KING PHARMACEUTICALS INC Form 10-Q May 10, 2005

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

Form 10-Q

(Mark One)

þ

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended March 31, 2005

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

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

54-1684963

(423) 989-8000

(*Registrant* s telephone number, including area code)

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 b No o

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

Number of shares outstanding of Registrant s common stock as of May 9, 2005: 241,730,668

TABLE OF CONTENTS

PART I -- FINANCIAL INFORMATION

Item 1. Financial Statements

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

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Item 4. Controls and Procedures

PART II -- OTHER INFORMATION

Item 1. Legal Proceedings

Item 6. Exhibits and Reports on Form 8-K

<u>SIGNATURES</u>

EX-31.1 SECTION 302 CERTIFICATION OF THE CEO

EX-31.2 SECTION 302 CERTIFICATION OF THE CFO

EX-32.1 SECTION 906 CERTIFICATION OF THE CEO

EX-32.2 SECTION 906 CERTIFICAION OF THE CFO

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

KING PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands)

| | March 31, 2005 (unaudited) | | De | cember 31, 2004 |
|--|----------------------------------|-----------|----|--------------------|
| ASSETS | | | | |
| Current Assets: | | | | |
| Cash and cash equivalents | \$ | 348,589 | \$ | 342,086 |
| Restricted cash | | 65,000 | | 97,730 |
| Marketable securities | | 8,534 | | 16,498 |
| Accounts receivable, net of allowance for doubtful accounts of \$15,095 and \$15,348 | | 206,170 | | 180,963 |
| Inventories | | 255,408 | | 274,412 |
| Deferred income taxes | | 122,857 | | 153,979 |
| Prepaid expenses and other current assets | | 63,706 | | 61,395 |
| Total current assets | | 1,070,264 | | 1,127,063 |
| Property, plant and equipment, net | | 281,222 | | 280,731 |
| Goodwill | | 121,152 | | 121,152 |
| Intangible assets, net | | 1,251,697 | | 1,285,961 |
| Other assets (includes restricted cash of \$13,882 and \$2,775) | | 26,689 | | 16,318 |
| Deferred income taxes | | 99,429 | | 92,931 |
| Total assets | \$ | 2,850,453 | \$ | 2,924,156 |
| LIABILITIES AND SHAREHO | LDER | S EQUITY | | |
| Current Liabilities: | | | | |
| Accounts payable | \$ | 44,028 | \$ | 92,920 |
| Accrued expenses | | 499,752 | | 596,010 |
| Income taxes payable | | 14,367 | | |
| Total current liabilities | | 558,147 | | 688,930 |
| Long-term debt | | 345,000 | | 345,000 |
| Other liabilities | | 29,226 | | 41,436 |
| | | | | |
| Total liabilities | | 932,373 | | 1,075,366 |
| Commitments and contingencies (Note 10) | | | | |
| Shareholders equity | | 1,918,080 | | 1,848,790 |
| Total liabilities and shareholders equity | \$ | 2,850,453 | \$ | 2,924,156 |

See accompanying notes.

KING PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited) (In thousands, except per share data)

Three Months Ended March 31,

| | 2005 | (1 | 2004* restated) |
|---|---------------|----|--------------------|
| Revenues: | | | |
| Net sales | \$ 350,570 | \$ | 274,693 |
| Royalty revenue | 18,055 | | 16,757 |
| Total revenues | 368,625 | | 291,450 |
| Operating costs and expenses: | | | |
| Cost of revenues, exclusive of depreciation, amortization and impairments shown below | 72,216 | | 83,541 |
| Selling, general and administrative, exclusive of co-promotion fees | 92,850 | | 87,602 |
| Mylan transaction costs | 3,277 | | |
| Co-promotion fees | 34,655 | | 23,544 |
| Total selling, general and administrative expenses | 130,782 | | 111,146 |
| Research and development | 11,472 | | 16,023 |
| Depreciation and amortization | 41,426 | | 39,318 |
| Intangible asset impairment | | | 34,936 |
| Restructuring charges | 2,023 | | |
| Gain on sale of intangible assets | (847) | | (858) |
| Total other operating costs and expenses | 54,074 | | 89,419 |
| Total operating costs and expenses | 257,072 | | 284,106 |
| Operating income | 111,553 | | 7,344 |
| Other income (expense): | | | |
| Interest income | 2,277 | | 1,054 |
| Interest expense | (2,701) | | (3,105) |
| Valuation charge convertible notes receivable | | | (449) |
| Write-down of investments | (6,853) | | |
| Other, net expense | (249) | | (703) |
| Total other expense | (7,526) | | (3,203) |
| Income from continuing operations before income taxes | 104,027 | | 4,141 |

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

| Income tax expense | | 36,922 | | 1,839 |
|---|----|--------|----|-----------|
| Income from continuing operations | | 67,105 | | 2,302 |
| Discontinued operations: | | | | |
| Income (loss) from discontinued operations, including expected loss | | | | |
| on disposal | | 4,682 | | (167,462) |
| Income tax expense (benefit) | | 1,732 | | (61,084) |
| Total income (loss) from discontinued operations | | 2,950 | | (106,378) |
| Net income (loss) | \$ | 70,055 | \$ | (104,076) |
| Income (loss) per common share: Basic: | | | | |
| Income from continuing operations | \$ | 0.28 | \$ | 0.01 |
| Total income (loss) from discontinued operations | ψ | 0.28 | ψ | (0.44) |
| Total income (1088) from discontinued operations | | 0.01 | | (0.44) |
| Net income (loss) | \$ | 0.29 | \$ | (0.43) |
| Diluted: | | | | |
| Income from continuing operations | \$ | 0.28 | \$ | 0.01 |
| Total income (loss) from discontinued operations | | 0.01 | | (0.44) |
| Net income (loss) | \$ | 0.29 | \$ | (0.43) |

* See Note 2.

See accompanying notes.

KING PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY AND OTHER COMPREHENSIVE INCOME

(Unaudited)

(In thousands, except share data)

| | Common | 1 Stock | Retained | Accumulated Other Comprehensive | |
|--|-------------|--------------|------------|---------------------------------------|--------------|
| | Shares | Amount | Earnings | Income | Total |
| Balance at December 31, 2003 | 241,190,852 | \$ 1,205,970 | \$ 797,408 | \$ 1,113 | \$ 2,004,491 |
| Comprehensive income: | | | (101050 | <u></u> | |
| Net loss Net unrealized loss on marketable securities, net of tax of \$(16) | | | (104,076 | (30) | (104,076) |
| Foreign currency translation | | | | 99 | 99 |
| Total comprehensive loss | | | | | (104,007) |
| Stock option activity | 177,792 | 946 | | | 946 |
| Balance at March 31, 2004, as restated | 241,368,644 | \$ 1,206,916 | \$ 693,332 | \$ 1,182 | \$ 1,901,430 |
| Balance at December 31, 2004 | 241,706,583 | \$ 1,210,647 | \$ 637,120 | \$ 1,023 | \$ 1,848,790 |
| Comprehensive income: Net income | | | 70,055 | | 70,055 |
| Net unrealized loss on marketable securities, net of tax of \$429 | | | 70,035 | (742) | (742) |
| Foreign currency translation | | | | (742) | (712) |
| Total comprehensive income | | | | | 69,234 |
| Stock option activity | 24,085 | 56 | | | 56 |
| Balance at March 31, 2005 | 241,730,668 | \$ 1,210,703 | \$ 707,175 | \$ 202 | \$ 1,918,080 |

See accompanying notes.

KING PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

| | Three Months Ended March 31, | | | ıded |
|--|---------------------------------|----------|----|--------------------|
| | | 2005 | | 2004* restated) |
| Cash flows from operating activities of continuing operations | \$ | 23,503 | \$ | 60,318 |
| Cash flows from investing activities of continuing operations: | | | | |
| Transfer to restricted cash | | (7,982) | | (351) |
| Proceeds from loan receivable | | | | 248 |
| Purchases of property, plant and equipment | | (9,075) | | (12,585) |
| Proceeds from sale of property and equipment | | 1 | | |
| Payment of contingent consideration | | | | (36,000) |
| Net cash used in investing activities of continuing operations | | (17,056) | | (48,688) |
| Cash flows from financing activities of continuing operations: | | | | |
| Proceeds from exercise of stock options, net | | 56 | | 946 |
| Payments on other long-term debt and capital lease obligations | | | | (93) |
| Net cash provided by financing activities of continuing operations | | 56 | | 853 |
| Net cash provided by discontinued operations | | | | 2,790 |
| | | 6.500 | | 15.050 |
| Increase in cash and cash equivalents | | 6,503 | | 15,273 |
| Cash and cash equivalents, beginning of period | | 342,086 | | 146,053 |
| Cash and cash equivalents, end of period | \$ | 348,589 | \$ | 161,326 |

* See Note 2.

See accompanying notes.

KING PHARMACEUTICALS, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS March 31, 2005 and 2004 (Unaudited) (In thousands)

1. General

The accompanying unaudited interim condensed consolidated financial statements of King Pharmaceuticals, Inc. (King or the Company) have been prepared by the Company in accordance with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X, and accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of items of a normal recurring nature) considered necessary for a fair presentation have been included. Operating results for the three months ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005. 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, 2004. The year-end condensed balance sheet was derived from the audited consolidated financial statements but does not include all disclosures required by generally accepted accounting principles.

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

2. Restatement of Previously Issued Financial Statements

As previously disclosed and discussed in detail in Note 2 to the Company s Annual Report on Form 10-K for the year ended December 31, 2004, the Company has in prior filings restated its financial statements for the years 2002 and 2003, including interim periods in 2003, and the first two quarters of 2004, primarily to reflect the correction of methodological errors related to its reserve for product returns. All amounts referenced in this Quarterly Report for those periods reflect the relevant amounts on a restated basis.

