KING PHARMACEUTICALS INC
Form 10-Q
November 14, 2003

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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 September 30, 2003

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 November 10, 2003: 241,140,832

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PART I FINANCIAL INFORMATION

Item 1. *Financial Statements*

KING PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2003 (unaudited)	December 31, 2002
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 118,504	$ 588,225
Restricted cash	122,253	
Marketable securities		227,263
Accounts receivable, net of allowance for doubtful accounts of $9,720 and $7,513	229,305	159,987
Inventories	251,728	167,153
Deferred income taxes	101,516	106,168
Prepaid expenses and other current assets	14,133	12,906
Total current assets	837,439	1,261,702
Property, plant and equipment, net	247,155	217,114
Intangible assets, net	1,785,838	1,219,571
Goodwill	126,616	12,742
Other assets (includes $46,120 of restricted cash)	103,470	39,531
Deferred income tax assets	9,287	
Total assets	$3,109,805	$2,750,660
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 55,729	$ 49,889
Accrued expenses	493,030	297,528
Income taxes payable	62,255	21,247
Current portion of long-term debt	1,176	1,300
Total current liabilities	612,190	369,964
Long-term debt:		
Convertible debentures	345,000	345,000
Senior subordinated notes	93	93
Deferred income taxes		33,596
Other long-term liabilities	152,400	70,824
Total liabilities	1,109,683	819,477
Commitments and contingencies (note 8)		
Shareholders equity	2,000,122	1,931,183

Total liabilities and shareholders equity	$3,109,805	$2,750,660

See accompanying notes.

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KING PHARMACEUTICALS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues:				
Net sales	$407,929	$300,708	$1,090,881	$815,278
Royalty revenue	16,275	14,997	47,876	41,025
Total revenues	424,204	315,705	1,138,757	856,303
Operating costs and expenses:				
Cost of revenues, exclusive of depreciation shown below	90,421	63,562	262,569	166,898
Selling, general and administrative	89,124	46,473	210,935	132,484
Co-promotion fees	46,109	53,652	163,049	134,747
Total selling, general, and administrative	135,233	100,125	373,984	267,231
Research and development	8,758	6,448	29,487	18,779
Research and development in process upon acquisition			193,000	
Total research and development	8,758	6,448	222,487	18,779
Depreciation and amortization	39,698	15,603	83,323	43,743
Intangible asset impairment			110,970	
Gain on sale of products	(10,312)		(10,312)	
Total operating costs and expenses	263,798	185,738	1,043,021	496,651
Operating income	160,406	129,967	95,736	359,652
Other income (expense):				
Interest income	1,037	5,952	5,729	17,410
Interest expense	(3,669)	(3,143)	(10,137)	(9,028)
Valuation benefit (charge) convertible notes receivable	9,338	548	24,952	(27,378)
Other, net	(36)	87	(134)	(994)
Total other income (expense)	6,670	3,444	20,410	(19,990)
Income before income tax	167,076	133,411	116,146	339,662
Income tax expense	60,989	49,166	52,267	125,699
Net income	$106,087	$ 84,245	$ 63,879	$213,963

Income per common share:				
Basic:				
Net income	$ 0.44	$ 0.35	$ 0.27	$ 0.87
Diluted:				
Net income	$ 0.44	$ 0.35	$ 0.26	$ 0.87

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, 2001	247,692,984	$1,361,563	$546,721	$	$1,908,284
Comprehensive income:					
Net income			213,963		213,963
Unrealized gain on marketable securities, net of tax				423	423
Total comprehensive income					214,386
Stock repurchases	(6,828,680)	(155,390)			(155,390)
Exercise of stock options	397,916	3,996			3,996
Balance at September 30, 2002	241,262,220	$1,210,169	$760,684	$ 423	$1,971,276
Balance at December 31, 2002	240,624,751	$1,201,897	$729,241	$ 45	$1,931,183
Comprehensive income:					
Net income			63,879		63,879
Unrealized gain on marketable securities, net of tax				1,341	1,341
Foreign currency translation				144	144
Total comprehensive income					65,364
Exercise of stock options	512,476	3,575			3,575
Balance at September 30, 2003	241,137,227	$1,205,472	$793,120	$1,530	$2,000,122

See accompanying notes.

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KING PHARMACEUTICALS, INC.

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

	Nine Months Ended September 30,	
	2003	**2002**
Cash flows from operating activities	$ 368,485	$ 325,552
Cash flows from investing activities:		
Purchases of marketable securities	(25,903)	(597,873)
Proceeds from the sale of marketable securities	253,097	457,461
Transfer (to)/from restricted cash	(48,083)	
Loans receivable	8,668	
Purchases of property, plant and equipment	(33,530)	(48,771)
Acquisition of primary care business of Elan	(761,745)	
Purchase of convertible senior notes		(10,044)
Acquisition of Meridian Medical Technologies, Inc., net of cash acquired	(238,498)	
Purchase of product rights	(9,000)	(120,300)
Proceeds from sale of products	13,310	
Proceeds from sale of assets	261	4,358
Net cash used in investing activities	(841,423)	(315,169)
Cash flows from financing activities:		
Proceeds from exercise of stock options, net	3,555	3,996
Purchase of common stock		(155,390)
Debt issuance costs	(214)	(4,850)
Proceeds from revolving credit facility	125,000	
Payments on revolving credit facility	(125,000)	
Payments on other long-term debt and capital lease obligations	(124)	(207)
Net cash provided by (used in) financing activities	3,217	(156,451)
Decrease in cash and cash equivalents	(469,721)	(146,068)
Cash and cash equivalents, beginning of period	588,225	874,602
Cash and cash equivalents, end of period	$ 118,504	$ 728,534

See accompanying notes.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2003 and 2002
(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 nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. 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, 2002. The year-end condensed consolidated 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 the prior consolidated financial statements have been reclassified to conform to the presentation adopted in 2003.

2. Stock Compensation

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock Based Compensation. Accordingly, since options were granted with exercise prices equal to the then quoted market prices, no compensation cost has been recognized for stock options granted to date. Had compensation cost for these plans been determined for options granted, consistent with SFAS No. 123, the Company s net income and diluted income per common share would have been adjusted to the following pro forma amounts:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income:				
As reported	$106,087	$84,245	$63,879	$213,963
Compensation costs for options granted	(353)	(42)	(445)	(556)
Pro forma	$105,734	$84,203	$63,434	$213,407
Diluted income per common share:				
Net income:				
As reported	$ 0.44	$ 0.35	$ 0.26	$ 0.87
Pro forma	$ 0.44	$ 0.35	$ 0.26	$ 0.86

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model. The following weighted-average assumptions were used for grants for the three months ended September 30, 2003 and 2002:

	Three Months Ended September 30,	
	2003	2002
Expected life of option	4.00	4.00
Risk-free interest rate	2.84%	3.49%
Expected volatility	71.79%	76.00%
Expected dividend yield	0.00%	0.00%

3. Earnings Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Basic income per common share:				
Weighted average common shares	241,066	241,840	240,932	245,535
Diluted income per common share:				
Weighted average common shares	241,066	241,840	240,932	245,535
Effect of stock options	517	1,033	567	1,472
Weighted average common shares	241,583	242,873	241,499	247,007

The weighted average stock options that were anti-dilutive at September 30, 2003 and 2002 were 2,898 and 2,578, respectively. The 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

Inventory consists of the following:

	September 30, 2003	December 31, 2002
Finished goods (including $14,361 and $17,951 of sample inventory, respectively)	$138,181	$110,623
Work-in-process	16,311	7,810
Raw materials	117,754	56,778

	272,246	175,211
Inventory valuation allowance	(20,518)	(8,058)
	$251,728	$167,153

5. Acquisitions

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, which includes the rights to two branded prescription pharmaceutical products, including the rights to potential new formulations of, Sonata® and Skelaxin®, together with Elan s United States primary care field sales force. The Company believes that the

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

acquisition of these branded pharmaceutical products should provide additional growth opportunities in the branded pharmaceuticals segment through promotional activities, development opportunities and a significantly expanded field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan s sale of Skelaxin® included related New Drug Applications, copyrights, trademarks, patents and U.S. rights to potential new formulations of Skelaxin®. Elan s sale of Sonata® included its rights to the product, as well as certain related copyrights. The Company also acquired certain intellectual property, regulatory, and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, the Company secured an exclusive license to the intellectual property rights, in the United States, its territories and possessions and Puerto Rico, of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals.

The total estimated purchase price of $814,368, includes the cost of acquisition, assumed liabilities, and a portion of contingent liabilities. See the allocation of the purchase price in the table below. The identifiable intangible assets have been assigned useful lives with a weighted-average range of 16.5 years. The purchase price allocation among the assets acquired and the assignment of lives to the intangible assets are preliminary and subject to further evaluation, as the Company has not yet finalized its valuation of intangible assets acquired. In connection with this acquisition, $163,416 was placed into escrow to satisfy the deferred obligations to Wyeth that were assumed by the Company in connection with the acquisition. Since the Company is entitled to the interest income and can direct investments of the escrow fund, the Company has included the escrow amount in current restricted cash and other long-term assets as restricted cash. The $163,416 placed into escrow was included in the purchase price as liabilities acquired. These deferred obligations are payable on a quarterly basis through March 2005. As of September 30, 2003, $120,290 remains in the escrow fund.

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

$71,000 if Elan achieves specific milestones in connection with the development of new formulations of Sonata®;

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

a $25,000 milestone payment to Elan relating to the ongoing exclusivity of Skelaxin® on January 2, 2004.

The acquired business is included in the branded pharmaceuticals segment. The Company financed the acquisition through borrowings of $125,000 under the senior secured revolving credit facility and with cash on hand.

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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the success of the project depends on the outcome of future clinical trials involving a modified-release formulation of Sonata® and the U.S. Food and Drug Administration (FDA) approval of the product. Management currently anticipates that the completion of the project should occur no earlier than 2006. If the project is not successfully completed before 2008, the Company s business, financial position, results of operations and cash flows could be materially adversely affected.

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

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

(1) Excludes restricted cash placed in escrow.

On January 8, 2003, the Company completed its acquisition of Meridian Medical Technologies, Inc. (Meridian). Meridian is a leading manufacturer of auto-injectors for the self-administration of injectable pharmaceuticals. The Company believes the acquisition of Meridian provides additional lines of pharmaceutical products, auto-injector technology and development opportunities. The Company paid a cash price of $44.50 per common share to Meridian shareholders, totaling approximately $246,592, and incurred $7,317 of expenses related to the transaction. Of the total purchase price, $140,400 was assigned to identifiable intangible assets, $18,000 was assigned to acquired in-process research and development, which was expensed during the first quarter of 2003 and included in research and development, and $113,874 was assigned to goodwill. None of the goodwill is expected to be deductible for tax purposes. The identifiable intangible assets have been assigned useful lives with a weighted-average range of 32.3 years. The purchase price allocation among the assets acquired and the assignment of lives to the intangible assets are preliminary and subject to further evaluation, as the Company has not yet finalized its valuation of tangible assets acquired. The acquisition is allocated to the Meridian Medical Technologies segment. The Company financed the acquisition using available cash on hand.

As mentioned above, $18,000 of the purchase price was allocated to an acquired in-process research and development project, an auto-injector pre-filled with diazepam indicated for, among other things, the treatment of epileptic seizures and management of anxiety disorders. The value of the acquired in-process research and development project was expensed on the date of acquisition, as it had not received regulatory approval and had no alternative future use. The project was valued through the application of a probability-weighted, discounted cash flow approach with the assistance of an independent valuation specialist. The estimated cash flows were projected over a 30-year period utilizing a discount rate of 21%. Pre-tax margins (after an adjustment to reflect the use of auto-injector core technology) were assumed to be (10%) in 2003 and increasing to 23% in 10 years. The estimated cost to complete the project was less than $700. The project was submitted to the FDA as an Abbreviated New Drug Application (ANDA), which references an approved New Drug Application (NDA) owned by the United States Army for a diazepam-filled auto- injector currently manufactured under contract exclusively by Meridian. The application for the project is under review by the FDA and the Company must satisfactorily respond to chemistry, microbiology,

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

manufacturing and other questions from the FDA that arise as a result of its normal review and approval process. The Company anticipates FDA approval of the project during 2004. The project was substantially complete as of the valuation date. The success of the project is dependent upon whether the FDA approves the ANDA for the Company s diazepam-filled auto-injector. The Company is not aware of any material issues with respect to the FDA s review of the ANDA. Even if the project is not successfully completed, it would not materially adversely affect the Company s results of operations.

