA litigation could have a material adverse effect on our business and elsewhere in this report, we are in the process of quantifying and reporting to governmental agencies our underpayment of amounts due under Medicaid and other governmental pricing programs.

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

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

From time to time studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. One example of these types of studies is the Women s Health Initiative, 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®. 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.

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Additionally sales of our products in the United States could be adversely affected by the importation of products that some may deem to be equivalent to ours that are manufactured by others and are available outside the United States.

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

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and related rules, will cause us to incur increased costs as we evaluate the implications of new rules and respond to new requirements. Failure to comply with the new rules and regulations could result in enforcement actions or assessment of other penalties. The new laws and regulations could make it more difficult for us to obtain certain types of insurance, including directors and officers liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause our general and administrative costs to increase beyond what we currently have planned. We are presently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

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

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

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

additional competitors will not enter the market; or

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

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

Competition for Acquisitions. We compete with other pharmaceutical companies for product and product line acquisitions. These competitors include Biovail Corporation, Forest Laboratories, Inc., Galen

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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 or license commercially attractive pharmaceutical products, companies or technologies;
- additional competitors will not enter the market; or
- competition for acquisition of products in development, currently marketed products, companies and technologies will not have a material adverse effect on our business, financial condition and results of operations.

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

Our largest product Altace® competes in a very competitive and highly genericized market with other cardiovascular therapies.

Our product Levoxyl® competes in a competitive and highly genericized market with other levothyroxine sodium products.

Our product Skelaxin® competes in a highly genericized market with other muscle relaxants.

Our product Sonata® competes with other insomnia treatments, including in particular Ambien®, a product of Sanofi-Synthelabo Inc. Additionally, other potential competitive insomnia products are in development and could enter the market as early as 2004 and over the next couple of years.

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

- detailing and sampling to the primary prescribing physician groups, and
- sponsoring physician symposiums, including continuing medical education seminars.

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

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

A Warning About Forward-Looking Statements

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

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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, a new inhaler for Intal® using the alternative propellant HFA and an Altace®-chlorthalidone combination product;
- 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 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.

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As of June 30, 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 June 30, 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 Control.* 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 6. ***Exhibits and Reports on Form 8-K***

(a) Exhibits

31.1	Certification of Brian A. Markison, President 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 Brian A. Markison, President 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 June 30, 2004:

(1) On May 6, 2004, a Current Report on Form 8-K furnished under Item 12 a press release announcing our first quarter 2004 financial results.

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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: August 9, 2004

By: /s/ BRIAN A. MARKISON

Brian A. Markison
President and Chief Executive Officer

Date: August 9, 2004

By: /s/ JAMES R. LATTANZI

James R. Lattanzi
Chief Financial Officer