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

Previous Restatement of Income Statement Amounts

The table below sets forth the effect of the previously disclosed restatement for the three months ended March 31, 2004:

| | riginally ported | Re | eturns eserve rrors | Im | Other naterial Items | As reviously Restated |
|--|---------------------|----|---------------------------|----|----------------------------|-----------------------------|
| Revenues: | | | | | | |
| Net sales | \$ 273,887 | \$ | 420 | \$ | 386 | \$ 274,693 |
| Royalty revenue | 16,757 | | | | | 16,757 |
| Total revenues | 290,644 | | 420 | | 386 | 291,450 |
| Operating costs and expenses: | | | | | | |
| Cost of revenues, exclusive of | | | | | | |
| depreciation shown below | 87,714 | | (138) | | (4,035) | 83,541 |
| Selling, general and administrative, | | | | | | |
| exclusive of co-promotion fees | 86,602 | | | | 1,000 | 87,602 |
| Co-promotion fees | 27,504 | | (3,206) | | (754) | 23,544 |
| Total selling, general and | | | | | | |
| administrative expense | 114,106 | | (3,206) | | 246 | 111,146 |
| name of the second second | | | (-,) | | | , |
| Research and development | 16,023 | | | | | 16,023 |
| Depreciation and amortization | 39,318 | | | | | 39,318 |
| Intangible asset impairment | 34,936 | | | | | 34,936 |
| Gain on sale of assets | (858) | | | | | (858) |
| Total operating costs and expenses | 291,239 | | (3,344) | | (3,789) | 284,106 |
| Operating (loss) income | (595) | | 3,764 | | 4,175 | 7,344 |
| Total other expense | (2,803) | | | | (400) | (3,203) |
| (Loss) income from continuing operations | | | | | | |
| before income taxes | (3,398) | | 3,764 | | 3,775 | 4,141 |
| Income tax (benefit) expense | (1,048) | | 1,441 | | 1,446 | 1,839 |
| (Loss) income from continuing operations | (2,350) | | 2,323 | | 2,329 | 2,302 |
| Discontinued operations: | | | | | | |
| (Loss) income from discontinued | | | | | | |
| operations, including expected loss on | | | | | | |
| disposal | (171,242) | | 4,027 | | (247) | (167,462) |

| Edgar Filing: KIN | IG PI | HARMACEUT | ICAL | S INC - | Form | 10-Q | |
|--|-------|-----------|------|---------|------|-------|-----------------|
| Income tax (benefit) expense | | (62,532) | | 1,542 | | (94) | (61,084) |
| Total (loss) income from discontinued operations | | (108,710) | | 2,485 | | (153) | (106,378) |
| Net (loss) income | \$ | (111,060) | \$ | 4,808 | \$ | 2,176 | \$ (104,076) |
| Basic (loss) income per common share | \$ | (0.46) | \$ | 0.02 | \$ | 0.01 | \$ (0.43) |
| Diluted (loss) income per common share | \$ | (0.46) | \$ | 0.02 | \$ | 0.01 | \$ (0.43) |
| | | 7 | | | | | |

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

3. Change in Estimate

Based on data received from the Company s inventory management agreements with its three key wholesale customers, during the first quarter of 2005, there was a significant reduction of wholesale inventory levels of the Company s products. While the Company s calculation for returns reserves is based on historical sales and return rates over the period which customers have a right of return, it also gives consideration to the amount of wholesale inventory levels. The significant reduction in wholesale inventories of the Company s products during the first quarter of 2005, primarily as a result of sell through to the marketplace as opposed to returns to the Company, resulted in a change in estimate of approximately \$25,000, decreasing the Company s reserve for returns and increasing net sales from branded pharmaceuticals.

4. Stock Compensation

The Company has adopted the disclosure only provision of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock Based Compensation, as amended by FAS 148. Accordingly, since options were granted at a strike price equal to market price at the date of grant, no compensation cost has been recognized for stock options granted to date. Had compensation costs for these plans been determined for options granted, consistent with SFAS No. 123, the Company s net income (loss), basic income (loss) per common share and diluted income (loss) per common share would include adjustments for the following pro forma amounts:

| | | | Thr | ee Months |
|--|----|-------------------|-----|--------------------|
| | | Three Months | | Ended |
| | | Ended | N | larch 31, 2004* |
| | N | March 31, 2005 | | restated) |
| Net income (loss): | | | | |
| As reported | \$ | 70,055 | \$ | (104,076) |
| Compensation costs for options granted | | (1,351) | | (1,191) |
| Pro forma | \$ | 68,704 | \$ | (105,267) |
| Basic income (loss) per share: | | | | |
| As reported | \$ | 0.29 | \$ | (0.43) |
| - | | | | |
| Pro forma | \$ | 0.28 | \$ | (0.44) |
| | | | | |
| Diluted income (loss) per share: | | | | |
| As reported | \$ | 0.29 | \$ | (0.43) |
| | | | | |
| Pro forma | \$ | 0.28 | \$ | (0.44) |

* See Note 2.

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

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

5. Earnings Per Share

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

| | Three Month March | |
|--------------------------------|----------------------|---------|
| | 2005 | 2004 |
| Basic loss per common share: | | |
| Weighted average common shares | 241,724 | 241,300 |
| Diluted loss per common share: | | |
| Weighted average common shares | 241,724 | 241,300 |
| Effect of stock options | 79 | |
| Convertible debentures | | |
| Weighted average common shares | 241,803 | 241,300 |

For the three months ended March 31, 2004, options to purchase 915 shares of common stock were not included in the computation of diluted income (loss) per share because their inclusion would have been antidilutive and would have reduced the loss per share. The Company s convertible debentures could also be converted into 6,878 shares of common stock in the future, subject to certain contingencies outlined in the indenture. Because the convertible debentures are anti-dilutive, they were not included in the calculation of diluted income (loss) per common share for either period.

6. Inventories

Inventories consist of the following:

| | March 31, 2005 | | Dec | cember 31, 2004 |
|--|-------------------|----------|-----|--------------------|
| Raw materials | \$ | 147,238 | \$ | 168,541 |
| Work-in-process | | 19,527 | | 20,287 |
| Finished goods (including \$11,712 and \$11,350 of sample inventory, | | | | |
| respectively) | | 127,419 | | 133,527 |
| | | | | |
| | | 294,184 | | 322,355 |
| Inventory valuation allowance | | (38,776) | | (47,943) |
| | | | | |
| | \$ | 255,408 | \$ | 274,412 |

7. Property, Plant and Equipment

The Company s Rochester facility manufactures products for the Company and various third-party manufacturers. At March 31, 2005, the net carrying value of the property, plant and equipment at the Rochester facility was \$89,257. Overall production volume at this facility has been declining. The Company currently is transferring to this facility the

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

manufacture of certain products that are currently manufactured by the Company at other Company facilities or for the Company by third parties. These transfers should increase production and cash flow at the Rochester facility. Management currently believes that these long-term assets associated with the Rochester facility are not impaired based on estimated undiscounted future cash flows. However, if production volumes continue to decline or if the Company is not successful in transferring additional production to Rochester, the Company may have to write-off a portion of the property, plant, equipment associated with this facility.

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

8. Intangible Assets and Goodwill

The following table reflects the components of intangible assets as of March 31, 2005:

| | Gross Carrying Amount | cumulated ortization |
|-------------------------------|-----------------------------|-----------------------------|
| Trademarks and product rights | \$ 1,370,711 | \$ 241,455 |
| Patents | 267,049 | 145,565 |
| Other intangibles | 9,459 | 8,502 |
| Total intangible assets | \$ 1,647,219 | \$ 395,522 |

Amortization expense for the three months ended March 31, 2005 and 2004 was \$34,263 and \$32,847, respectively. Estimated annual amortization expense as of March 31, 2005 for each of the five succeeding fiscal years is as follows:

Fiscal Year Ended December 31:

| 2005 | \$ 116,906 |
|------|------------|
| 2006 | 99,588 |
| 2007 | 97,962 |
| 2008 | 91,933 |
| 2009 | 80,417 |

Demand for some of the Company s non-key products, including but not limited to Intal®, Tilade®, Synercid®, and Corzide®, has been declining. The net intangible assets associated with these four specific products totals approximately \$248,631. The Company believes that these intangible assets are not currently impaired based on estimated undiscounted cash flows associated with these assets. However, if demand for the products associated with these intangible assets declines below current expectations, the Company may have to write off a portion or all of these intangible assets.

A new competitor to Sonata® recently entered the market and the entry of additional competition is anticipated in the near future. The net intangible assets associated with Sonata® total approximately \$195,959. The Company believes that these intangible assets are not currently impaired based on estimated undiscounted cash flows associated with these assets. Should demand for Sonata® decline in the face of this competition, the Company may have to write off a portion or all of these intangible assets.

The Company s forecast of future cash flows reflects estimated improvements in sales from planned marketing activities for certain products. If the Company s estimates regarding improvements in sales and operating results prove to be incorrect or adversely change, an impairment charge could be required.

Goodwill at December 31, 2004 and March 31, 2005 is as follows:

| | randed egment | leridian egment | Total |
|----------|------------------|--------------------|---------------|
| Goodwill | \$ 12,742 | \$ 108,410 | \$ 121,152 |

Amount

9. Discontinued Operations

On March 30, 2004, the Company s Board of Directors approved management s decision to market for divestiture many of the Company s women s health products. On November 22, 2004 the Company sold all of its rights in Prefest® for approximately \$15,000. On December 23, 2004, the Company sold all of its rights in Nordette® for approximately \$12,000.