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

Cash consideration, including transaction fees	$253,909
Allocation of purchase price:	
Current assets	$ 38,574
Property, plant and equipment	15,791
Goodwill	113,874
Intangible assets	140,400
In process research and development	18,000
Other assets	662
Current liabilities	(14,505)
Deferred income taxes	(57,612)
Other liabilities	(1,275)
	$253,909

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 nine months ended September 30, 2003 and on January 1, 2002 for the three and nine months ended September 30, 2002. These pro forma results have been prepared for comparative purposes and do not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2003 or January 1, 2002, nor is it indicative of future results.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Total revenues	$424,204	$411,601	$1,255,522	$1,122,000
Net income	$106,638	$ 89,222	$ 73,753	$ 107,708
Basic earnings per common share	$ 0.44	$ 0.37	$ 0.31	$ 0.44
Diluted earnings per common share	$ 0.44	$ 0.37	$ 0.31	$ 0.44

6. Intangible Assets

The following table reflects the components of intangible assets as of September 30, 2003:

	Gross Carrying Amount	Accumulated Amortization
Trademarks and product rights	$1,708,083	$166,799
Patents	299,523	57,442
Other intangibles	10,346	7,873
Total intangible assets	$2,017,952	$232,114

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Amortization expense for the three months ended September 30, 2003 and 2002 was $33,781 and $12,760, respectively. Estimated annual amortization expense at September 30, 2003 for each of the five succeeding fiscal years is as follows:

Fiscal Year Ended December 31:	Amount
2003	$102,650
2004	135,091
2005	115,014
2006	95,359
2007	92,043

Goodwill at December 31, 2002 and September 30, 2003 is as follows:

	Branded Segment	Meridian Segment	Total
Goodwill at December 31, 2002	$12,742	$	$ 12,742
Goodwill associated with Meridian acquisition		113,874	113,874
Goodwill at September 30, 2003	$12,742	$113,874	$126,616

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 has completed its impairment review and has recorded an impairment charge in the amount of $110,970 in the first quarter of 2003 reflecting the reduction in the fair value of the Florinef® intangible assets. The Company determined the fair value of its Florinef® product based on management s current discounted cash flow projections for the product. Florinef® is included in the Company s branded pharmaceuticals reporting segment.

The Company acquired the antibiotic Lorabid® in the United States and Puerto Rico from Eli Lilly and Company (Eli Lilly) on August 19, 1999 for a purchase price of $91,700, including acquisition costs. Since the acquisition, sales declined for a variety of reasons. During the fourth quarter of 2002, the Company decided to divest its rights to Lorabid®.

As a result of a continuing decline of Lorabid® prescriptions, management determined that it would not be able to sell all the Lorabid® product the Company is required to purchase under its supply contract with Eli Lilly. Accordingly, under the requirements of Accounting Research Bulletin No. 43, the Company recorded a $49,877 liability related to Lorabid® purchase commitments in excess of expected demand as a charge to cost of revenues in the fourth quarter of 2002. At September 30, 2003, the excess purchase commitment accrual is $40,599.

Sales of Nordette®, a women s health product, have continued to decline over the past year. The Nordette® product right has net intangible assets associated with it of $97.1 million. Management currently believes that this asset is not impaired based on estimated undiscounted future cash flows, however, if revenue declines exceed current expectations, the Company may have to write-off a portion or all of the intangible assets associated with this product right.

7. Accounting Developments

In July 2002, the Financial Accounting Standards Board issued SFAS No. 146, Accounting for Exit or Disposal Activities. SFAS No. 146 addresses the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including costs related to terminating a contract that is not a capital lease and termination benefits that employees who are involuntarily terminated receive under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

compensation contract. SFAS No. 146 supersedes Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 was effective for exit or disposal activities of the Company initiated after December 31, 2002.

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

In January 2003, the Financial Accounting Standards Board issued Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46). FIN 46 requires a variable interest entity to be consolidated by a company if that company is required to absorb a majority of the variable interest entity s expected losses or entitled to receive a majority of the entity s residual returns or both. The Company is in the process of assessing what impact this pronouncement will have on its consolidated financial statements. Based on its preliminary analysis of the impact of FIN 46, the Company believes that it is reasonably possible that Novavax, Inc. (Novavax) could be a variable interest entity, and the Company s variable interest in Novavax may require that the Company consolidate Novavax in the fourth quarter of 2003.

During the period from December 2000 through June 2002, the Company provided $40.0 million in financing to Novavax in the form of notes receivable convertible to common stock of Novavax. In addition, during 2001, the Company obtained an exclusive worldwide license to promote, market, distribute and sell Estrasorb™ and Androsorb™, following approval, except in the United States and Puerto Rico, where King and Novavax will co-market the products. Once approved, the Company will pay Novavax a royalty based on a percentage of net sales of the products outside of the United States and Puerto Rico. Novavax will pay King a co-promotion fee equal to 50% of net sales less cost of revenues of the products within the United States and Puerto Rico. The New Drug Application for Estrasorb™ was approved by the U.S. Food and Drug Administration during October 2003. King owns approximately 1.1% of Novavax common stock.

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

8. 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 10 lawsuits that claim damages for personal injury arising from the Company s production of the anorexigenic drug phentermine under contract for GlaxoSmithKline. The Company expects to be named in additional lawsuits related to the Company s production of the anorexigenic drug under contract for GlaxoSmithKline.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

While the Company cannot predict the outcome of these suits, the Company believes that the claims against it are without merit and intends to vigorously pursue all defenses available to it. The Company is being indemnified in all of these suits by GlaxoSmithKline for which the Company manufactured the anorexigenic product, provided that neither the lawsuits nor the associated liabilities are based upon the independent negligence or intentional acts of the Company, and intends to submit a claim for all unreimbursed costs to the Company s product liability insurance carrier. However, in the event that GlaxoSmithKline is unable to satisfy or fulfill its obligations under the indemnity, the Company would have to defend the lawsuits and be responsible for damages, if any, that are awarded against it or for amounts in excess of the Company s product liability coverage. A reasonable estimate of possible losses related to these suits cannot be made.

In addition, Jones Pharma, Incorporated (Jones), a wholly owned subsidiary of the Company, is a defendant in approximately 916 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine. These suits have been filed in various jurisdictions throughout the United States, and in each of these suits Jones is one of many defendants, including manufacturers and other distributors of these drugs. Although Jones has not at any time manufactured dexfenfluramine, fenfluramine, or phentermine, Jones was a distributor of a generic phentermine product and, after the acquisition of Abana Pharmaceuticals, was a distributor of Obenix®, its branded phentermine product. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs and are seeking compensatory and punitive damages as well as medical care and court supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to, product liability, strict liability, negligence, breach of warranty, and misrepresentation.

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

While the Company cannot predict the outcome of these suits, management believes that the claims against Jones are without merit and intends to vigorously pursue all defenses available. The Company is unable to disclose an aggregate dollar amount of damages claimed because many of these complaints are multi-party suits and do not state specific damage amounts. Rather, these claims typically state damages as may be determined by the court or similar language and state no specific amount of damages against Jones. The Company, at this time, cannot provide an aggregate dollar amount of damages claimed or a reasonable estimate of possible losses related to the lawsuits.

Thimerosal/Vaccine Related Litigation

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

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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company s product liability insurance carrier has been given proper notice of all of these matters, and defense counsel is vigorously defending the Company s interests. The Company intends to file a motion to be dismissed from the litigation due, among other things, to lack of product identity in the plaintiffs complaints. In 2001, the Company was dismissed on this basis in a similar case. The Company intends to defend these lawsuits vigorously but is unable currently to predict the outcome or reasonably estimate the range of potential loss, if any.

Governmental Investigations and Securities Litigation

On March 10, 2003, the Company learned that it was the subject of a formal SEC investigation. Over the course of this continuing investigation, the SEC has requested the production of documents and information related to, among other things, 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. The Company has cooperated, and will continue to cooperate, in providing information to the SEC.

In connection with the Company s previously announced determination that it has underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002, the Company contacted the Centers for Medicare and Medicaid Services, the Public Health Service, the Office of Inspector General at the Department of Health and Human Services, the Department of Justice, and the Department of Veterans Affairs. In August 2003, the Company met with representatives of several of these agencies, including the Office of Inspector General, and provided detailed briefings on the results of the reviews conducted by the Company and its Audit Committee. The Company expects to engage in more detailed discussions with these and other appropriate agencies in order to determine the precise amount of the underpayments. The Company currently expects to make the requisite payments in 2004.

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 related to the matters being investigated by the SEC and to the Company s sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®. The Company intends to cooperate in providing information to the Office of Inspector General.

The SEC, the Office of Inspector General at the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Public Health Service, the Department of Justice, the Department of Veterans Affairs and other governmental agencies that might be investigating or might commence an investigation of the Company 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. 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 us, our directors, former directors, executive officers, former executive officers, a Company subsidiary, and one of its former officers 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. Plaintiffs in the consolidated action 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

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. 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. We removed these two cases to the United States District Court for the Eastern District of Tennessee where, pursuant to the Private Securities Litigation Reform Act of 1995, these two cases were consolidated with the other class actions. Plaintiffs in these actions have, however, moved to remand these actions back to Tennessee state court.

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. 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). The complaint alleges that the Company and certain executive officers, former executive officers, directors and former directors of the Company violated fiduciary duties that they allegedly owed the Company s 401(k) Retirement Savings Plan s participants and beneficiaries under ERISA. The allegations underlying each of these additional lawsuits are similar in many respects to those in the class action litigation described above. 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 the Company were not to prevail in the securities litigation, neither of which can be predicted or reasonably estimated 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 securities litigation have 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 Parkedale facility was one of six facilities owned by Pfizer subject to a Consent Decree of Permanent Injunction issued August 1993 in United States of America v. Warner-Lambert Company and Melvin R. Goodes and Lodewijk J.R. DeVink (U.S. Dist. Ct., Dist. of N.J.) (the Consent Decree). The Company acquired the Parkedale facility in February 1998. The Parkedale facility is currently manufacturing pharmaceutical products subject to the Consent Decree that prohibits the manufacture and delivery of specified drug products unless, among other things, the products conform to current good manufacturing practices and are produced in accordance with an approved ANDA or NDA. The Company intends, when appropriate, to petition for relief from the Consent Decree.

Cobalt Pharmaceuticals, Inc. (Cobalt), a generic drug manufacturer located in Mississauga, Ontario, Canada, has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA s *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book): U.S. Patent Nos. 4,587,258 (the 258 patent) and 5,061,722 (the 722 patent), two composition of matter patents related to Altace®, and U.S. Patent No. 5,403,856 (the 856 patent), a method of use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and the Company has filed suit 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. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, the Company would not receive the full benefit of that 30 month stay. The Company has also recently amended its

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

complaint, without opposition, to include an allegation of infringement of the 856 patent by Cobalt. 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.

Eon Labs, Inc. (Eon Labs) and CorePharma, LLC (CorePharma) have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin®. United States Patent No. 6,407,128 (the 128 patent), a method of use patent relating to Skelaxin®, is listed in the FDA s Orange Book and does not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 patent. The Company has filed separate suits against Eon Labs and CorePharma and intends to vigorously enforce its rights under the 128 patent to the full extent of the law.

Mylan Pharmaceuticals, Inc. (Mylan) and KV Pharmaceutical Company (KV Pharmaceutical) 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. On June 24, 2003, the Company received notice of KV Pharmaceutical s Paragraph IV certification, which alleges noninfringement and invalidity of the 581 patent. The Company has filed separate suits against Mylan and KV Pharmaceutical and intends to vigorously enforce its rights under the 581 patent to the full extent of the law.