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

The Prefest® and Nordette® product rights, which the Company divested on November 22, 2004 and December 23, 2004, respectively, had identifiable cash flows that were largely independent of the cash flows of other groups of assets and liabilities and are classified as discontinued operations in the accompanying financial statements. Prefest® and Nordette® formerly were included in the Company s branded pharmaceuticals segment. During the first quarter of 2004, the Company wrote down intangible assets by the amount of \$169,591 to reduce the carrying value of the intangible assets associated with these products to their estimated fair value less costs to sell. The Company determined the fair value of these assets based on management s discounted cash flow projections for the products less expected selling costs. During the first quarter of 2005, adjustments to reserves for product returns and rebates associated with Prefest® and Nordette® due to changes in estimates resulted in revenues and net income from discontinued operations.

Summarized financial information for the discontinued operations are as follows:

| | rch 31, 2005 | arch 31, 2004* estated) |
|--|-----------------|-------------------------------|
| Total revenues | \$ 4,682 | \$ 10,896 |
| Operating income (loss), including expected loss on disposal | 4,682 | (167,462) |
| Net income (loss) | 2,950 | (106,378) |

Three Months Ended

* See Note 2.

10. Contingencies

Fen/ Phen Litigation

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

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

In addition, King Research and Development, Inc. (King R&D), successor to Jones Pharma, Incorporated (Jones) and a wholly owned subsidiary of the Company, is a defendant in approximately 380 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine

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

and phentermine. These suits have been filed in various jurisdictions throughout the United States, and in each of these suits King R&D is one of many defendants, including manufacturers and other distributors of these drugs. Although Jones did not at any time manufacture 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.

King R&D denies any liability incident to the distribution of Obenix® or Jones generic phentermine product and intends to pursue all defenses available to it. King R&D has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending King R&D in these suits. The manufacturers of fenfluramine and dexfenfluramine have settled many of these cases. In the event that King R&D s insurance coverage is inadequate to satisfy any resulting liability, King R&D 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 King R&D 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 King R&D. Additionally, the Company cannot reasonably estimate possible losses related to the lawsuits.

Thimerosal/ Vaccine Related Litigation

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

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

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

Hormone Replacement Therapy

The Company has been named as a defendant in eight lawsuits involving the manufacture and sale of hormone replacement therapy drugs. Numerous pharmaceutical companies have also been sued. These cases have been filed in Alabama, Pennsylvania, Ohio and Mississippi. The plaintiffs allege that King and other defendants failed to conduct adequate pre-approval research and post-approval surveillance to establish the safety of the long-term hormone therapy regimen, thus misleading consumers when marketing their products. Plaintiffs claims include allegations of negligence, strict liability, breach of implied

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

warranty, breach of express warranty, fraud and misrepresentation. 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.

Average Wholesale Pricing Litigation

In August 2004, King and Monarch Pharmaceuticals, Inc. (Monarch), a wholly owned subsidiary of King, were named as defendants along with 44 other pharmaceutical manufacturers in an action brought by the City of New York (NYC) in federal court in the state of New York. NYC claims that the defendants fraudulently inflated their Average Wholesale Prices (AWP) and fraudulently failed to accurately report their Best Prices and their Average Manufacturer's Prices (AMP) and failed to pay proper rebates pursuant to federal law. Additional claims allege violations of federal and New York statutes, fraud and unjust enrichment. For the period from 1992 to the present, NYC is requesting money damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, and treble and punitive damages.

In August 2004, a defendant in the NYC action sought to have the action transferred to the United States District Court for the District of Massachusetts and combined with existing multi-district litigation, entitled In re Average Wholesale Pricing Litigation, being heard by that court. A conditional transfer order was issued during September 2004 indicating that the action is subject to transfer for pretrial proceedings to the United States District Court for the District of Massachusetts. The Company intends to defend this lawsuit vigorously but is unable currently to predict the outcome or reasonably estimate the range of loss, if any.

The Company also has been named as a defendant along with other pharmaceutical manufacturers in eight other lawsuits containing allegations of fraudulently inflating average wholesale prices. These lawsuits have been filed in federal courts in New York and Massachusetts, and in state courts in New York and Alabama, all of which the Company will seek to have transferred to the United States District Court for the District of Massachusetts and combined with the existing multi-district litigation.

Governmental Investigations and Securities and ERISA Litigation

As previously reported, in March 2003 the SEC initiated a formal investigation of King relating to, among other topics, sales of its products to VitaRx and Prison Health Services, its best price lists, the pricing of its 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., its calculations related to Medicaid rebates, and the Audit Committee s internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, the Company received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to its sales, marketing and other business practices for Altace®, Aplisol®, and Levoxyl®. The Company has also reviewed with the staff of the SEC the circumstances giving rise to the restatement of its issued financial statements for 2002, 2003 and the first two quarters of 2004.

In connection with the Company s determination that it underpaid amounts due to Medicaid and other government pricing programs from 1998 through 2002, the Company has continued to engage in discussions with representatives of the SEC, the United States Attorney for the Eastern District of Pennsylvania, the Department of Justice, the National Association of Medicaid Fraud Control Units, the Office of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, and the Public Health Service. The Company s objective in these discussions has been to achieve a comprehensive settlement relating to all the matters being investigated by or discussed with all the governmental authorities.

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

The Company has not yet reached any agreements or understandings with respect to the terms of such a settlement, and may not ever be able to reach such an agreement. However, based on the status of the discussions to date, the Company now believes that it is reasonably likely that it will be able to achieve a comprehensive settlement with all relevant governmental parties on the following terms:

The Company has accrued \$130,400 in respect of its estimated underpayments to Medicaid and other government pricing programs and estimated settlement costs with all relevant governmental parties. This amount includes \$65,400 accrued for estimated underpayments to Medicaid and other governmental pricing programs, and an additional \$65,000 for estimated settlement costs to cover interest, costs, fines, penalties and all other additional amounts. The Company s current expectation is that the aggregate cost to settle with the governmental authorities should not materially exceed the amounts already accrued.

With respect to the matters being investigated by or discussed with the staff of the SEC, the Company currently anticipates that it would settle, without admitting or denying, one or more charges that the Company had failed to maintain adequate books and records and internal controls. The Company anticipates that the action to be settled could also include one or more charges that our public filings contained material misstatements or omissions relating to our financial results for some or all of the periods for which results have been restated. The Company does not anticipate being required to restate any results for periods prior to 2002.

The Company expects that it will be required to enter into a Corporate Integrity Agreement with the Department of Health and Human Services, which would require the Company to submit to audits relating to its Medicaid rebate calculations over a five-year period. The Company does not expect that the resolution of the pending investigations will result in any prohibitions on the Company s sales to Medicaid or any related state or Federal program, nor does the Company expect any other material restriction on its ability to conduct its business, although the Company will be required to incur consultant fees and other expenses in order to comply with the Corporate Integrity Agreement.

The Company does not expect that any criminal charges will be asserted against it or against any present or former director, officer or employee in connection with the matters being investigated.

The Company s ability to achieve a settlement on these or other terms is subject to substantial uncertainties. The Company s discussions to date have been conducted with the staffs of various agencies and other governmental authorities. The Company does not yet have any agreements or understandings with any of them. Even if the Company were to reach such an agreement or understanding with staff personnel, it would be subject to the approval of numerous more senior representatives of the governmental parties, including the members of the U.S. Securities and Exchange Commission, the United States Attorney for the Eastern District of Pennsylvania, senior officials in the Departments of Justice, Health and Human Services and Veterans Affairs, and senior officials in most or all of the States. The Company expects that its agreements with the various governmental parties would also require that those governmental parties reach numerous agreements among themselves, and that the consummation of the Company s agreements with other governmental parties. The Company also expects that some aspects of a comprehensive settlement would require court approval.

In light of these uncertainties, the Company stresses that it may not be able to reach a settlement with the governmental parties, whether on the terms described above or at all. As a result, the ultimate amount that the Company will actually have to pay to resolve these matters could be materially more than the amount accrued to date, and the terms could otherwise be materially less favorable than those described above. Because of these uncertainties and the complexity of completing a comprehensive

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

resolution, the Company is not yet able to estimate with reasonable confidence the amount of time that will be required to enter into and consummate comprehensive settlement agreements.

The possible settlement described above would not apply to the related pending class actions and derivative suits, or any other claims by private plaintiffs. While the Company denies any liability, it is unable to predict the outcome of the class actions and derivative suits or reasonably estimate the range of loss, if any.

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

On August 12, 2004, the United States District Court for the Eastern District of Tennessee ruled on defendants motions to dismiss. The Court dismissed all claims as to Jones and as to defendants Dennis Jones and Henry Richards. The Court also dismissed certain claims as to five other individual defendants. The Court denied the motions to dismiss in all other respects. Following the Court s ruling, on September 20, 2004, the Company and the other remaining defendants filed answers to plaintiffs consolidated amended complaint. Discovery and other proceedings in the case are continuing, and no trial date has been set.

Seven purported shareholder derivative complaints have also been filed in federal and state courts in Tennessee alleging a breach of fiduciary duty, among other things, by some of the Company s officers and directors. On October 26, 2004, all of the defendants named in this action filed an answer to the amended consolidated derivative and class action complaint. Discovery in this action has commenced. No trial date has been set.

Another purported class action complaint was filed on August 16, 2004 in Tennessee state court against the Company and the members of the Company s board of directors. This new case largely asserts substantially the same claims and seeks the same relief as the class action claim that was recently added to the state derivative action described above. Defendants in that action filed a motion to dismiss on November 30, 2004; that motion is pending and no hearing date has been set.

Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act (ERISA). As amended, the complaint alleges that the Company and certain of its executive officers, former executive officers, directors, former directors and an employee of the Company violated fiduciary duties that they allegedly owed the Company s 401(k) Retirement Savings Plan s participants and beneficiaries under ERISA. The

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

allegations underlying this action are similar in many respects to those in the class action litigation described above. The defendants filed a motion to dismiss the ERISA action on March 5, 2004. The District Court Judge referred the motion to a Magistrate Judge for a report and recommendation. On December 8, 2004, the Magistrate Judge held a hearing on this motion, and, on December 10, 2004, he recommended that the District Court Judge dismiss the action. The District Court Judge accepted the recommendation and dismissed the case on February 4, 2005.