Barr Laboratories Inc. (Barr) has filed an ANDA, which included a Paragraph IV Certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995 (the 995 patent), a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573 (the 573 patent), a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 9, 2003, the Company received notice of Barr s Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. Under the Hatch-Waxman Act, the Company has until December 1, 2003, to sue Barr for infringement of those patents to invoke a statutory 30-month stay of FDA approval. The Company intends to vigorously enforce its rights under both patents.

The Company is involved in various routine legal proceedings incident to the ordinary course of its business.

9. Segment Information

The Company s business is classified into five reportable segments: branded pharmaceuticals, Meridian Medical Technologies, contract manufacturing, royalties, and all other. Branded pharmaceuticals include a variety of branded prescription products over eight therapeutic areas, including cardiovascular, endocrinology/women s health, orthopedic, critical care, neurology/central nervous system, anti-infective, respiratory, and other. These branded prescription products have been aggregated because of the similarity in regulatory environment, manufacturing processes, methods of distribution, and types of customer. The Meridian Medical Technologies segment is a new segment in the first quarter of 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

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Total revenues:				
Branded pharmaceuticals	$363,892	$293,728	$ 972,941	$788,624
Meridian Medical Technologies	38,379		98,317	
Royalties	16,275	14,997	47,876	41,025
Contract manufacturing	58,425	27,767	215,594	97,842
All other		280		682
Eliminations	(52,767)	(21,067)	(195,971)	(71,870)
Consolidated total net revenues	$424,204	$315,705	$1,138,757	$856,303
Segment profit:				
Branded pharmaceuticals	$297,993	$241,667	$ 799,523	$657,917
Meridian Medical Technologies	22,272		45,545	
Royalties	13,788	12,197	39,919	33,674
Contract manufacturing	(270)	(1,328)	(8,761)	(2,142)
All other		(393)	(38)	(44)
Consolidated segment profit	333,783	252,143	876,188	689,405
Other operating costs and expenses	173,377	122,176	780,452	329,753
Operating income	$160,406	$129,967	$ 95,736	$359,652

	As of September 30, 2003	As of December 31, 2002
Total assets:		
Branded pharmaceuticals	$2,730,183	$2,597,499
Meridian Medical Technologies	254,032	
Royalties	15,484	18,738
Contract manufacturing	191,473	143,285
All other	5	11
Eliminations	(81,372)	(8,873)

Consolidated total assets	$3,109,805	$2,750,660

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following represents branded pharmaceutical revenues by therapeutic area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Total revenues:				
Cardiovascular	$135,376	$141,075	$444,912	$366,921
Endocrinology/women s health	48,190	86,470	143,072	229,602
Orthopedic	87,890		117,700	
Critical care	42,604	24,243	114,128	71,805
Neurology/central nervous system	20,526		36,710	
Anti-infective	11,677	31,426	72,976	97,436
Respiratory	10,868	267	26,173	1,677
Other branded	6,761	10,247	17,270	21,183
Consolidated branded pharmaceutical revenues	$363,892	$293,728	$972,941	$788,624

10. Sale of Animal Health Products

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

11. Subsequent Event

On October 21, 2003, the Company amended its agreement with Eli Lilly concerning the supply and distribution of Lorabid® and settled a disputed liability. As a result, King obtained the rights to donate excess supply outside of the United States, excluding specific countries. King also agreed to the amendment of the supply contract with new specified purchase requirements causing an increase in the required purchase commitments in excess of expected demand. As a result of the settlement agreement, King anticipates a special charge in the fourth quarter of 2003 of approximately $10,000.

12. Guarantor Financial Statements

Each of the Company s subsidiaries (the Guarantor Subsidiaries) has guaranteed, on a full, unconditional, and joint and several basis, the Company s performance under the $345,000, 2 3/4% Convertible Debentures due 2021 and under the $400,000 Senior Secured Revolving Credit Facility on a joint and several basis. There are no restrictions under the Company s financing arrangements on the ability of the Guarantor Subsidiaries to distribute funds to the Company in the form of cash dividends, loans or advances. The following combined financial data provides information regarding the financial position, results of operations and cash flows of the Guarantor Subsidiaries (condensed consolidating financial data). Separate financial statements and other disclosures concerning the Guarantor Subsidiaries are not presented because management has determined that such information would not be material to the holders of the debt.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In January 2003, the Company formed Monarch Pharmaceuticals Ireland Limited for the purpose of maintaining certain of the Company s international assets. While Monarch Pharmaceuticals Ireland Limited is not a guarantor subsidiary, the assets, liabilities, income and expenses are not material for the three and nine months ended September 30, 2003 and are included in the guarantor subsidiary column in the guarantor subsidiary financial statements which follow.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING BALANCE SHEETS

(In thousands)

	September 30, 2003				December 31, 2002			
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
	(Unaudited)							
ASSETS								
Current assets:								
Cash and cash equivalents	$ 117,148	$ 1,356	$	$ 118,504	$ 594,385	$ (6,160)	$	$ 588,225
Restricted cash	48,083	74,170		122,253				
Marketable securities					227,263			227,263
Accounts receivable, net	4,645	224,660		229,305	17,352	151,469	(8,834)	159,987
Inventories	107,543	144,185		251,728	45,761	121,392		167,153
Deferred income taxes	17,486	84,030		101,516	36,328	69,840		106,168
Prepaid expenses and other current assets	5,905	8,228		14,133	7,996	4,910		12,906
Total current assets	300,810	536,629		837,439	929,085	341,451	(8,834)	1,261,702
Property, plant, and equipment, net	53,456	193,699		247,155	51,587	165,527		217,114
Intangible assets, net	15,731	1,896,723		1,912,454	892,793	339,520		1,232,313
Investment in subsidiaries	2,282,786		(2,282,786)		1,126,245		(1,126,245)	
Other assets	51,597	51,873		103,470	25,254	14,277		39,531
Deferred income tax assets	4,071	5,216		9,287				
Total assets	$2,708,451	$2,684,140	$(2,282,786)	$3,109,805	$3,024,964	$ 860,775	$(1,135,079)	$2,750,660
LIABILITIES AND SHAREHOLDERS EQUITY								
Current liabilities:								
Accounts payable	$ 19,280	$ 36,449	$	$ 55,729	$ 26,119	$ 32,604	$ (8,834)	$ 49,889
Accrued expenses	33,718	459,312		493,030	42,542	254,986		297,528
Income taxes payable	56,849	5,406		62,255	18,870	2,377		21,247
Current portion of long-term debt	1,176			1,176	1,300			1,300
Total current liabilities	111,023	501,167		612,190	88,831	289,967	(8,834)	369,964
Long-term debt	345,093			345,093	345,093			345,093
Deferred income taxes					11,991	21,605		33,596

Other liabilities	63,255	89,145		152,400	70,074	750		70,824
Intercompany (receivable) payable	188,958	(188,958)			577,792	(577,792)		
Total liabilities	708,329	401,354		1,109,683	1,093,781	(265,470)	(8,834)	819,477
Shareholders equity	2,000,122	2,282,786	(2,282,786)	2,000,122	1,931,183	1,126,245	(1,126,245)	1,931,183
Total liabilities and shareholders equity	$2,708,451	$2,684,140	$(2,282,786)	$3,109,805	$3,024,964	$ 860,775	$(1,135,079)	$2,750,660

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF INCOME

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

	Three Months Ended September 30, 2003				Three Months Ended September 30, 2002			
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Revenues:								
Net sales	$ 41,615	$407,884	$ (41,570)	$407,929	$ 12,495	$300,297	$ (12,,084)	$300,708
Royalty revenue		16,275		16,275		14,997		14,997
Total revenues	41,615	424,159	(41,570)	424,204	12,495	315,294	(12,084)	315,705
Operating costs and expenses:								
Costs of revenues	30,925	101,066	(41,570)	90,421	9,372	66,274	(12,084)	63,562
Selling, general and administrative	19,199	116,034		135,233	4,454	95,671		100,125
Depreciation and amortization	1,822	37,876		39,698	9,674	5,929		15,603
Research and development	225	8,533		8,758		6,448		6,448
Intangible asset impairment								
Gain on sale of products	(5)	(10,307)		(10,312)				
Total operating costs and expenses	52,166	253,202	(41,570)	263,798	23,500	174,322	(12,084)	185,738
Operating (loss) income	(10,551)	170,957		160,406	(11,005)	140,972		129,967
Other income (expense):								
Interest income	607	430		1,037	5,600	352		5,952
Interest expense	(3,669)			(3,669)	(3,143)			(3,143)
Valuation change convertible notes receivable	9,338			9,338	548			548
Other, net	11	(47)		(36)	161	(74)		87
Equity in earnings of subsidiaries	116,298		(116,298)		105,791		(105,791)	
Intercompany reclassification(1)		(74,481)	74,481					
Intercompany interest income (expense)	5,298	(5,298)			8,243	(8,243)		
Total other income (expense)	127,883	(79,396)	(41,817)	6,670	117,200	(7,965)	(105,791)	3,444
(Loss) income before income taxes	117,332	91,561	(41,817)	167,076	106,195	133,007	(105,791)	133,411
Income tax expense	11,245	49,744		60,989	21,950	27,216		49,166

Net (loss) income	$106,087	$ 41,817	$ (41,817)	$106,087	$ 84,245	$105,791	$(105,791)	$ 84,245

(1) Intercompany reclassification caused by the formation of two new legal entities.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF INCOME

(Unaudited)

(In thousands, except per share data)

	Nine Months Ended September 30, 2003				Nine Months Ended September 30, 2002			
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Revenues:								
Net sales	$142,435	$1,090,614	$(142,168)	$1,090,881	$ 48,480	$820,764	$ (53,966)	$815,278
Royalty revenue		47,876		47,876		41,025		41,025
Total revenues	142,435	1,138,490	(142,168)	1,138,757	48,480	861,789	(53,966)	856,303
Operating costs and expenses:								
Costs of revenues	66,096	338,641	(142,168)	262,569	48,933	171,931	(53,966)	166,898
Selling, general and administrative	44,477	329,507		373,984	7,283	259,948		267,231
Depreciation and amortization	5,781	77,542		83,323	26,132	17,611		43,743
Research and development	675	221,812		222,487	225	18,554		18,779
Intangible asset impairment		110,970		110,970				
Gain on sale of products	(5)	(10,307)		(10,312)				
Total operating costs and expenses	117,024	1,068,165	(142,168)	1,043,021	82,573	468,044	(53,966)	496,651
Operating (loss) income	25,411	70,325		95,736	(34,093)	393,745		359,652
Other income (expense):								
Interest income	5,138	591		5,729	16,347	1,063		17,410
Interest expense	(10,135)	(2)		(10,137)	(9,009)	(19)		(9,028)
Valuation change convertible notes receivable	24,952			24,952	(27,378)			(27,378)
Other, net	(57)	(77)		(134)	(190)	(804)		(994)
Equity in earnings of subsidiaries	35,409		(35,409)		234,722		(234,722)	
Intercompany income (expense)	11,591	(11,591)			31,924	(31,924)		
Total other income (expense)	66,898	(11,079)	(35,409)	20,410	246,416	(31,684)	(234,722)	(19,990)
(Loss) income before income taxes	92,309	59,246	(35,409)	116,146	212,323	362,061	(234,722)	339,662
	28,430	23,837		52,267	(1,640)	127,339		125,699

Income tax expense (benefit)								
Net (loss) income	$ 63,879	$ 35,409	$ (35,409)	$ 63,879	$213,963	$234,722	$(234,722)	$213,963

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

GUARANTOR SUBSIDIARIES

CONDENSED CONSOLIDATING STATEMENTS OF CASH FLOWS

(Unaudited)
(In thousands)

	Nine Months Ended September 30, 2003				Nine Months Ended September 30, 2002			
	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated	King	Guarantor Subsidiaries	Eliminating Entries	King Consolidated
Cash flows from operating activities	$ 16,443	$ 352,042	$	$ 368,485	$(134,241)	$ 459,793	$	$ 325,552
Cash flows from investing activities:								
Purchases of marketable securities	(25,903)			(25,903)	(597,873)			(597,873)
Proceeds from sale of marketable securities	253,097			253,097	457,461			457,461
Transfer (to)/from restricted cash	(48,083)			(48,083)				
Proceeds from loans receivable		8,668		8,668				
Purchases of property, plant and equipment	(6,044)	(27,486)		(33,530)	(11,110)	(37,661)		(48,771)
Purchases of product rights	(9,000)			(9,000)	(120,300)			(120,300)
Acquisition of primary case business of Elan		(761,745)		(761,745)				
Convertible senior note					(10,044)			(10,044)
Intercompany transfer of property, plant, and equipment					(323)	323		
Investment in Meridian	(253,908)	15,410		(238,498)				
Proceeds from sale of products	13,310			13,310				
Proceeds from sale of assets	12	249		261	19	4,339		4,358
Net cash used in investing activities	(76,519)	(764,904)		(841,423)	(282,170)	(32,999)		(315,169)
Cash flows from financing activities:								
Proceeds from exercise of stock options, net	3,555			3,555	3,996			3,996
Purchase of common stock					(155,390)			(155,390)
Debt issuance costs	(214)			(214)	(4,850)			(4,850)
Proceeds from revolving credit facility	125,000			125,000				
Payments on revolving credit facility	(125,000)			(125,000)				
Payments on other long-term debt	(124)			(124)	(194)	(13)		(207)
Other Intercompany	(420,378)	420,378			425,796	(425,796)		

Net cash provided by (used in) financing activities	(417,161)	420,378		3,217	269,358	(425,809)	(156,451)
Increase (decrease) in cash and cash equivalents	(477,237)	7,516		(469,721)	(147,053)	985	(146,068)
Cash and cash equivalents, beginning of period	594,385	(6,160)		588,225	882,391	(7,789)	874,602
Cash and cash equivalents, end of period	$ 117,148	$ 1,356	$	$ 118,504	$ 735,338	$ (6,804)	$ $ 728,534

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PART I FINANCIAL INFORMATION

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

The following discussion contains certain forward-looking statements that reflect management s current views of future events and operations. This discussion should be read in conjunction with the following: (a) Risk Factors set out below and other sections of our Annual Report on Form 10-K for the year ended December 31, 2002, which are supplemented by the discussion which follows; (b) our audited consolidated financial statements and related notes which are included in our Annual Report on Form 10-K for the year ended December 31, 2002; 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

General

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2003	2002	2003	2002
Branded pharmaceuticals	$363,892	$293,728	$ 972,941	$788,624
Meridian Medical Technologies	38,379		98,317	
Royalties	16,275	14,997	47,876	41,025
Contract manufacturing	5,658	6,700	19,623	25,972
Other		280		682
Total	$424,204	$315,705	$1,138,757	$856,303

Results of Operations

Three Months Ended September 30, 2003 and 2002

Revenues

Total revenues increased $108.5 million, or 34.4%, to $424.2 million in 2003 from $315.7 million in 2002, due primarily to our acquisition of Sonata® and Skelaxin® from Elan Corporation, plc on June 12, 2003, our acquisition of Meridian Medical Technologies, Inc. (Meridian) on January 8, 2003, and increased net sales of some of our branded pharmaceutical products.

Net sales from branded pharmaceuticals increased $70.2 million, or 23.9%, to $363.9 million in 2003 from $293.7 million in 2002. This increase was primarily due to our acquisition of Sonata® and Skelaxin® from Elan Corporation, plc on June 12, 2003, our acquisition of Intal®, Tilade® and Synercid® from Aventis on December 30, 2002, and the growth in net sales of some of our pharmaceutical products, in particular Thrombin-JMI®, partially offset by lower sales, of Levoxyl®, and some of our anti-infective and women s health products.

Revenues from Meridian totaled $38.4 million for the quarter ended September 30, 2003. This is a new segment in 2003 due to our acquisition of Meridian on January 8, 2003.

Revenues from royalties is derived from payments we receive based on sales of Adenoscan® and Adenocard®. Revenue from royalties increased $1.3 million, or 8.7%, to $16.3 million in 2003 from $15.0 million in 2002 primarily due to royalty revenue derived from increased sales of Adenoscan®.

Revenues from contract manufacturing decreased $1.0 million, or 14.9%, to $5.7 million in 2003 from $6.7 million in 2002 primarily due to a lower unit volume of products manufactured for third parties in 2003.

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Operating Costs and Expenses

Total operating costs and expenses increased $78.1 million, or 42.1%, to $263.8 million in 2003 from $185.7 million in 2002. The increase was primarily due to cost of revenues associated with increased unit sales of some of our branded pharmaceutical products and costs of revenues, depreciation, and amortization associated with our acquisition of additional branded pharmaceutical products and Meridian. Special items included in operating costs and expenses during the third quarter of 2003 consist of a $10.3 million gain on the sale of our animal health products to Virbac Corporation, charges totaling $8.6 million primarily related to professional fees that are primarily related to the ongoing Securities and Exchange Commission, which we refer to in this report as the SEC, investigation of our company and the completed internal review conducted by the Audit Committee of our Board of Directors, and $0.7 million of recall expenses. Special items included in operating costs and expenses during the third quarter of 2002 consists of a $1.2 million charge primarily related to an increase in the reserve for our voluntary recall during 2001 of products manufactured for us by DSM Pharmaceuticals, Inc.

Sales of Nordette®, a women s health product, have continued to decline over the past year. The Nordette® product right has net intangible assets associated with it of $97.1 million. Management currently believes that this asset is not impaired based on estimated undiscounted future cash flows, however, if revenue declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with this product right.

On October 21, 2003, we amended our agreement with Eli Lilly concerning the supply and distribution of Lorabid® and settled a disputed liability. As a result, we obtained the rights to donate excess supply outside of the United States, excluding specific countries. We also agreed to the amendment of the supply contract with new specified purchase requirements causing an increase in the required purchase commitments in excess of expected demand. As a result of the settlement agreement, we anticipate a special charge in the fourth quarter of 2003 of approximately $10.0 million.

Special items are those particular material income or expense items that our management believes are not related to our ongoing, underlying business, are not recurring, or are not generally predictable. These items include, but are not limited to, merger and restructuring expenses; non-capitalized expenses associated with acquisitions, such as in-process research and development charges and one-time inventory valuation adjustment charges; charges resulting from the early extinguishments of debt; asset impairment charges; expenses of drug recalls; and gains and losses resulting from the divestiture of assets. We believe the identification of special items enhances an analysis of our on-going, underlying business and an analysis of our financial results when comparing those results to that of a previous or subsequent like period. However, it should be noted that the determination of whether to classify an item as a special charge involves judgments by us.

Cost of revenues increased $26.8 million, or 42.1%, to $90.4 million in 2003 from $63.6 million in 2002. This increase was primarily due to our acquisition of Sonata® and Skelaxin® and our acquisition of Meridian. As a percentage of revenues, cost of revenues increased to 21.3% for the third quarter of 2003 from 20.1% in 2002 primarily due to the acquisition of Meridian, whose products have lower margins, and differences associated with the mix of products we sold during each of these periods.

Cost of revenues from branded pharmaceuticals increased $13.8 million, or 26.5%, to $65.9 million in 2003 from $52.1 million in 2002. This increase was primarily due to costs associated with unit sales of Sonata® and Skelaxin®, which we acquired on June 12, 2003.

Cost of revenues from Meridian Medical Technologies was $16.1 million in 2003. This is a new segment in 2003 due to our acquisition of Meridian on January 8, 2003.

Cost of revenues from royalties was $2.5 million in 2003 compared to $2.8 million in 2002.

Cost of revenues associated with contract manufacturing decreased $2.1 million, or 26.3%, to $5.9 million in 2003 from $8.0 million in 2002 primarily due to a lower unit volume of products manufactured for third parties in 2003.

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Selling, general and administrative expenses increased $35.1 million, or 35.1%, to $135.2 million in 2003 from $100.1 million in 2002. This increase was primarily attributable to an increase in the number of sales representatives, and a special charge in the amount of $7.9 million for professional fees that are primarily related to the ongoing SEC investigation of the Company and the completed internal review conducted by our Audit Committee, partially offset by a decrease of $7.5 million in the fees associated with the promotion of Altace under our Co-Promotion Agreement with Wyeth. As a percentage of revenues, selling, general, and administrative expenses increased to 31.9% in 2003 compared to 31.7% in 2002.

Depreciation and amortization expense increased $24.1 million, or 154.5%, to $39.7 million in 2003 from $15.6 million in 2002. This increase was primarily attributable to the amortization of the intangible assets related to acquisitions during the past year including: Intal®, Tilade® and Synercid® on December 30, 2002; Meridian on January 8, 2003; and Sonata® and Skelaxin® on June 12, 2003.

Research and development expense increased to $8.8 million in the third quarter of 2003 from $6.4 million in 2002.

Operating Income

Operating income for the third quarter of 2003 totaled $160.4 million, an increase of 23.4% from operating income equaling $130.0 million in the same period of the prior year.

Other Income

Interest income decreased $5.0 million, or 83.3%, to $1.0 million in 2003 from $6.0 million in 2002 primarily due to lower balances of invested cash, cash equivalents and marketable securities during 2003 as compared to 2002.

Interest expense totaled $3.7 million in 2003, an increase of $0.6 million from $3.1 million in 2002.

Our financial results for the third quarter of 2003 include a special income item in the amount of $9.3 million to reflect a decrease in the valuation allowance for the convertible notes receivable from Novavax, Inc. Statement of Financial Accounting Standards No. 114, Accounting by Creditors for Impairment of a Loan an amendment of FASB Statements No. 5 and 15 which we refer to as SFAS No. 114, requires that we treat the Novavax convertible notes as an impaired loan because of the decline in the share price of Novavax common stock to levels below that established by our common stock conversion options associated with the convertible notes. We will adjust the amount of the valuation allowance in future periods based on the value of the underlying collateral (Novavax common stock) as of the last business day of each respective calendar quarter or until the loan is no longer considered to be impaired. If the Novavax common stock price declines, we may incur charges related to the investment in the convertible notes. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities . See Note 7, Accounting Developments, in our Notes to Condensed Consolidated Financial Statements included in this report.

Income Tax Expense

During the third quarter of 2003 our income tax expense equaled $61.0 million as compared to $49.2 million during the same period of the prior year. The effective tax rates of 36.5% in 2003 and of 36.9% in 2002 were higher than the federal statutory rate of 35% due primarily to permanent differences related to state income taxes.

Net Income

Due to the factors set forth above, we had net income of $106.1 million during the third quarter of 2003, an increase of 26.0% from net income of $84.2 million in 2002.

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Nine Months Ended September 30, 2003 and 2002

Revenues

Total revenues increased $282.5 million, or 33.0%, to $1,138.8 million for the nine months ended September 30, 2003 from $856.3 million in 2002, due primarily to our acquisition of Sonata® and Skelaxin® on June 12, 2003, increased net sales of some of our branded pharmaceutical products, particularly Altace® and Thrombin-JMI®, and our acquisition of Meridian on January 8, 2003.

Net sales from branded pharmaceuticals increased $184.3 million, or 23.4%, to $972.9 million in 2003 from $788.6 million in 2002. This increase was primarily due to our acquisition of Sonata® and Skelaxin®, growth in net sales of some of our pharmaceutical products, particularly Altace® and Thrombin-JMI®, partially offset by lower sales of Levoxyl®, and our women s health products.

Revenues from Meridian totaled $98.3 million for the nine months ended September 30, 2003. This is a new segment in 2003 due to our acquisition of Meridian on January 8, 2003.

Revenues from royalties is derived from payments we receive based on sales of Adenoscan® and Adenocard®. Revenues from royalties increased $6.9 million, or 16.8%, to $47.9 million in 2003 from $41.0 million in 2002 primarily due to royalty revenues derived from increased sales of Adenoscan®.

Revenues from contract manufacturing decreased $6.4 million, or 24.6%, to $19.6 million in 2003 from $26.0 million in 2002 due to a lower unit volume of products manufactured for third parties in 2003.