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

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

Other Legal Proceedings

The Rochester facility was one of six facilities owned by Pfizer subject to a Consent Decree of Permanent Injunction issued August 1993 in United States of America v. Warner-Lambert Company and Melvin R. Goodes and Lodewijk J.R. DeVink (U.S. Dist. Ct., Dist. of N.J.) (the Consent Decree). The Company acquired the Rochester facility in February 1998. The Rochester facility is currently manufacturing pharmaceutical products subject to the Consent Decree that prohibits the manufacture and delivery of specified drug products unless, among other things, the products conform to current good manufacturing practices and are produced in accordance with an approved ANDA or NDA.

Cobalt Pharmaceuticals, Inc. (Cobalt), a generic drug manufacturer located in Mississauga, Ontario, Canada, filed an ANDA with the U.S. Food and Drug Administration (the FDA) seeking permission to market a generic version of Altace[®]. The following U.S. patents are listed for Altace[®] in the FDA s Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book): U.S. Patent Nos. 4,587,258 (the 258 patent) and 5,061,722 (the 722 patent), two composition of matter patents related to Altace®, and U.S. Patent No. 5,403,856 (the 856 patent), a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the federal Hatch-Waxman Act of 1984, any generic manufacturer may file an ANDA with a certification (a Paragraph IV certification) challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and the Company filed suit on March 14, 2003 in the District Court for the District of Massachusetts to enforce its rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides the Company an automatic stay of FDA approval of Cobalt s ANDA for 30 months from no earlier than February 5, 2003. In March 2004, Cobalt stipulated to infringement of the 722 patent. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, the Company would not receive the full benefit of that 30 month stay. Subsequent to filing its original complaint, the Company amended its complaint to add an allegation of infringement of the 856 patent. The 856 patent covers one of Altace® s three indications for use. In response to the amended complaint, Cobalt informed the FDA that it no longer seeks approval to market its proposed product for the indication covered by the 856 patent. On this basis, the court granted Cobalt summary judgment of non-infringement of the 856 patent. The court s decision does not affect Cobalt s infringement of the 722 patent. The Company intends to vigorously enforce its rights under the 722 and 856 patents. If a generic version of Altace[®] enters the market, the Company s business,

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

financial condition, results of operations and cash flows could be materially adversely affected. As of March 31, 2005, the Company had net intangible assets related to Altace® of \$261,180.

Eon Labs, Inc. (Eon Labs), CorePharma, LLC (CorePharma) and Mutual Pharmaceutical Co., Inc. (Mutual) have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. Additionally, Eon Labs ANDA seeks permission to market a generic version of Skelaxin® 800 mg tablets. United States Patent Nos. 6,407,128 (the 128 patent) and 6,683,102 (the 102 patent) two method-of-use patents relating to Skelaxin®, are listed in the FDA s Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications against the 128 and 102 patents alleging noninfringement and invalidity of those patents. Mutual has filed a Paragraph IV certification against the 102 patent alleging noninfringement and invalidity of that patent. A patent infringement suit was filed against Eon Labs on January 2, 2003 in the District Court for the Eastern District of New York; CorePharma on March 7, 2003 in the District Court for the District of New Jersey (subsequently transferred to the District Court for the Eastern District of New York); and Mutual on March 12, 2004 in the District Court for the Eastern District of Pennsylvania concerning their proposed 400 mg products. Additionally, the Company filed a separate suit against Eon Labs on December 17, 2004 in the District Court for the Eastern District of New York, concerning its proposed 800 mg product. Pursuant to the Hatch-Waxman Act, the filing of the suit against CorePharma provides the Company with an automatic stay of FDA approval of CorePharma s ANDA for 30 months from no earlier than January 24, 2003. Also pursuant to the Hatch-Waxman Act, the filing of the suits against Eon Labs provides the Company with an automatic stay of FDA approval of Eon Labs ANDA for its proposed 400 mg and 800 mg products for 30 months from no earlier than November 18, 2002, and November 3, 2004, respectively. The Company intends to vigorously enforce its rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, the Company received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. The Company believes that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. The Company filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004 and on July 21, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information corresponding to the use listed in the Orange Book. King concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated the Company s Citizen Petition.

On March 12, 2004, the FDA sent a letter to the Company explaining that King s proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, the Company submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of the Company s proposed labeling revision until the FDA has fully evaluated and ruled upon the Company s Citizen Petition, as well as all comments submitted in response to that petition. Discussions with the FDA concerning appropriate labeling are ongoing. The Company, CorePharma and Mutual have filed responses and supplements to the pending Citizen Petitions.

If the Company s Citizen Petition is rejected, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and the Company s business, financial condition, results of operations and cash flows could be materially adversely affected. As of March 31, 2005, the Company had net intangible assets related to Skelaxin® of \$192,304.

In addition to the matters discussed above, the Company is involved in various other legal proceedings incident to the ordinary course of its business. The Company does not believe that unfavorable outcomes

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

as a result of these other legal proceedings will have a material adverse effect on its financial position, results of operations and cash flows.

11. Accounting Developments

In December 2004, the FASB issued SFAS No. 123(R), (Share-based Payment) that requires the Company to expense costs related to share-based payment transactions with employees. The Securities and Exchange Commission issued Amendment 4-01(a) of Regulation S-X, changing the compliance date for SFAS 123(R) to the annual reporting period beginning on or after June 15, 2005. The Company is in the process of evaluating the effect that SFAS No. 123(R) will have on the Company s financial reporting.

In November 2004, the FASB issued SFAS No. 151, (Inventory Costs), an amendment of ARB No. 43. SFAS No. 151 requires certain abnormal expenditures to be recognized as expenses in the current period. It also requires that the amount of fixed production overhead allocated to inventory be based on the normal capacity of the production facilities. The standard is effective for the fiscal year beginning January 1, 2006. The Company is currently evaluating the effect that SFAS No. 151 will have on the Company s financial reporting.

12. Segment Information

The Company s business is classified into five reportable segments: branded pharmaceuticals, Meridian Medical Technologies, royalties, contract manufacturing and all other. Branded pharmaceuticals include a variety of branded prescription products over seven therapeutic areas, including cardiovascular, endocrinology, neuroscience, critical care, anti-infective, respiratory, and other. Such branded prescription products have been aggregated because of the similarity in regulatory environment, manufacturing processes, methods of distribution, and the types of customer. Meridian develops, manufactures, and sells auto-injector pharmaceutical products to both commercial and government markets. The principal source of revenues in the commercial market is the EpiPen® product line marketed by Dey, L.P., which is primarily prescribed for the treatment of severe allergic reactions. Government revenues are principally derived from the sale of nerve agent antidotes and other emergency medicine auto-injector products marketed to the U.S. Department of Defense and other federal, state and local agencies, particularly those involved in homeland security, as well as to approved foreign governments. Contract manufacturing includes pharmaceutical manufacturing services the Company provides to third-party pharmaceutical and biotechnology companies. Royalties include revenues the Company derives from pharmaceutical products after the Company has transferred the manufacturing or marketing rights to third parties in exchange for licensing fees or royalty payments.

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

. .

. . . .

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 March 31, | | | | | | |
|--|---------------------------------|-----------|----|--------------------|--|--|--|
| | | 2005 | (1 | 2004* restated) | | | |
| Total revenues: | | | | | | | |
| Branded pharmaceuticals | \$ | 321,769 | \$ | 234,014 | | | |
| Meridian Medical Technologies | | 23,214 | | 34,501 | | | |
| Royalties | | 18,055 | | 16,757 | | | |
| Contract manufacturing | | 119,365 | | 132,892 | | | |
| Eliminations | | (113,778) | | (126,714) | | | |
| Consolidated total net revenues | \$ | 368,625 | \$ | 291,450 | | | |
| Segment profit (loss): | | | | | | | |
| Branded pharmaceuticals | \$ | 272,112 | \$ | 176,010 | | | |
| Meridian Medical Technologies | | 12,313 | | 19,454 | | | |
| Royalties | | 15,806 | | 14,177 | | | |
| Contract manufacturing | | (3,822) | | (1,732) | | | |
| Other operating costs and expenses | | (184,856) | | (200,565) | | | |
| Other expenses | | (7,526) | | (3,203) | | | |
| Income from continuing operations before tax | \$ | 104,027 | \$ | 4,141 | | | |

* See Note 2.

| | Ν | As of Aarch 31, 2005 | De | As of cember 31, 2004 |
|-------------------------------|----|----------------------------|----|-----------------------------|
| Total assets: | | | | |
| Branded pharmaceuticals | \$ | 2,815,917 | \$ | 2,865,803 |
| Meridian Medical Technologies | | 251,122 | | 275,850 |
| Royalties | | 19,610 | | 22,430 |
| Contract manufacturing | | 98,882 | | 95,151 |
| All other | | | | |
| Eliminations | | (335,078) | | (335,078) |
| Consolidated total assets | \$ | 2,850,453 | \$ | 2,924,156 |

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

-

. .

41

- - -

The following represents branded pharmaceutical revenues by therapeutic area:

| | Three Months Ended March 31, | | | | | |
|--|---------------------------------|----|--------------------|--|--|--|
| | 2005 | | 2004* restated) | | | |
| Total revenues: | | | | | | |
| Cardiovascular | \$ 88,873 | \$ | 70,507 | | | |
| Anti-infective | 21,222 | | 13,590 | | | |
| Critical care | 64,020 | | 40,303 | | | |
| Endocrinology | 46,220 | | 31,653 | | | |
| Respiratory | 4,365 | | 8,441 | | | |
| Neuroscience | 91,395 | | 62,125 | | | |
| Other branded | 5,674 | | 7,395 | | | |
| Consolidated branded pharmaceutical revenues | \$ 321,769 | \$ | 234,014 | | | |

* See Note 2.

13. Restructuring Activities and Executive Retirements

During 2005 the Company incurred restructuring charges as a result of the relocation of the Company s sales and marketing operations from Bristol, Tennessee to Princeton, New Jersey, and the decision to end principal operations of a small subsidiary of Meridian Medical Technologies located in Northern Ireland. A summary of the types of costs accrued and incurred are summarized below:

| | Ac | crued | | | | | | | Accrued |
|---------------------------|------|---------------------|----|---------------------|----|----------|----|-----------|------------------|
| | Bala | ance at | In | come | | | | I | Balance at |
| | | ecember 31, 2004 | | Statement Impact | | Payments | | M Cash | arch 31, 2005 |
| Employee relocation | \$ | | \$ | 159 | \$ | 159 | \$ | \$ | |
| Facility demolition costs | | 924 | | | | | | | 924 |
| Termination of lease | | | | 1,733 | | 1,733 | | | |
| Other | | | | 131 | | 131 | | | |
| | \$ | 924 | \$ | 2,023 | \$ | 2,023 | \$ | \$ | 924 |

It is anticipated that the relocation of key sales and marketing employees to New Jersey will be completed within the next three months and will require additional costs, which in accordance with FAS 146, Accounting for Costs Associated with Exit or Disposal Activities, have not yet been accrued. All of the accrued restructuring charges relate to the Meridian Medical Technologies segment, except for \$159 related to the branded pharmaceutical segment. As of March 31, 2005, \$924 of the contract manufacturing restructuring charges had not yet been paid and remained

accrued.

14. Marketable Securities

During 2005 the Company incurred a charge of \$6,853 due to the determination that the decline in fair value of our equity interest in Novavax at March 31, 2005 was other than temporary.

15. Guarantor Financial Statements

Each of the Company s subsidiaries, except Monarch Pharmaceuticals Ireland Limited (the Guarantor Subsidiaries), has guaranteed, on a full, unconditional and joint and several basis, the Company s performance under the \$345,000, 2³/4% Convertible Debentures due 2021 and under the \$400,000 Senior Secured Revolving Credit Facility on a joint and several basis. There are no restrictions under the Company s financing arrangements on the ability of the Guarantor Subsidiaries to distribute funds to the Company in the form of cash dividends, loans or advances. The following combined financial data provides information regarding the financial position, results of operations and cash flows of the Guarantor Subsidiaries (condensed consolidating financial data). Separate financial statements and other disclosures concerning the Guarantor Subsidiaries are not presented because management has determined that such information would not be material to the holders of the debt.

KING PHARMACEUTICALS, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) GUARANTOR SUBSIDIARIES CONDENSED CONSOLIDATING BALANCE SHEETS (In thousands, except share data)

March 31, 2005 (unaudited)

December 31, 2004

| | King | | | Eliminating 5 Entries | King Consolidated | King | Guarantor Subsidiaries | | 0 | Kin Consolio |
|-------------------------------|-----------|-----------|----------|--------------------------|----------------------|-----------------|---------------------------|-----------|-------------|-----------------|
| ETS | | | | | | | | | | |
| ent assets: | | | | | | | | | | |
| h and cash | | | | * | | * • • • • • • • | * • • • • • • | + · · = 0 | * | * • • • |
| valents \$ | 344,282 | \$ 2,295 | \$ 2,012 | \$ | \$ 348,589 | \$ 313,881 | \$ 27,035 | \$ 1,170 | \$ | \$ 342 |
| ketable | 0 524 | | | | 9 524 | 16 400 | | | | 16 |
| rities | 8,534 | | | | 8,534 | 16,498 | | | | 16 |
| ricted | 65,000 | | | | 65,000 | 66,543 | 31,187 | | | 97 |
| ounts | 05,000 | | | | 05,000 | 00,545 | 51,107 | | | 97 |
| ivable, | 2 700 | 201.250 | 2 0 2 4 | | 006 150 | 2.2.1.1 | 154505 | 2 0 2 2 | | 100 |
| | 2,788 | 201,358 | 2,024 | | 206,170 | 3,344 | 174,797 | 2,822 | | 180 |
| ntories erred me tax | 213,562 | 41,671 | 175 | | 255,408 | 237,448 | 36,743 | 221 | | 274 |
| ts | 26,998 | 95,859 | | | 122,857 | 32,809 | 121,170 | | | 153 |
| aid enses and r current | | | | | | | | | | |
| ts | 19,898 | 43,808 | | | 63,706 | 22,846 | 38,481 | 68 | | 61 |
| al current ets | 681,062 | 384,991 | 4,211 | | 1,070,264 | 693,369 | 429,413 | 4,281 | | 1,127 |
| erty, plant | | | | | | | | | | |
| ment, net | 109,831 | 171,389 | 2 | | 281,222 | 112,416 | 168,313 | 2 | | 280 |
| will | 107,051 | 121,152 | 2 | | 121,152 | 112,110 | 121,152 | 2 | | 121 |
| gible | | | | | 121,102 | | 121,102 | | | |
| s, net | 153 | 1,241,417 | 10,127 | | 1,251,697 | 194 | 1,275,474 | 10,293 | | 1,285 |
| r assets | 26,449 | 240 | | | 26,689 | 16,078 | 240 | | | 16 |
| rred ne tax | 19,963 | 79,466 | | | 99,429 | 14 107 | 70 724 | | | 92 |
| s tments in | 19,903 | /9,400 | | | 99,429 | 14,197 | 78,734 | | | 92 |
| | 2,265,812 | | | (2,265,812) |) | 2,186,234 | | | (2,186,234) |) |

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

al assets \$3,103,270 \$1,998,655 \$14,340 \$(2,265,812) \$2,850,453 \$3,022,488 \$2,073,326 \$14,576 \$(2,186,234) \$2,924