Operating Costs and Expenses

Total operating costs and expenses increased $546.3 million, or 110.0%, to $1,043.0 million in 2003 from $496.7 million in 2002. The increase was primarily due to special items resulting in a net charge of $322.3 million during the nine months ending September 30, 2003, additional operating costs and expenses associated with our acquisition of Meridian and our acquisition of additional branded pharmaceutical products, increased fees associated with the promotion of Altace® under our Co-Promotion Agreement with Wyeth, and cost of revenues associated with increased unit sales of some of our branded pharmaceutical products. Special items included in operating costs and expenses during the first nine months of 2003 consist of charges totaling $193.0 million for acquired research and development associated with our acquisition of rights to new formulations of Sonata® presently under development and our acquisition of Meridian, a $111.0 million intangible asset impairment charge related to Florinef®, a $22.2 million charge for professional fees that are primarily related to the ongoing SEC investigation and the completed internal review conducted by our Audit Committee, special inventory charges totaling $6.5 million primarily related to the recall of some lots of Levoxyl®, and a $10.3 million gain on the sale of the Company s animal health products to Virbac.

Sales of Nordette®, a women s health product, have continued to decline over the past year. The Nordette® product right has net intangible assets associated with it of $97.1 million. Management currently believes that this asset is not impaired based on estimated undiscounted future cash flows, however, if revenue declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with this product right.

Cost of revenues increased $95.7 million, or 57.3%, to $262.6 million in 2003 from $166.9 million in 2002. The increase was primarily due to our acquisition of Meridian, our acquisition of additional branded pharmaceutical products, and increased unit sales of some of our branded pharmaceutical products, particularly Altace®. Additionally, cost of revenues included special charges totaling $6.5 million primarily related to the recall of some lots of Levoxyl®. As a percentage of revenues, cost of revenues increased to 23.1% for the first nine months of 2003 from 19.5% in 2002 primarily due to the acquisition of Meridian, whose products have lower margins, the special charges mentioned above, and differences associated with the mix of products we sold during each of these periods.

Cost of revenues from branded pharmaceuticals increased $42.7 million, or 32.7%, to $173.4 million in 2003 from $130.7 million in 2002. This increase was primarily due to our acquisition of additional pharmaceutical products, and increased unit sales of some of our pharmaceutical products, particularly

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Altace®. Additionally, cost of revenues from branded pharmaceuticals included special charges totaling $4.3 million primarily related to our recall of some lots of Levoxyl®.

Cost of revenues from Meridian Medical Technologies was $52.8 million in 2003, including a $2.2 million special inventory charge relating to our acquisition of Meridian. Meridian Medical Technologies is a new segment in the first nine months of 2003 due to our acquisition of Meridian on January 8, 2003.

Cost of revenues from royalties totaled $8.0 million in 2003, an increase of $0.6 million from $7.4 million in 2002.

Cost of revenues associated with contract manufacturing increased $0.3 million to $28.4 million in 2003 from $28.1 million in 2002.

Selling, general and administrative expenses increased $106.8 million, or 40.0%, to $374.0 million in 2003 from $267.2 million in 2002. This increase was primarily attributable to fees and marketing expenses associated with the promotion of Altace® under our Co-Promotion Agreement with Wyeth, special charges totaling $22.2 million for professional fees that are primarily related to the ongoing SEC investigation of our company and the completed internal review conducted by our Audit Committee, an increase in the number of sales representatives, and selling, general and administrative expenses associated with our acquisition of Meridian. As a percentage of revenues, selling, general, and administrative expenses increased to 32.8% in 2003 compared to 31.2% in 2002.

Depreciation and amortization expense increased $39.6 million, or 90.6%, to $83.3 million in 2003 from $43.7 million in 2002. This increase was primarily attributable to the amortization of the intangible assets associated with our acquisitions of Intal®, Tilade® and Synercid® on December 30, 2002; Meridian on January 8, 2003; and Sonata® and Skelaxin® on June 12, 2003.

Research and development expense increased to $222.5 million in the first nine months of 2003 from $18.8 million in 2002. This increase was primarily due to special charges totaling $193.0 million for acquired in-process research and development associated with the company s acquisition of the rights to new formulations of Sonata® presently under development and our acquisition of Meridian.

Operating Income

We had operating income of $95.7 million for the first nine months of 2003, a decrease from operating income totaling $359.7 million in the same period of the prior year. This decrease was primarily due to the special items described above, particularly special charges totaling $193.0 million for acquired in-process research and development relating to our acquisition of rights to new formulations of Sonata® presently under development and our acquisition of Meridian, and a $111.0 million intangible asset impairment special charge related to Florinef®.

Other Income (Expense)

Interest income decreased $11.7 million, or 67.2%, to $5.7 million in 2003 from $17.4 million in 2002 primarily due to lower balances of invested cash, cash equivalents and marketable securities during 2003 as compared to 2002.

Interest expense totaled $10.1 million in 2003, an increase of $1.1 million from $9.0 million in 2002.

Our financial results in 2003 include a special income item in the amount of $25.0 million to reflect the decrease in the valuation allowance for the convertible notes receivable from Novavax, Inc. SFAS 114 requires that we treat the Novavax convertible notes as an impaired loan because of the decline in the share price of Novavax common stock to levels below that established by our common stock conversion options associated with the convertible notes. We will adjust the amount of the valuation allowance in future periods based on the value of the underlying collateral (Novavax common stock) as of the last business day of each respective calendar quarter or until the loan is no longer considered to be impaired. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable

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Interest Entities. See Note 7, Accounting Developments, in our Notes to Condensed Consolidated Financial Statements included in this report.

Income Tax Expense

For the nine months ended September 30, 2003 the effective tax rate of 45.0% was higher than the federal statutory rate due primarily to permanent differences related to state income taxes and non-deductible in-process research and development changes incurred in connection with our acquisition of Meridian. The effective tax rate in 2002 of 37.0% was higher than the federal statutory rate of 35% due primarily to permanent differences related to state income taxes.

Net Income

Due to the factors set forth above, we had net income of $63.9 million during the nine months ending September 30, 2003 as compared to net income of $214.0 million during the nine months ending September 30, 2002.

Liquidity and Capital Resources

We believe that existing balances of cash, cash equivalents and marketable securities, cash generated from operations, existing capacity under our senior secured 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 December 30, 2002 we acquired Synercid® from Aventis. As part of our acquisition of Synercid® we will potentially pay Aventis milestone payments totaling $75.1 million, more specifically, we will potentially pay Aventis milestone payments totaling $50.1 million, payable in annual installments of $10.3 million, $21.2 million, and $18.6 million beginning on December 31, 2003, which relate to the indication for the treatment of vancomycin-resistant enterococcus faecium. The remaining $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.

On January 8, 2003, we completed our acquisition of Meridian. We paid $44.50 per common share to Meridian shareholders, totaling approximately $246.6 million. We financed the acquisition using our available cash.

On June 12, 2003, we acquired the primary care business of Elan and of some of its subsidiaries in the United States and Puerto Rico, which includes the rights to two branded prescription pharmaceutical products, including the rights to potential new formulations, of Sonata® and Skelaxin®, together with Elan s United States primary care field sales force. Product rights subject to the agreement include those related to Sonata®, a nonbenzodiazepine treatment for insomnia, and Skelaxin®, a muscle relaxant, in the United States, its territories and possessions, and Puerto Rico. Under the terms of the agreement, Elan s sale of Skelaxin® included the related NDAs, copyrights, trademarks, patents and U.S. rights to potential new formulations of Skelaxin®. Elan s sale of Sonata® included its rights to the product, as well as certain related copyrights. We also acquired certain intellectual property, regulatory, and other assets relating to Sonata® directly from Wyeth. Under the terms of the agreement, we secured an exclusive license to the intellectual property rights, in this territory, of both Wyeth and Elan to the extent they relate to new formulations of Sonata®, other than for use in animals. We paid approximately $598.3 million, including transaction costs, plus an additional $163.4 million which was placed into escrow to satisfy the deferred obligations to Wyeth that we assumed in connection with the acquisition. We financed the acquisition through borrowings of $125.0 million under our

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senior secured revolving credit facility and with cash on hand. The purchase price included the transfer of inventory with a value of approximately $40.0 million. We will also

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

pay up to $71.0 million if Elan achieves certain milestones in connection with the development of a reformulated version of Sonata®;

potentially pay $15.0 million if annual net sales of a reformulated version of Sonata® exceed $100.0 million; and

potentially pay an additional $25.0 million milestone payment to Elan relating to the ongoing exclusivity of Skelaxin® on January 2, 2004.

On March 10, 2003, we learned that the Company was the subject of a formal SEC investigation. Over the course of this continuing investigation, the SEC has requested the production of documents and information related to, among other things, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and our Audit Committee s internal review of issues raised by the SEC investigation. We have cooperated, and will continue to cooperate, in providing information to the SEC.

In connection with our previously announced determination that we have underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002, we contacted the Centers for Medicare and Medicaid Services, the Public Health Service, the Office of Inspector General at the Department of Health and Human Services, the Department of Justice, and the Department of Veterans Affairs. In August 2003, we met with representatives of several of these agencies, including the Office of Inspector General, and provided detailed briefings on the results of the reviews conducted by us and our Audit Committee. We expect to engage in more detailed discussions with these and other appropriate agencies in order to determine the precise amount of the underpayments. We currently expect to make the requisite payments in 2004.

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 related to the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®. We intend to cooperate in providing information to the Office of Inspector General.

The SEC, the Office of Inspector General at the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Public Health Service, the Department of Justice, the Department of Veterans Affairs and other governmental agencies that might be investigating or might commence an investigation of us could impose, based on a claim of violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time. For additional information, please see the Risk Factors section under the heading If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of our securities against us, our directors, former directors, executive officers, former executive officers, a company subsidiary and one of its former officers 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. Plaintiffs in the consolidated action filed a consolidated amended complaint on October 21, 2003 alleging that we, through some of our executive officers,

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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 King s November 2001 public offering as defendants. 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, pursuant to the Private Securities Litigation Reform Act of 1995, these two cases were consolidated with the other class actions. Plaintiffs in these actions have, however, moved to remand these actions back to Tennessee state court.

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. 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). The complaint alleges that we and certain of our executive officers, former executive officers, directors and former directors violated fiduciary duties that they 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 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 securities litigation, neither of which can be predicted or reasonably estimated at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the government investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending King in the securities 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.

We have placed $46.5 million of our cash on hand in an interest-bearing escrow account. This amount, which we accrued in the fourth quarter of 2002, represents our best estimate of the extent to which we underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002 and is included in restricted cash in our financial statements. The accrual adjustment relates solely to the estimated underpayments and excludes any interest, fines, penalties or other amounts that might be owed in connection with the underpayments, as we cannot predict or reasonably estimate their likelihood or magnitude at this time. We contacted the Centers for Medicare and Medicaid Services, the Public Health Service, the Office of Inspector General at the Department of Health and Human Services, the Department of Justice, and the Department of Veterans Affairs in connection with the underpayments and expect to engage in more detailed discussions with these and other appropriate agencies in order to determine the precise amount of the underpayments. We expect to make the requisite payments in 2004.

We drew down a total of $125.0 million on our $400.0 million senior secured revolving credit facility on June 3 and June 6, 2003, the proceeds of which were used to fund a portion of the Elan acquisition on June 12, 2003. During the third quarter of 2003, we paid off the principal balance and have no outstanding balance as of September 30, 2003.

Nine Months Ended September 30, 2003

We generated net cash from operations of $368.5 million for the nine months ended September 30, 2003. Our net cash provided from operations was primarily the result of $63.9 million net income, adjusted for non-cash depreciation and amortization of $84.0 million, a decrease in prepaid expenses of $43.2 million, an increase in accrued expenses of $59.3 million, the non-cash write-off of in-process research and development of $193.0 million, an increase in income taxes payable of $39.5 million, and a non-cash impairment charge for intangible assets of $111.0 million. Net cash provided from operations was decreased by an increase in accounts receivable of $66.3 million, an increase in inventory of $37.9 million, a change in deferred taxes of $93.7 million, a non-cash decrease in the reserve for the Novavax convertible senior notes of $25.0 million, and

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a gain of $10.3 million on the sale of our animal health products, all of which offset the items previously described.