| 5 | | | | | | | | | | | | | | | | | | |
|-------|------------------------------|--|---|--|--|--|--|--|---|---|---|--|---|---|--|---|--|---|
|)ER | .S | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| \$ | 21,396 | \$ | 22,581 | \$ 51 | \$ | | \$ | 44,028 | \$ | 61,427 | \$ | 31,339 | \$ | 154 | \$ | | \$ | 92 |
| | 119,359 | | 380,382 | 11 | | | | 499,752 | | 125,095 | | 470,899 | | 16 | | | | 596 |
| | 10,104 | | 4,440 | (177 |) | | | 14,367 | | | | | | | | | | |
| | 150,859 | | 407,403 | (115 |) | | | 558,147 | | 186,522 | | 502,238 | | 170 | | | | 688 |
| | 345,000 | | | | | | | 345,000 | | 345,000 | | | | | | | | 345 |
| | 26,812 | | 2,414 | | | | | 29,226 | | 29,417 | | 12,019 | | | | | | 41 |
| | 662,519 | (| (670,541) | 8,022 | | | | | | 612,759 | | (620,511) | | 7,752 | | | | |
| 1 | ,185,190 | (| (260,724) | 7,907 | | | | 932,373 |] | 1,173,698 | | (106,254) | | 7,922 | | | 1 | 1,075 |
| 1 | ,918,080 | 2. | ,259,379 | 6,433 | (| (2,265,812) |) 1 | 1,918,080 | 1 | 1,848,790 | 2 | 2,179,580 | | 6,654 | (2, | 186,234 |) 1 | 1,848 |
| | | | | | | | | | | | | | | | | | | |
| \$ 3. | ,103,270 | \$1, | ,998,655 | \$ 14,340 | \$(| (2,265,812) | 1\$2 | 2,850,453 | \$3 | 3,022,488 | \$2 | .,073,326 | \$1 | 4,576 | \$ (2, | 186,234 |) \$2 | 2,924 |
| | DER \$ 1, 1, | 21,396 119,359 10,104 150,859 345,000 26,812 662,519 1,185,190 1,918,080 | PERS \$ 21,396 \$ 119,359 10,104 150,859 1 345,000 26,812 662,519 (1,185,190 (1,918,080 2, | PERS \$ 21,396 \$ 22,581 119,359 380,382 10,104 4,440 150,859 407,403 345,000 2,414 662,519 (670,541) 1,185,190 (260,724) 1,918,080 2,259,379 | Series \$ 21,396 \$ 22,581 \$ 51 119,359 380,382 11 10,104 4,440 (177) 150,859 407,403 (115) 345,000 26,812 2,414 26,812 2,414 4,022 1,185,190 (260,724) 7,907 1,918,080 2,259,379 6,433 | SPERS \$ 21,396 \$ 22,581 \$ 51 \$ 119,359 380,382 11 11 10,104 4,440 (177) 11 150,859 407,403 (115) 11 345,000 2,414 115 11 26,812 2,414 8,022 11 1,185,190 (260,724) 8,022 1 1,918,080 2,259,379 6,433 (115) | Sers \$ 21,396 \$ 22,581 \$ 51 \$ 119,359 380,382 11 10,104 4,440 (177) 150,859 407,403 (115) 345,000 26,812 2,414 26,812 2,414 10,104 1,185,190 (260,724) 7,907 1,918,080 2,259,379 6,433 (2,265,812) | Sers \$ 21,396 \$ 22,581 \$ 51 \$ \$ \$ 119,359 380,382 11 11 10,104 4,440 (177) 12 150,859 407,403 (115) 12 26,812 2,414 12 12 1,185,190 (260,724) 7,907 12 1,918,080 2,259,379 6,433 (2,265,812) 1 | SERS \$ 21,396 \$ 22,581 \$ 51 \$ 44,028 119,359 380,382 11 499,752 10,104 4,440 (177) 14,367 150,859 407,403 (115) 558,147 26,812 2,414 29,226 345,000 26,812 2,414 29,226 29,226 662,519 (670,541) 8,022 29,226 1,185,190 (260,724) 7,907 932,373 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 | SERS \$ 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 119,359 380,382 11 499,752 499,752 10,104 4,440 (177) 14,367 14,367 150,859 407,403 (115) 558,147 14,367 345,000 26,812 2,414 29,226 24,229,226 662,519 (670,541) 8,022 29,226 1 1,185,190 (260,724) 7,907 932,373 1 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 1 | Servers 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 119,359 380,382 11 499,752 125,095 10,104 4,440 (177) 14,367 125,095 150,859 407,403 (115) 558,147 186,522 345,000 22,6812 24,14 29,226 29,417 662,519 (670,541) 8,022 22,259,379 6,433 (2,265,812) 1,918,080 1,848,790 | \$ 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 119,359 119,359 380,382 11 499,752 125,095 14,367 10,104 4,440 (177) 14,367 186,522 14,367 150,859 407,403 (115) 558,147 186,522 186,522 345,000 26,812 2,414 29,226 29,417 14,367 662,519 (670,541) 8,022 612,759 612,759 14,368 1,185,190 (260,724) 7,907 932,373 1,173,698 148,8790 2 | Server 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 31,339 119,359 380,382 11 499,752 125,095 470,899 10,104 4,440 (177) 14,367 588,147 186,522 502,238 345,000 407,403 (115) 558,147 186,522 502,238 345,000 2,414 29,226 29,417 12,019 662,519 (670,541) 8,022 29,226 29,417 12,019 1,185,190 (260,724) 7,907 932,373 1,173,698 (106,254) 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 1,848,790 2,179,580 | S 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 31,339 \$ 119,359 380,382 11 499,752 125,095 470,899 470,899 10,104 4,440 (177) 14,367 125,095 502,238 150,859 407,403 (115) 558,147 186,522 502,238 345,000 2,414 150 345,000 345,000 12,019 26,812 2,414 29,226 29,417 12,019 12,019 662,519 (670,541) 8,022 29,226 29,417 12,019 12,019 1,185,190 (260,724) 7,907 932,373 1,173,698 (106,254) 1 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 1,848,790 2,179,580 1 | SERS \$ 21,396 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 119,359 380,382 11 499,752 125,095 470,899 16 10,104 4,440 (177) 14,367 - <td>PERS \$ 21,390 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ 119,359 380,382 11 499,752 125,095 470,899 16 16 10,104 4,440 (177) 14,367 558,147 186,522 502,238 170 16 150,859 407,403 (115) 558,147 186,520 502,238 170 1 26,812 2,414 29,226 29,417 12,019 26,812 2,414 932,373 1,173,698 (106,254) 7,922 1,185,190 (260,724) 7,907 932,373 1,173,698 (106,254) 7,922 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 1,848,790 2,179,580 6,654 (2,344)</td> <td>SERS \$ 21,396 \$ 22,581 \$ 51 \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ 119,359 380,382 11 499,752 125,095 470,899 16 16 10,104 4,440 (177) 14,367 125,095 502,238 170 16 150,859 407,403 (115) 558,147 186,522 502,238 170 16 26,812 2,414 115 345,000 345,000 12 12,019 10,014 12,019 10,014 12,019 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014</td> <td>SERS \$ 21,396 \$ 22,581 \$ 51 \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ \$ 119,359 380,382 11 499,752 125,095 470,899 16 10,104 4,440 (177) 14,367 </td> | PERS \$ 21,390 \$ 22,581 \$ 51 \$ \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ 119,359 380,382 11 499,752 125,095 470,899 16 16 10,104 4,440 (177) 14,367 558,147 186,522 502,238 170 16 150,859 407,403 (115) 558,147 186,520 502,238 170 1 26,812 2,414 29,226 29,417 12,019 26,812 2,414 932,373 1,173,698 (106,254) 7,922 1,185,190 (260,724) 7,907 932,373 1,173,698 (106,254) 7,922 1,918,080 2,259,379 6,433 (2,265,812) 1,918,080 1,848,790 2,179,580 6,654 (2,344) | SERS \$ 21,396 \$ 22,581 \$ 51 \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ 119,359 380,382 11 499,752 125,095 470,899 16 16 10,104 4,440 (177) 14,367 125,095 502,238 170 16 150,859 407,403 (115) 558,147 186,522 502,238 170 16 26,812 2,414 115 345,000 345,000 12 12,019 10,014 12,019 10,014 12,019 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014 12,019 10,014 | SERS \$ 21,396 \$ 22,581 \$ 51 \$ 44,028 \$ 61,427 \$ 31,339 \$ 154 \$ \$ 119,359 380,382 11 499,752 125,095 470,899 16 10,104 4,440 (177) 14,367 |

GUARANTOR SUBSIDIARIES CONDENSED CONSOLIDATING STATEMENTS OF INCOME (Unaudited) (In thousands, except per share data)

Three Months Ended March 31, 2005 Three Months Ended March 31, 2004 (restated)*

| | King | Guaranto Subsidiar Se | | | King Sonsolidated | King | GuarantoıG Subsidiari S s | | or Estimination© | King onsolidated |
|-----------------------------------|------------------|---------------------------------|--------|------------|----------------------|------------|-------------------------------------|--------|---------------------|---------------------|
| Revenues: | 04 210 | ¢ 240.250 | ¢ 440 | ¢ (02 447) | ¢ 250 570 | ¢ 106 500 | ф. ОТ А 152 | ¢ 410 | ¢ (10C 200) (| t 074 (02 |
| Royalty | 94,318 | \$ 349,259 | \$ 440 | \$(93,447) | \$ 350,570 | \$ 106,502 | \$ 2/4,153 | \$ 418 | \$ (106,380) \$ | \$ 274,693 |
| revenue | | 18,055 | | | 18,055 | | 16,757 | | | 16,757 |
| Total revenues Operating | 94,318 | 367,314 | 440 | (93,447) | 368,625 | 106,502 | 290,910 | 418 | (106,380) | 291,450 |
| costs and | | | | | | | | | | |
| expenses: | | | | | | | | | | |
| Cost of revenues | 39,170 | 126,263 | 230 | (93,447) | 72,216 | 31,997 | 157,807 | 117 | (106,380) | 83,541 |
| Selling, general and | 57,170 | 120,205 | 230 | (75,++7) | 72,210 | 51,777 | 157,007 | 117 | (100,500) | 05,541 |
| administrati | v ð 9,079 | 88,330 | 96 | | 127,505 | 36,694 | 73,601 | 851 | | 111,146 |
| Transaction | | | | | | | | | | |
| costs | 3,277 | | | | 3,277 | | | | | |
| Depreciation and | n | | | | | | | | | |
| amortization | n 3,887 | 37,373 | 166 | | 41,426 | 4,340 | 34,872 | 106 | | 39,318 |
| Research and | | | | | | · | | | | |
| developmen | nt 161 | 11,311 | | | 11,472 | 110 | 15,913 | | | 16,023 |
| Intangible asset impairment | | | | | | | 34,936 | | | 34,936 |
| Gain on sale of intangible | | | | | | | | | | |
| assets | | (847) | | | (847) | | (858) | | | (858) |
| Restructurin | U | 1.064 | | | 2.022 | | | | | |
| charges | 159 | 1,864 | | | 2,023 | | | | | |
| Total operating costs | 85,733 | 264,294 | 492 | (93,447) | 257,072 | 73,141 | 316,271 | 1,074 | (106,380) | 284,106 |

and

expenses

| Operating income (loss) | 8,585 | 103,020 | (52) | | 111,553 | 33,361 | (25,361) | (656) | | 7,344 |
|--|----------|---------|-------|----------|---------|-----------|----------|-------|---------|---------|
| Other income (expense): | -) | , | | | , | | (-)) | () | | |
| Interest income | 2,042 | 235 | | | 2,277 | 893 | 161 | | | 1,054 |
| Interest expense | (2,686) | (15) | | | (2,701) | (3,100) | (5) | | | (3,105) |
| Valuation change convertible notes | | | | | | | | | | |
| receivable | | | | | | (449) | | | | (449) |
| Write-down of | | | | | | | | | | |
| investment Other, | (6,853) | | | | (6,853) | | | | | |
| net | (77) | (32) | (140) | | (249) | (325) | (331) | (47) | | (703) |
| Equity in earnings (loss) of | | | | | | | | | | |
| subsidiaries | | | | (79,657) | | (117,756) | | | 117,756 | |
| Intercompaninterest (expense) | іу | | | | | | | | | |
| - | (12,193) | 12,342 | (149) | | | (7,166) | 7,166 | | | |
| Total other income (expense) | 59,890 | 12,530 | (289) | (79,657) | (7,526) | (127,903) | 6,991 | (47) | 117,756 | (3,203) |
| Income (loss) from continuing operations before income | | | | | | | | | | |
| taxes | 68,475 | 115,550 | (341) | (79,657) | 104,027 | (94,542) | (18,370) | (703) | 117,756 | 4,141 |
| Income tax (benefit) | | | | | | | | | | |
| expense | (1,580) | 38,621 | (119) | | 36,922 | 9,534 | (7,449) | (246) | | 1,839 |
| | 70,055 | 76,929 | (222) | (79,657) | 67,105 | (104,076) | (10,921) | (457) | 117,756 | 2,302 |

Table of Contents

| | - | | | | |
|------------------|-----------|-------------------------|---------|---|--|
| Income | | | | | |
| (loss) | | | | | |
| from | | | | | |
| continuing | | | | | |
| operations | | | | | |
| 1 | | | | | |
| Discontinued | | | | | |
| operations: | | | | | |
| Income | | | | | |
| (loss) | | | | | |
| from | | | | | |
| discontinued | | | | | |
| operations | 4,682 | | 4,682 | (167,462) | (167,462) |
| Income | ., | | ., | () | () |
| tax | | | | | |
| expense | | | | | |
| (benefit) | 1,732 | | 1,732 | (61,084) | (61,084) |
| (001101) | 1,702 | | 1,701 | | (01,001) |
| Total | | | | | |
| income | | | | | |
| (loss) | | | | | |
| from | | | | | |
| discontinued | | | | | |
| operations | 2,950 | | 2,950 | (106,378) | (106,378) |
| operations | 2,930 | | 2,750 | (100,570) | (100,570) |
| Net | | | | | |
| income | | | | | |
| | \$ 79 879 | \$ (222) \$ (79 657) \$ | 70.055 | \$ (104,076) \$ (117,299) \$ (457) \$ 117,756 | \$ (104 076) |
| (1000) \$ 70,000 | + ,,,,,,, | Ψ () Ψ (/>,00/) Ψ | . 5,000 | +(10,1,0,0) $+(11,1,0,0)$ $+(10,1)$ $+(11,1,0)$ | <i>\(\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\</i> |
| | | | | | |
| * See Note 2. | | | | | |
| 500 1,000 2. | | | 22 | | |

GUARANTOR SUBSIDIARIES CONDENSED CONSOLIDATING STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

| | Three Months Ended March 31, 2005 | | | | Three Months Ended March 31, 2004 (restated)* | | | |
|---|-----------------------------------|-------------------------------------|-----------|---------------------|--|------------------------------|--------|----------------------|
| | King | Guarantor (Subsidiarie S | | King onsolidated | King | Guarantor (Subsidiarie\$ | | King Sonsolidated |
| Cash flows from | | | | | | | | |
| operating activities \$ | (7,771) | \$ 30,702 | \$ 572 \$ | \$ 23,503 | \$ (91,452) | \$ 151,661 | \$ 109 | \$ 60,318 |
| Cash flows from investing activities: | | | | | | | | |
| Transfer to | $(0, \epsilon(A))$ | 1 592 | | (7,092) | | (251) | | (251) |
| restricted cash Proceeds from | (9,564) | 1,582 | | (7,982) | | (351) | | (351) |
| loans receivable | | | | | | 248 | | 248 |
| Purchases of | | | | | | | | |
| property, plant and equipment | (2,081) | (6,994) | | (9,075) | (3,477) | (9,108) | | (12,585) |
| Proceeds from sale of property and equipment | 1 | | | 1 | | | | |
| Acquisition of Primary Care from Elan | | | | | | (36,000) | | (36,000) |
| Net cash used in | | | | | | | | |
| investing activities | (11,644) | (5,412) | | (17,056) | (3,477) | (45,211) | | (48,688) |
| Cash flows from financing activities: | | | | | | | | |
| Proceeds from exercise of stock | 56 | | | 56 | 946 | | | 946 |
| options, net Payments on other long-term | 50 | | | 50 | | | | |
| debt Intercompany | 49,760 | (50,030) | 270 | | (93) 104,892 | (105,027) | 135 | (93) |
| Net cash provided by (used in) financing activities | 49,816 | (50,030) | 270 | 56 | 105,745 | (105,027) | 135 | 853 |

| Net cash provided by discontinued operations | | | | | | | 2,790 | | 2,790 |
|---|------------|----------|----------|------------|------------|----|-------|----------|------------|
| Increase | | | | | | | | | |
| (decrease) in cash | | | | | | | | | |
| and cash | 20,401 | | 0.40 | 6 500 | 10.016 | | 4.010 | 244 | 15.050 |
| equivalents | 30,401 | (24,740) | 842 | 6,503 | 10,816 | | 4,213 | 244 | 15,273 |
| Cash and cash equivalents, beginning of period | 313,881 | 27,035 | 1,170 | 342,086 | 140,617 | | 3,641 | 1,795 | 146,053 |
| period | 515,001 | 27,033 | 1,170 | 342,080 | 140,017 | | 5,041 | 1,795 | 140,033 |
| Cash and cash equivalents, end of | | ¢ 2.205 | ¢ 0.010 | ¢ 240 500 | ¢ 151 400 | ¢ | 7.054 | ¢ 0.000 | ¢ 1(122) |
| period | \$ 344,282 | \$ 2,295 | \$ 2,012 | \$ 348,589 | \$ 151,433 | \$ | 7,854 | \$ 2,039 | \$ 161,326 |
| | | | | | | | | | |

* See Note 2.

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

The following discussion contains certain forward-looking statements that reflect management s current views of future events and operations. This discussion should be read in conjunction with the following: (a) Risk Factors set out below and in our Annual Report on Form 10-K for the year ended December 31, 2004, which are supplemented by the discussion which follows; (b) our audited consolidated financial statements which are included in our Annual Report on Form 10-K for the year ended December 31, 2004; 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.

I. OVERVIEW

Introduction

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

Updates and Developments

Wholesale Inventory Reductions

During late 2003, we became aware of the need to improve our visibility of wholesale inventory levels of our branded pharmaceutical products. As a result, in April 2004 we successfully entered into IMAs with each of our three key wholesale customers covering all of our branded products for the purpose of improving our visibility and reducing the level of wholesale inventories of our products. As we anticipated, entering into the inventory management agreements adversely affected net sales of some of our branded pharmaceutical products during 2004, as we aggressively reduced wholesale inventory levels of these products.

During the fourth quarter of 2004 and first quarter of 2005 we worked to amend our IMAs with our key wholesale customers with the objective of further reducing their inventory of our products. As a result, the average wholesale inventory level of our key products was further reduced during the fourth quarter of 2004 and first quarter of 2005. We believe the wholesale channel inventory reductions of our key products was complete as of March 31, 2005.

As of March 31, 2005, the wholesale inventory levels of four of our key branded pharmaceutical products, Altace®, Skelaxin®, Sonata® and Levoxyl®, based on data obtained through our inventory management agreements with our three largest customers and IMS America prescription data, were on average at a level of one month of end-user demand.

General Review of Financial Results

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

For the Three Months Ended March 31,

| | 2005 | 2004 (restated) | | |
|-------------------------------|---------------|--------------------|---------|--|
| Branded pharmaceuticals | \$ 321,769 | \$ | 234,014 | |
| Meridian Medical Technologies | 23,214 | | 34,501 | |
| Royalties | 18,055 | | 16,757 | |
| Contract manufacturing | 5,587 | | 6,178 | |
| Total | \$ 368,625 | \$ | 291,450 | |

II. RESULTS OF OPERATIONS

As previously disclosed and discussed in detail in our 2004 Annual Report on Form 10-K, we in prior filings restated our financial statements for the first quarter of 2004, among other periods, primarily to reflect the correction of methodological errors related to our reserve for product returns. All amounts referenced in this Quarterly Report for that period reflect the relevant amounts on a restated basis.

Three Months Ended March 31, 2005 and 2004

Revenues

Total net revenue increased \$77.2 million, or 26.5%, to \$368.6 million in 2005 from \$291.5 million in 2004, primarily due to increased net sales from our branded pharmaceuticals segment during 2005.

Net sales from branded pharmaceutical products increased \$87.8 million, or 37.5%, to \$321.8 million in 2005 from \$234.0 million in 2004. This increase was primarily due to decreased wholesale channel inventory reductions of some of our branded pharmaceutical products during 2005 as compared to 2004, particularly with respect to Altace® and Skelaxin®, significantly higher net-sales of Thrombin-JMI®, and the effect of the reduction in reserves for returns and rebates described in the Liquidity and Capital Resources section under the heading Critical Accounting Policies. As a result of continued wholesale inventory reductions, net sales of some of our branded pharmaceutical products, particularly Altace®, during 2005 were below the level that prescription demand for such products would indicate. However, we believe that wholesale inventory reductions of our key products was complete as of March 31, 2005. Accordingly, we expect net sales of our key products to closely reflect demand-based sales going forward.

Revenues from Meridian Medical Technologies decreased \$11.3 million, or 32.7%, to \$23.2 million in 2005 from \$34.5 million in 2004 primarily due to a decrease in government sales as a result of lower unit demand. Higher government sales in 2004 primarily reflected increased military and homeland preparedness in early 2004.

Revenues from royalties increased \$1.3 million, or 7.7%, to \$18.1 million in 2005 from \$16.8 million in 2004 primarily due to an increase in sales of Adenoscan®. Revenues from royalties are derived primarily from payments we receive based on sales of Adenoscan®. While we anticipate continued growth from royalty revenues, we are not responsible for the marketing of Adenoscan® and, thus, are not able to predict whether growth will continue, if at all, at the rate experienced in the first quarter of 2005.

Net revenues from contract manufacturing and other were \$5.6 million in 2005 compared to \$6.2 million in 2004. *Operating Costs and Expenses*

Total operating costs and expenses decreased \$27.0 million, or 9.5%, to \$257.1 million in 2005 from \$284.1 million in 2004. Variables, including special items, affecting total operating costs and expenses during 2005 and 2004 are discussed below. Special items are those particular material income or expense items that our management believes are not related to our ongoing, underlying business, are not recurring, or are not generally predictable. These items include, but are not limited to, merger and restructuring expenses; non-capitalized expenses associated with acquisitions, such as in-process research and development charges and one-time inventory valuation adjustment charges; charges resulting from the early extinguishments of debt; asset impairment charges; expenses of drug recalls; and gains and losses resulting from the divestiture of assets. We believe the identification of special items enhances an analysis of our ongoing, underlying business and an analysis of our financial results when comparing those results to that of a previous or subsequent like period. However, it should be noted that the determination of whether to classify an item as a special charge involves judgments by us.

Cost of revenues decreased \$11.3 million, or 13.5%, to \$72.2 million in 2005 from \$83.5 million in 2004. This decrease is primarily associated with reduced cost of revenues from branded pharmaceuticals. As a percentage of total revenues, cost of revenues decreased to 19.6% in 2005 from 28.7% in 2004.