Investing activities reduced cash flow by $841.4 million which amount primarily consisted of $238.5 million for our purchase of Meridian, $48.1 million for our transfer of cash to restricted cash, $33.5 million for our purchase of property, plant and equipment, and $761.7 million for our purchase of the primary care business of Elan, partially offset by net proceeds from the sale of marketable securities of $227.2.

Financing activities contributed $3.2 million to cash flow due primarily to proceeds in the amount of $3.6 million from the exercise of employee stock options.

Certain Indebtedness and Other Matters

As of September 30, 2003, we had $346.3 million of long-term debt (including current portion), up to $400.0 million available under our revolving credit facility, and $616.0 million available under our universal shelf registration. As described above, on June 3 and June 6, 2003, we drew down a total of $125.0 million under our senior secured revolving credit facility to fund a portion of our acquisition of Elan s primary care business on June 12, 2003. During the third quarter of 2003, we paid off the principal balance owing on our senior secured revolving credit facility and have no outstanding balance as of September 30, 2003.

On September 20, 2001, we registered a $1.3 billion universal shelf registration statement on Form S-3 with the Securities and Exchange Commission. This universal shelf registration statement allows us to sell any combination of debt and/or equity securities in one or more offerings up to a total of $1.3 billion. During November 2001, we completed the sale of 17,992,000 newly issued shares of common stock for $38.00 per share ($36.67 per share net of commissions and expenses) resulting in net proceeds of $659.8 million. At September 30, 2003, approximately $616.0 million remains available to us under the $1.3 billion universal shelf registration statement. Additionally, during November 2001, we issued $345.0 million of 2 3/4% Convertible Debentures due November 15, 2021 in a private placement.

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 prime rate or 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 $4.9 million of deferred financing costs, which are being amortized over five years, the life of the senior secured revolving credit facility. This facility requires us to maintain a minimum net worth of no less than $1.2 billion plus 50% of our consolidated net income for each fiscal quarter after April 23, 2002, excluding any fiscal quarter for which consolidated income is negative; an EBITDA to interest expense ratio of no less than 3.00 to 1.00; and a funded debt to EBITDA ratio of no greater than 3.50 to 1.00 prior to April 24, 2004 and of no greater than 3.00 to 1.00 on or after April 24, 2004. As of September 30, 2003, we have complied with these covenants. As of September 30, 2003, there was no outstanding balance under this facility.

Capital Expenditures

Capital expenditures, including capital lease obligations, were $33.5 million and $48.8 million for the nine months ended September 30, 2003 and 2002, respectively. The principal capital expenditures during the nine months ended September 30, 2003 included property and equipment purchases, new information technology system implementation costs and building improvements for facility upgrades and increased capacity.

We anticipate capital expenditures, including capital lease obligations, for the year ending December 31, 2003 of approximately $55 million. The principal capital expenditures are anticipated to include property and

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equipment purchases, new information technology system implementation costs, building improvements for facility upgrades, cost associated with improving our production capabilities, and costs associated with moving production of some of our pharmaceutical products to our facilities in St. Louis, Missouri, and Rochester, Michigan.

Impact of Inflation

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

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 allowances for doubtful accounts, values of inventories and intangible assets, impairment, accruals for rebates, returns and chargebacks, as well as estimates used in applying the revenue recognition policy and accounting for the Novavax convertible senior notes and the Co-Promotion Agreement with Wyeth. 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.

Allowance for doubtful accounts. We maintain an allowance for doubtful receivables for estimated losses resulting from the inability of our trade customers to make required payments. We provide an allowance for specific customer accounts where collection is doubtful and also provide a general allowance for other accounts based on historical collection and write-off experience. Judgment is necessary and if the financial condition of our customers were to worsen, additional allowances may be required.

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

Intangible assets. When we purchase products we classify the purchase price, including expenses and assumed liabilities, as intangible assets. The purchase price is allocated to product rights, 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.

Long-lived assets. 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. Assumptions and estimates used in the evaluation of impairment may affect the carrying value of long-lived assets, which could result in impairment

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charges in future periods. Such assumptions include projections of future cash flows and, in some cases, the current fair value of the asset. In addition, our depreciation and amortization policies reflect judgments on the estimated useful lives of assets.

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

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

Novavax convertible senior notes. Our Novavax 4% convertible senior notes are carried at cost, with a valuation allowance which reduces the convertible senior notes to estimated fair value. The estimated fair value was determined by the quoted market price of the underlying securities at the end of the period. The amount of the valuation allowance will be adjusted in future periods based on the value of the underlying collateral (Novavax common stock) as of the last business day of each respective calendar quarter or until the time the loan is no longer considered to be impaired. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities . See Note 7, Accounting Developments, in our Notes to Condensed Consolidated Financial Statements included in this report.

Co-Promotion Agreement with Wyeth. We have a Co-Promotion Agreement with Wyeth to promote Altace®. A $75.0 million upfront fee was paid to us by Wyeth and this fee is being amortized on a straight line basis over the life of the agreement as a reduction of co-promotion marketing expenses. Co-promotion fees are paid to Wyeth based on a percentage of net sales of Altace®. We accrue co-promotion fees paid by us at the rate expected for the entire year. The rate is adjusted during the year, if necessary, as it becomes clearer what the actual rate will be. Co-promotion marketing expenses are marketing costs incurred by either us or Wyeth in accordance with the Co-Promotion Agreement. Co-promotion marketing expenses are expensed ratably throughout the year based on our expected portion of the total co-marketing expenses incurred by both 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, 2002, 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, 2002 actually occurs, our business, results of operations and financial condition could be materially adversely affected, the trading price, if any, of our securities could decline and you might lose all or part of your investment.

Risks Related to our Business

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

On March 10, 2003, we learned that the Company was the subject of a formal SEC investigation. Over the course of this continuing investigation, the SEC has requested the production of documents and information related to, among other things, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and our Audit Committee s internal review of issues raised by the SEC investigation. We have cooperated, and will continue to cooperate, in providing information to the SEC.

In connection with our previously announced determination that we have underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002, we contacted the Centers for Medicare and Medicaid Services, the Public Health Service, the Office of Inspector General at the Department of Health and Human Services, the Department of Justice, and the Department of Veterans Affairs. In August 2003, we met with representatives of several of these agencies, including the Office of Inspector General, and provided detailed briefings on the results of the reviews conducted by us and our Audit Committee. We expect to engage in more detailed discussions with these and other appropriate agencies in order to determine the precise amount of the underpayments. We currently expect to make the requisite payments in 2004.

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 related to the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®. We intend to cooperate in providing information to the Office of Inspector General.

The SEC, the Office of Inspector General at the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Public Health Service, the Department of Justice, the Department of Veterans Affairs and other governmental agencies that might be investigating or might commence an investigation of us could impose, based on a claim of a violation of fraud and false claims laws or otherwise, civil and/or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of these laws may impose liability even in the absence of specific intent to defraud. We cannot predict or reasonably estimate the likelihood or magnitude of any such sanctions at this time. For additional information, please see this Risk Factors section under the heading If we fail to comply with our reporting and payment obligations under the Medicaid rebate program or other governmental pricing programs, we could be subject to additional reimbursements, penalties, sanctions and fines which could have a material adverse effect on our business.

Subsequent to the announcement of the SEC investigation described above, beginning in March 2003, 22 purported class action complaints were filed by holders of our securities against us, our directors, former

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directors, executive officers and former executive officers 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. Plaintiffs in the consolidated action 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 King s November 2001 public offering as defendants. 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, pursuant to the Private Securities Litigation Reform Act of 1995, these two cases were consolidated with the other class actions. Plaintiffs in these actions have, however, moved to remand these actions back to Tennessee state court.

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. 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). The complaint alleges that we and certain of our executive officers, former executive officers, directors and former directors violated fiduciary duties that they 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 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 securities litigation, neither of which we can predict or reasonably estimate at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the government investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending King in the securities litigation has resulted, and is expected to continue to result, in a significant diversion of management s attention and resources and an increase in professional fees.

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

Altace®, Thrombin-JMI®, Levoxyl® and royalty revenues for the last twelve months ended September 30, 2003 accounted for 37.5%, 10.0%, 9.0% and 4.6% of our total revenues, respectively, or 61.1% in total. In addition, we acquired Sonata® and Skelaxin® on June 12, 2003, which together had net sales in the United States and Puerto Rico of approximately $238.0 million in 2002. We believe that sales of these products may constitute a significant portion of our revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of any of these products or products for which we receive royalty payments could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Cobalt Pharmaceuticals, Inc., a generic drug manufacturer located in Mississauga, Ontario, Canada, has filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA s *Approved Drug Products With Therapeutic Equivalence Evaluations,* which we refer to as the FDA s 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 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 federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification, which we refer to as a Paragraph IV certification , challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the

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pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and we have filed suit 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. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, we would not receive the full benefit of that 30 month stay. We have also recently amended our complaint, without opposition, to include an allegation of infringement of the 856 patent by Cobalt. 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.

Eon Labs, Inc. and CorePharma, LLC have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin®. United States Patent No. 6,407,128, the 128 patent, a method of use patent relating to Skelaxin®, is listed in the FDA s Orange Book and does not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 patent. We have filed separate suits against Eon Labs and CorePharma and intend to vigorously enforce our rights under the 128 patent to the full extent of the law.

Mylan Pharmaceuticals, Inc. and KV Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Levoxyl®. United States Patent No. 6,555,581, the 581 patent, a utility patent with formulation claims relating to Levoxyl®, was issued to us on April 29, 2003. The 581 patent is listed in the FDA s Orange Book and does not expire until February 15, 2022. No earlier than April 30, 2003, we received notice of Mylan s Paragraph IV certification, which alleges noninfringement of the 581 patent. On June 24, 2003, we received notice of KV Pharmaceutical s Paragraph IV certification, which alleges noninfringement and invalidity of the 581 patent. We have filed separate suits against Mylan and KV Pharmaceutical and intend to vigorously enforce our rights under the 581 patent to the full extent of the law.

Barr Laboratories Inc. has filed an ANDA, which included a Paragraph IV certification, with the FDA seeking permission to market a generic version of Prefest®. United States Patent No. 5,108,995, the 995 patent, a utility patent with method of treatment claims relating to Prefest®, and United States Patent No. 5,382,573, the 573 patent, a utility patent with pharmaceutical preparation claims relating to Prefest®, were issued on April 28, 1992, and January 17, 1995, respectively. The 995 patent and the 573 patent are both listed in the FDA s Orange Book and do not expire until April 28, 2009, and January 17, 2012, respectively. On October 9, 2003, we received notice of Barr s Paragraph IV certification, which alleges noninfringement and invalidity of the 995 patent and the 573 patent. Under the Hatch-Waxman Act, we have until December 1, 2003, to sue Barr for infringement of those patents to invoke a statutory 30-month stay of FDA approval. We intend to vigorously enforce our rights under both patents.

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

Our charter and bylaws require that we indemnify our directors and officers to the fullest extent provided by applicable law. Although we have purchased directors and officers liability insurance 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 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 increases significantly, or if this insurance is unavailable, we may not be able to maintain or increase our levels of insurance coverage for our directors and officers. This could make it difficult to attract or retain qualified directors and officers.

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

We entered into the Co-Promotion Agreement with Wyeth for Altace® partially because we believed a larger pharmaceutical company with more sales representatives and, in our opinion, with substantial

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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 and profits of Altace® and to optimize the marketing of the product by coordinating our promotional activities.

Under the Co-Promotion Agreement, Wyeth and we agreed to establish an annual budget of marketing expenses to cover, among other things, direct-to-consumer advertising, such as television advertisements and advertisements in popular magazines and professional journals. One of the goals of the direct-to-consumer advertising campaign is to encourage the targeted audience to ask their own physicians about Altace® and whether it might be of benefit for them. The direct-to-consumer campaign may not be effective in achieving this goal. Physicians may not prescribe Altace® for their patients to the extent we might otherwise hope if patients for whom Altace® is indicated do not ask their physicians about Altace®.

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

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

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

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

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

All prescription drugs currently marketed by pharmaceutical companies may be grouped into existing drug classes, but the criteria for inclusion vary from class to class. For some classes, specific biochemical properties may be the defining characteristic. For example, Altace® (ramipril) is a member of a class of

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

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

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

If another company were to acquire, directly or indirectly, over 50% of the combined voting power of Wyeth s voting securities or more than half of its total assets, then Wyeth could assign its rights and obligations under the Altace® Co-Promotion Agreement to a successor without our prior consent. However, a successor would be required to first assume in writing the obligations of Wyeth under the Co-Promotion Agreement before the rights of Wyeth were assigned to it. Another party might not market Altace® as effectively or efficiently as Wyeth did. Also, a company that acquires Wyeth might not place as much emphasis on the Co-Promotion Agreement, might expend fewer marketing resources, such as a fewer number of 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

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Altace® under the Co-Promotion Agreement if the product were acquired by Wyeth through a merger with or acquisition by a third party and the product were no longer actively promoted by Wyeth or its successor through detailing the product to physicians.

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

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

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

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

During 2001 and 2002, we filed with the U.S. Patent and Trademark Office in excess of 40 applications for U.S. patents concerning our FDA-approved product Levoxyl®. We cannot assure you that any or all of the other patent applications currently under review will be granted, or whether any or all of the resulting patents will provide Levoxyl® with additional protection from possible generic substitution. As noted above, Mylan and KV Pharmaceutical 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. The 581 patent is listed in the FDA s Orange Book and does not expire until February 15, 2002. 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

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the law. If we are not successful in enforcing our patents, our business, financial condition, results of operations and cash flows could be materially adversely affected.

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

We filed a Citizen s Petition with the FDA on March 28, 2003 requesting that the FDA refrain from approving or accepting for filing any ANDA or supplemental ANDA for levothyroxine sodium drug products until adequate standards for establishing bioequivalence for levothyroxine sodium drug products are adopted in accordance with FDA procedures. If the FDA approves an ANDA for a generic equivalent of Levoxyl® under the current standards, our business, financial condition, results of operations and cash flows could be materially adversely affected.

We cannot assure you that we will not have to take additional charges related to the divestiture of Lorabid® or that sales of Lorabid® will increase in the future.

Under the supply agreement with Eli Lilly, we continue to be obligated to make minimum purchases of Lorabid® inventory. Based on changes in estimated prescription trends, we believe the minimum purchase commitments under the supply agreement are greater than inventory quantities we will be able to sell to our customers. As a result, during the fourth quarter of 2002, we recorded a $49.9 million charge related to the liability associated with the amount of the purchase commitments in excess of expected demand. Additionally, during the fourth quarter of 2002, we recorded an intangible asset impairment charge in the amount of $66.8 million and a charge in the amount of $15.2 million attributable to inventory contributions, the latter resulting from our decision to divest our rights to Lorabid®. On October 21, 2003, we amended our agreement with Eli Lilly concerning the supply and distribution of Lorabid® and settled a disputed liability. As a result, we obtained the rights to donate excess supply outside of the United States, excluding specific countries. We also agreed to the amendment of the supply contract with new specified purchase requirements causing an increase in the required purchase commitments in excess of expected demand. As a result of the agreement, we anticipate a special charge in the fourth quarter of 2003 of approximately $10 million. If sales of Lorabid® continue to decline or if we are unable to secure adequate Lorabid® inventory purchase commitments from a buyer of the Lorabid® rights, we may incur additional losses in the future. Further, in the event of further decline in the fair value of Lorabid®, we may incur additional charges. We have not been successful in divesting Lorabid® to date and we cannot assure you that we will be able to divest our rights to Lorabid® on acceptable terms or at all or that we will not incur additional charges in connection with this product. These charges and minimum purchase requirements could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

From time to time studies on various aspects of pharmaceutical products, therapies or classes of drugs are conducted by academics or others, including government agencies, the results of which when published may

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

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

As of September 30, 2003, we had $1.9 billion of net intangible assets and goodwill. Intangible assets primarily include the net book value of various product rights, trademarks, patents and other intangible rights. If future sales of a product decline significantly, it could result in an impairment of the declining product s net book value, resulting in a non-cash impairment charge. For example, during the fourth quarter of 2002, we decided to divest our rights to Lorabid®, resulting in an impairment charge of $66.8 million. Additionally, the FDA approved for sale generic substitutes for our product Florinef® in March 2002 and in January 2003. During the first quarter of 2003, we recorded an intangible asset impairment charge of $111.0 million related to this product due to revised sales projections for Florinef® triggered by the entry of a second generic product into the market. Sales of Nordette® and Prefest®, two of our women s health products, have continued to decline over the past year due to the perception created by data associated with the Women s Health Initiative mentioned above and a second generic of Nordette®. The Nordette® and Prefest® product rights have net intangible assets associated with them of $97.1 million and $110.1 million, respectively. Management currently believes that these assets are not presently impaired based on estimated undiscounted future cash flows; however, if revenue declines exceed current expectations, we may have to write-off a portion or all of the intangible assets associated with these product rights. Any impairment of the net book value of any product or combination of products, depending on the size of the product or products, could result in a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

Other companies, some of which have substantially greater financial, marketing and sales resources than we do, compete with us for the acquisition of FDA-approved products, products in development or companies. We may not be able to acquire rights to additional FDA-approved products, products in development, or companies on acceptable terms, if at all, or be able to obtain future financing for acquisitions on acceptable terms, if at all. The inability to effect acquisitions of additional branded FDA-approved products and products in development 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.

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

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

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

We 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 in a cost effective manner; or
- obtain FDA approvals necessary to successfully implement the strategies described above.

For example, we are

- engaged in the development of a modified-release formulation of Sonata®;
- engaged in new formulation development for Skelaxin®;
- in exclusive license agreements with Novavax to promote, market, distribute and sell Androsorb , once approved, a topical testosterone replacement therapy for testosterone deficient women, and other women s health products;
- engaged in the development of binodenoson, a myocardial pharmacologic stress imaging agent, and T-62, an investigational drug for the treatment of neuropathic pain;
- engaged in the development of a new inhaler for Intal® using the alternative propellant hydrofluoro-alkane, or HFA, and a diazepam-filled auto-injector, each of which is under FDA review;
- in an exclusive licensing agreement with Beartown to manufacture, market, distribute and sell tetrac, once approved, as a compound for the suppression of pituitary secretion of thyroid stimulating hormone (TSH); and
- in a licensing agreement with SkyePharma PLC to develop and commercialize a modified-release formulation of Altace® utilizing SkyePharma s patented oral drug delivery technology Geomatrix®.

However, we cannot assure you that we will be successful in any or all of these projects. If we are not successful, 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

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license. Because there is rapid technological change in the industry and because many other companies may have more financial resources than we do, other companies may

develop or license their products more rapidly than we can,

complete any applicable regulatory approval process sooner than we can,

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

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

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

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

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

Effective August 18, 2003, the FDA may approve generic substitutes of branded pharmaceutical products in a shorter period of time due to recent regulatory changes. 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 listed patents. If we filed a patent infringement suit against the generic applicant within 45 days of receiving such notice, the FDA was barred from approving the ANDA for 30 months unless specific events occurred sooner. To avoid multiple 30-month stays for the same branded drug, the FDA s new regulations now only require one such notice. Under the new regulations, if an ANDA applicant has already provided patent invalidity or non-infringement notice to us about a particular branded drug, we will not get a second notice or opportunity for another stay for that drug. As a result, generic substitutes of our branded pharmaceutical products could be approved sooner. The FDA s new rule, however, is a regulatory rather than a statutory change and may be subject to challenge.

The FDA s new regulations also significantly change 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

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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.

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 56.5% of our revenues for the last twelve months ended September 30, 2003. Many of our production processes are complex and require specialized and expensive equipment. Any unforeseen delays or interruptions in our manufacturing operations may reduce our profit margins and revenues. If we are unable to resume manufacturing, after interruption, we may not be able to distribute our products as planned. Furthermore, growing demand for our products could exceed our ability to supply the demand. If such situations occur, it may be necessary for us to seek alternative manufacturers which could adversely impact our ability to produce and distribute our products. We cannot assure you that we would be able to utilize third-party manufacturers for our products in a timely manner or at all. In addition, our manufacturing output may decline as a result of power outages, supply shortages, accidents, natural disasters or other disruptions of the manufacturing process. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

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

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

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

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The occurrence of any of these events could result in significant back orders 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 Parkedale facility has been the subject of FDA concerns. If we cannot adequately address the FDA s concerns, we may be unable to operate the Parkedale facility and, accordingly, our business may suffer.

Our Parkedale facility, located in Rochester, Michigan, manufactures both drug and biological pharmaceutical products. The Parkedale 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 Parkedale facility continues to be subject to the consent decree.

The Parkedale facility was inspected by the FDA in February/March 2003 and by an FDA Team Biologics inspector in August 2003. When an FDA inspector completes an authorized inspection of a manufacturing facility, the inspector typically provides the owner/operator of the facility with a written report listing the inspector s observations of objectionable conditions and practices. This written report is known as an FDA Form 483 or simply as a 483. The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a pharmaceutical manufacturer receives a 483 after an inspection and our Parkedale 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 Parkedale 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. The 483 from March 2003 does not require us to delay or discontinue the production of any products made at the Parkedale facility. Our Parkedale facility did not receive a 483 following the August 2003 inspection.

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

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

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

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

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

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

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

In November 2000, we began the process of implementing a new information technology system which became operational at our Bristol facilities in July 2003. In connection with its implementation, we have incurred related costs of approximately $30 million. 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 the event we do not successfully convert our other sites in a timely manner from our existing information system to the new one or in the event the new system does not operate as expected, our business could be disrupted. We could lose what we have invested and still have to incur additional costs for another system. This disruption or additional costs, if required, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Our results of operations, including, in particular, product sales revenue, may vary from quarter to quarter due to many factors. Wholesalers and distributors represent a substantial portion of our sales. Buying patterns of our wholesalers and distributors may vary from time to time. In the event wholesalers and distributors with

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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 or announced 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. Other factors include expenditures related to the acquisition, sale and promotion of pharmaceutical products, a changing customer base, the availability and cost of raw materials, interruptions in supply by third-party manufacturers, new products introduced by us or our competitors, the mix of products we sell, sales and marketing expenditures, product recalls, competitive pricing pressures and general economic and industry conditions that may affect customer demand. We cannot assure you that we will be successful in maintaining or improving our profitability or avoiding losses in any future period.

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

During the period from December 2000 through June 2002, we provided $40.0 million in financing to Novavax in the form of notes receivable convertible to common stock of Novavax. The loan is impaired as defined under Statement of Financial Accounting Standards No. 114, Accounting by Creditors for Impairment of a Loan. We established a valuation allowance in the second quarter of 2002 which was adjusted in subsequent quarters during 2002 and 2003. As of September 30, 2003, the valuation allowance for the Novavax convertible notes equaled $10.5 million. We will adjust the amount of the valuation allowance in future periods until the loan is no longer considered to be impaired. We may incur additional charges related to our investment in the convertible notes. Accordingly, these charges may adversely impact our earnings. This accounting treatment may change under Financial Accounting Standards Board Interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46).

We hold notes receivable convertible to common stock of Novavax with a face value of $40.0 million at September 30, 2003. We also have an exclusive worldwide license to promote, market, distribute and sell Estrasorb and Androsorb , products owned by Novavax, following approval, except in the United States and Puerto Rico, where we will co-market the products with Novavax. Once approved, we will pay Novavax a royalty based on a percentage of net sales of the products outside of the United States and Puerto Rico. Novavax will pay us a co-promotion fee equal to 50% of net sales less cost of revenues of the products within the United States and Puerto Rico. The NDA for Estrasorb was approved by the FDA during October 2003. We own approximately 1.1% of Novavax common stock.

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

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

Our wholly owned subsidiary, Jones Pharma Incorporated, is a defendant in 916 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine, which is usually

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

Sales of Thrombin-JMI® may be affected by the perception of risks associated with some of the raw materials used in its manufacture; if we are unable to 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. Bovine-sourced materials 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. Although no BSE has been documented in the United States, the United States is considered a Category II BSE-risk country, meaning that the United States is probably BSE-free but has some history of importing cattle from the United Kingdom and Canada.

We receive the bovine raw materials from a single vendor and any interruption or delay in the supply of that material 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 BSE spreads to the United States, 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.

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

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

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

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

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

All U.S. government contracts provide that they may be terminated for the convenience of the government as well as for default. The unexpected termination of one or more of our significant government contracts could result in a material adverse effect on our business, financial condition, results of operations and cash flows. A surge capability provision allows for the coverage of defense mobilization requirements in the event of rapid military deployment. If this surge capability provision becomes operative, we may be required to devote more of our Meridian Medical Technologies segment manufacturing capacity to the production of products for the government which could result in less manufacturing capacity being devoted to products in this segment with higher profit margins. Our supply contracts with the Department of Defense are subject to post-award audit and potential price determination. These audits may include a review of our performance on the contract, our pricing practices, our cost structure and our compliance with applicable laws, regulations and standards. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while costs already reimbursed must be refunded. Therefore, a post-award audit or price redetermination could result in an adjustment to our revenues. From time to time the Department of Defense makes claims for pricing adjustments with respect to completed contracts. No claims are currently pending. 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-injector 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

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these programs could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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

As discussed in this Risk Factors section under the heading Investigations by the SEC and Office of Inspector General at the Department of Health and Human Services, other possible governmental investigations, and securities litigation could have a material adverse effect on our business, and elsewhere in this report we determined recently that we have underaccrued for estimated 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 represents our best estimate of the extent to which we underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002, including amounts owing to the Department of Veterans Affairs and the Public Health Service. We contacted the Centers for Medicare and Medicaid Services, the Public Health Service, the Office of Inspector General at the Department of Health and Human Services, the Department of Justice, and the Department of Veterans Affairs in connection with the underpayments. In August 2003, we met with representatives of several of these agencies, including the Office of Inspector General at the Department of Health and Human Services, and provided detailed briefings on the results of the reviews conducted by us and our Audit Committee. We expect to engage in more detailed discussions with these and other appropriate agencies in order to determine the precise amount of the underpayments. We currently expect to make the

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requisite payments in 2004. We have placed $46.5 million of our cash on hand in an interest-bearing escrow account from which the requisite payment will be made.

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 related to the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®. We intend to cooperate in providing information to the Office of Inspector General.

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

Although the new information technology system is intended to significantly enhance the accuracy of our calculations for estimating amounts due under Medicaid and other governmental pricing programs, our processes for these calculations will continue to involve considerable manual input, and, as a result, these calculations will remain subject to the risk of errors arising from manual processes at least until mid-2004. Even thereafter, despite our best efforts, the system could incorrectly calculate amounts due under Medicaid and other governmental pricing programs.

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

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

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

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

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,

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our charter and bylaws contain provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions include:

- a classified Board of Directors;
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock;
- advance notice requirements for nominations for election to our Board of Directors; and
- special voting requirements for the amendment of our charter and bylaws.

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

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

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

- variations in our results of operations;
- perceived risks and uncertainties concerning our business;
- announcements of earnings;
- 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 government regulations could affect our ability to operate our business.

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

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Department of Agriculture, the Occupational Safety and Health Administration, and the EPA, as well as by foreign governments in countries where we distribute some of our products.

Noncompliance with applicable FDA policies or requirements could subject us to enforcement actions, such as suspensions of manufacturing or distribution, seizure of products, product recalls, fines, criminal penalties, injunctions, failure to approve pending drug product applications or withdrawal of product marketing approvals. Similar civil or criminal penalties could be imposed by other government agencies, such as the DEA, the EPA or various agencies of the states and localities in which our products are manufactured, sold or distributed, and could have ramifications for our contracts with government agencies such as the 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 FDC Act or the PHS Act or both. New drugs, as defined in the FDC Act, and new human biological drugs, as defined in the PHS Act, must be the subject of an FDA-approved new drug or biologic license application before they may be marketed in the United States. Some prescription and other drugs are not the subject of an approved marketing application but, rather, are marketed subject to the FDA s regulatory discretion and/or enforcement policies. Any change in the FDA s enforcement discretion and/or policies could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We manufacture some pharmaceutical products containing controlled substances and, therefore, are also subject to statutes and regulations enforced by the DEA and similar state agencies which impose security, record keeping, reporting and personnel requirements on us. Additionally, we manufacture biological drug products for human use and are subject to regulatory burdens as a result of these aspects of our business. There are additional FDA and other regulatory policies and requirements covering issues such as advertising, commercially distributing, selling, sampling and reporting adverse events associated with our products with which we must continuously comply. Noncompliance with any of these policies or requirements could result in enforcement actions which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

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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 $60.0 million for aggregate annual claims with a $10.0 million aggregate annual deductible; however, we cannot assure you that the level or breadth of any insurance coverage will be sufficient to cover fully all potential claims. Also, adequate insurance coverage might not be available in the future at acceptable costs, if at all. For example, we are not able to obtain product liability insurance with respect to our products Prefest®, Menest®, Delestrogen®, Pitocin® and Nordette®, each a women s healthcare product. With respect to any product liability claims relating to these products, we would be responsible for any monetary damages awarded by any court or any voluntary monetary settlements. Significant judgments against us for product liability for which we have no insurance could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Product recalls or product field alerts may be issued at our discretion or at the discretion of the FDA, other government agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons, including failure of our products to maintain their stability through their expiration dates. Any recall or product field alert has the potential of damaging the reputation of the product. To date, these recalls have not been significant and have not had a material adverse effect on our business, financial condition, results of operations and cash flows. However, we cannot assure you that the number and significance of recalls will not increase in the future. Any significant recalls could materially affect our sales, the prescription trends for the products and damage the reputation of the products. In these cases, our business, financial condition, results of operations and cash flows could be materially adversely affected.

Although product returns were approximately 4.2% of gross sales for the last twelve months ended September 30, 2003, 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 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 are now controlling the pharmaceutical products that are on their formulary lists. The resulting competition among pharmaceutical companies to place their products on these formulary lists has reduced prices across the industry. In addition, many managed care organizations are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. We cannot assure you that our products will be included on the formulary lists of managed care organizations or that downward pricing pressures in the industry generally will not negatively impact our operations.

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

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to include, the referral of business, including the purchase or prescription of a particular drug. The federal government has published regulations that identify safe harbors or exemptions for certain payment arrangements that do not violate the anti-kickback statutes. We seek to comply with the safe harbors. Due to the breadth of the statutory

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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 may be subject to scrutiny under these laws. As discussed in this Risk Factors section under the heading The SEC investigation, other possible governmental investigations, and securities litigation could have a material adverse effect on our business and elsewhere in this report, we are in the process of quantifying and reporting to governmental agencies our underpayment of amounts due under Medicaid and other governmental pricing programs.

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

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

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

New legislation or regulatory proposals may adversely affect our revenues.

A number of legislative and regulatory proposals aimed at changing the health care system, including the cost of prescription products, reimportation of prescription products 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.

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, 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, companies, technologies and product lines will not have a material adverse effect on our business, financial condition and results of operations.

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

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

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

additional competitors will not enter the market; or

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

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

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

Zestril® (AstraZeneca plc),

Acupril® (Pfizer, Inc.),

Prinivil® (Merck & Co., Inc.),

Lotensin® (Novartis AG),

Monopril® (Bristol-Myers Squibb Company),

Vasotec® (Biovail Corporation),

Capoten® (Bristol-Myers Squibb Company), and

Mavik® (Abbott Laboratories).

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

Synthroid® (Abbott Laboratories),

Levothroid® (Forest Laboratories, Inc.), and

Unithroid® (Jerome Stevens Pharmaceuticals, Inc.).

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

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

detailing and sampling to the primary prescribing physician groups, and

sponsoring physician symposiums, including continuing medical education seminars.

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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.

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 products with challenging bioequivalence or complex manufacturing requirements and products with a strong brand image with the prescriber or the consumer, supported by the development of a broader range of alternative product formulations or dosage forms, we are better able to maintain market share, gross margins and cash flows. However, we cannot assure you that any of our products will remain exclusive without generic competition, or maintain their market share, gross margins and cash flows as a result of these efforts, the failure of which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

A Warning About Forward-Looking Statements

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

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

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

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

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

expected trends and projections with respect to particular income and expense line items;

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

the development and approval of binodenoson, pre-clinical programs, and product life-cycle development projects;

the development of a modified-release Altace®;

the development of a modified-release Sonata®;

the development of new formulations for Skelaxin®;

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

our continued successful execution of our growth strategies;

anticipated developments and expansions of our business;

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anticipated expansion of our manufacturing capacity for Thrombin-JMI®;

anticipated increases in sales of acquired products or royalty revenues;

the success of our Co-Promotion Agreement with Wyeth;

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

the development of product line extensions;

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

the products which we expect to offer;

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

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

expectations regarding 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® and Skelaxin® patent challenges, the SEC investigation, other possible governmental investigations, securities litigation, and other legal proceedings described in this report;

the ongoing implementation of our new information technology system; and

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

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

Item 3. ***Quantitative and Qualitative Disclosure about Market Risk***

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

As of September 30, 2003, 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 to ensure that material information relating to us and our consolidated

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subsidiaries is made known to them by others within these entities, particularly during the period this quarterly report was prepared, in order to allow timely decisions regarding required disclosure.

(b) *Changes in Internal Controls.* As set forth in our 2002 Form 10-K in the Management s Discussion and Analysis of Financial Condition and Results of Operations section under the heading Recent Developments, we have undertaken a substantial process to enhance our compliance with Medicaid and other governmental pricing program requirements. Also, effective August 1, we appointed a corporate compliance officer whose responsibilities include enhancement of internal controls. In addition, during July 2003, we implemented a new information technology system for selected locations of the company. This implementation has resulted in certain changes to business processes and internal controls impacting financial reporting. We are taking the necessary steps to monitor and maintain appropriate internal controls during this period of change. These steps include deploying resources to mitigate internal control risks and performing additional verifications and testing to ensure data integrity. There have not been any additional significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

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PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

The information required by this Item is incorporated by reference to Note 8 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 Jefferson J. Gregory, Chairman and Chief Executive Officer of King Pharmaceuticals, Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Jefferson J. Gregory, the Chairman and Chief Executive Officer of King Pharmaceuticals, Inc., Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, Inc. Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(b) Reports on Form 8-K

We filed the following Current Reports on Form 8-K during the quarter ended September 30, 2003:

(1) A Current Report on Form 8-K filed July 29, 2003 reported under Item 5 the issuance of a press release announcing the completion of the previously announced internal review conducted by the Audit Committee of our Board of Directors. Additionally, we reported under Item 5 that we filed with the Securities and Exchange Commission (the SEC) our form 10-K containing the audited consolidated financial statements for the year ended December 31, 2002 and our Form 10-Q containing the unaudited consolidated financial statements for the first quarter ended March 31, 2003.

(2) A Current Report on Form 8-K filed July 29, 2003 furnished under Item 12 our financial results for the quarter ended June 30, 2003.

(3) A Current Report on Form 8-K filed August 26, 2003 amended the Current Report on Form 8-K that we filed June 12, 2003 reporting under Item 2 the acquisition of Elan Corporation, plc s primary care business in the United States and Puerto Rico. This amendment was filed to provide the financial statement information required by Item 7(a) and Item 7(b) of Form 8-K within the timeframe specified by Item 7 of Form 8-K following the closing of the acquisition on June 12, 2003.

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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: November 14, 2003

By: /s/ JEFFERSON J. GREGORY

Jefferson J. Gregory
Chief Executive Officer

Date: November 14, 2003

By: /s/ JAMES R. LATTANZI

James R. Lattanzi
Chief Financial Officer