Cost of revenues from branded pharmaceutical products decreased \$8.3 million, or 14.3%, to \$49.7 million in 2005 from \$58.0 million in 2004. Cost of revenues from branded pharmaceuticals was

higher in 2004 primarily due to a charge in the amount of \$17.2 million for the write-off of excess inventory associated with our branded pharmaceuticals segment, which was to some extent attributable to dramatically reduced net sales of branded pharmaceutical products during 2004 as a result of reductions of wholesale inventories of our products, partially offset by the cost of revenues associated with higher unit sales of our pharmaceutical products during 2005. Special items related to cost of revenues included income of \$1.6 million in 2005 and a charge of \$0.2 million in 2004 related to a changes in estimate regarding the effect of some excess purchase commitments.

Cost of revenues from Meridian Medical Technologies decreased \$4.1 million, or 27.3%, to \$10.9 million in 2005 from \$15.0 million in 2004 primarily due to decreased government sales as described above.

Cost of revenues from royalties decreased \$0.4 million to \$2.2 million in 2005 from \$2.6 million in 2004.

Cost of revenues associated with contract manufacturing increased \$1.5 million, or 19.0% to \$9.4 million in 2005 from \$7.9 million in 2004.

Total selling, general and administrative expense increased \$19.7 million, or 17.7%, to \$130.8 million in 2005 from \$111.1 million in 2004. This increase was primarily attributable to increases in co-promotion fees paid under our Co-Promotion Agreement with Wyeth Pharmaceuticals due to higher net sales of Altace® during 2005, as compared to 2004. Increased net sales of Altace® during 2005 is primarily due to a lower amount of wholesale inventory reductions compared to that in 2004. Now that wholesale inventory reductions are complete, we believe Altace® net sales in the remaining quarters of 2005 should closely reflect demand-based sales. Accordingly, our co-promotion fees paid to Wyeth should also reflect demand based sales.

Selling, general and administrative expense includes special items of \$3.7 million in 2005 and \$5.7 million in 2004 mostly due to professional fees that were primarily related to the ongoing investigations of our company by the SEC and the Office of Inspector General of the Department of Health and Human Services. A special charge in the amount of \$3.3 million was also incurred in 2005 for merger related costs associated with our terminated merger agreement with Mylan Laboratories, Inc.

As a percentage of total revenues, total selling, general, and administrative expense decreased to 35.5% in 2005 compared to 38.1% in 2004. We anticipate that total selling, general and administrative expense, as a percentage of total revenues, should be less than the percentage experienced in the first quarter of 2005 for the remainder of 2005.

Depreciation and amortization expense increased \$2.1 million, or 5.3%, to \$41.4 million in 2005 from \$39.3 million in 2004. For more information regarding estimated future amortization expense, please see Note 8 to our condensed consolidated financial statements included in this report.

Total research and development expense decreased \$4.5 million, or 28.1% to \$11.5 million in 2005 from \$16.0 million in 2004. This decrease was primarily due to timing variances associated with actual expenditures. We anticipate that research and development expense should equal approximately \$95.0 million for the year ending December 31, 2005.

In addition to the special items related to cost of revenues from branded pharmaceutical products and selling, general and administrative expense described above, we incurred other special items affecting operating costs and expenses during 2005 and 2004 resulting in net charges of \$1.2 million and \$34.0 million, respectively. These other special items include:

Restructuring charges in the amount of \$2.0 million in 2005 primarily due to our decision to discontinue some relatively insignificant products associated with our Meridian Medical Technologies business.

Income of \$0.8 million and \$0.9 million in 2005 and 2004, respectively, primarily due to gains on the sale of some of our assets.

An intangible asset impairment charge totaling \$34.9 million in 2004 which is primarily related to a greater than expected decline in prescriptions for Florinef® and Tapazole® due to availability of generics for these products. This special item was recorded in order to adjust the carrying value of the intangible assets on our balance sheet associated with these products so as to reflect the

estimated fair value of such assets. We determined the fair value of the intangible assets associated with Florinef® and Tapazole® based on our estimated discounted cash flows for these products.

Operating Income

Due to the factors discussed above, we had operating income equaling \$111.6 million during 2005 compared to operating income of \$7.3 million during 2004.

Other Income (Expense)

Interest income equaled \$2.3 million in 2005 and \$1.1 million in 2004.

Interest expense was \$2.7 million in 2005 compared to \$3.1 million in 2004.

Special items affecting other income (expense) include a charge of \$6.9 million in 2005 to reflect our determination that the decline in the fair value of our equity interest in Novavax, Inc. as of March 31, 2005 was other than temporary, and a charge of \$0.5 million in 2004 to reflect an increase in the valuation allowance for the convertible notes receivable from Novavax. Novavax repurchased the convertible notes from us in July 2004.

Income Tax Expense

Our effective tax rate for continuing operations was 35.5% and 44.4% in 2005 and 2004, respectively. The effective tax rate in 2004 was higher than the federal statutory rate due primarily to certain permanent book-tax differences, state income taxes, and a valuation allowance established against certain state deferred tax assets.

Income from Continuing Operations

Due to the factors set forth above, we had income from continuing operations of \$67.1 million in 2005 compared to income from continuing operations of \$2.3 million in 2004.

Discontinued Operations

During the first quarter of 2004, our Board of Directors approved management s decision to market for divestiture some of our women s health products, including Prefest® and Nordette® which we sold in the fourth quarter of 2004. These product rights had identifiable cash flows that were largely independent of the cash flows of other groups of assets and liabilities and are classified as discontinued operations in the accompanying financial statements. Accordingly, all net sales, cost of revenues, selling, general and administrative costs and amortization associated with Prefest® and Nordette® are included in discontinued operations in 2004 and 2005.

Special items include results from discontinued operations. During 2005, we had income from discontinued operations of \$4.7 million, or \$3.0 million net of tax, as a result of changes in estimates resulting in the reduction in our reserves for returns and rebates previously accrued for Prefest® and Nordette®. During 2004, we had a loss from discontinued operations of \$167.5 million, or \$106.4 million net of income tax benefit, primarily due to an intangible asset write-down to reduce the carrying value of the intangible assets associated with these products to their estimated fair value less anticipated costs to sell.

Net Income (Loss)

Due to the factors discussed above, we had net income equaling \$70.1 million during 2005 compared to a net loss of \$104.1 million in 2004.

Liquidity and Capital Resources

General

We believe that existing balances of cash, cash equivalents and marketable securities, cash generated from operations, our existing revolving credit facility and funds available to us under our universal shelf registration are sufficient to finance our current operations and working capital requirements on both a

short term and long term basis. However, in the event we make significant future acquisitions or change our capital structure, we may be required to raise funds through additional borrowings or the issuance of additional debt or equity securities.

As additional consideration for Synercid®, an injectable antibiotic acquired on December 30, 2002, we agreed to potential milestone payments. We will pay Sanofi-Aventis a milestone payment of \$18.6 million on December 31, 2005, if there is continued recognition of Synercid® as an effective treatment for vancomycin-resistant enterococcus faecium on that date. An additional \$25.0 million milestone is payable to Aventis if Synercid® should receive FDA approval to treat methicillin resistant staphylococcus aureus, or we will pay Aventis a one-time payment of \$5.0 million the first time during any twelve-month period net sales of Synercid® exceed \$60.0 million, and a one-time payment of \$20.0 million the first time during any twelve-month period net sales of Synercid® exceed \$60.0 million, and a \$75.0 million.

On June 12, 2003, we acquired the primary care business of Elan Corporation, plc and of some of its subsidiaries in the United States and Puerto Rico, which includes the rights to two branded prescription pharmaceutical products, Sonata® and Skelaxin®. We will pay royalties on the current formulation of Skelaxin® from the date of closing.

Elan was working to develop a modified release formulation of Sonata®, which we refer to as Sonata® MR, pursuant to an agreement we had with them. We recently decided to discontinue the program to develop Sonata MR. Accordingly, we have advised Elan that we consider the agreement terminated. However, we can provide no assurance that we will not be required to engage in dispute resolution as provided in the agreement. The agreement required us to pay up to an additional \$60.0 million if Elan achieved certain milestones in connection with the development of a reformulated version of Sonata® and \$15.0 million as a milestone payment if annual net sales of a reformulated version of Sonata® exceed \$100.0 million, plus costs associated with the development of a reformulated version of Sonata® have not and cannot in the future be achieved.

On August 12, 2004, we entered into a collaborative agreement with Palatin Technologies, Inc. to jointly develop and, on obtaining necessary regulatory approvals, commercialize Palatin s PT-141 for the treatment of male and female sexual dysfunction. In connection with this agreement, we agreed to pay potential milestone payments to Palatin of up to \$100.0 million upon achieving certain development and regulatory approval targets. Following regulatory approval and commercialization of PT-141, we may also pay potential net sales milestone payments to Palatin of up to \$130.0 million.

Governmental Investigations and Securities Litigation

As previously reported, in March 2003 the SEC initiated a formal investigation of King relating to, among other topics, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and the Audit Committee s internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, we received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol®, and Levoxyl®. We have also reviewed with the staff of the SEC the circumstances giving rise to the restatement of our previously issued financial statements for 2002, 2003 and the first two quarters of 2004.

In connection with our determination that we underpaid amounts due to Medicaid and other government pricing programs from 1998 through 2002, we have continued to engage in discussions with representatives of the SEC, the United States Attorney for the Eastern District of Pennsylvania, the Department of Justice, the National Association of Medicaid Fraud Control Units, the Office of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, and the Public Health Service. Our objective in these discussions has been to achieve a comprehensive settlement relating to all the matters being investigated by or discussed with all the governmental authorities.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

Table of Contents

We have not yet reached any agreements or understandings with respect to the terms of such a settlement and may not ever be able to reach such an agreement. However, based on the status of the discussions to date, we now believe that it is reasonably likely that we will be able to achieve a comprehensive settlement with all relevant governmental parties on the following terms:

We have previously accrued \$130.4 million in respect of our estimated underpayments to Medicaid and other government pricing programs, and estimated settlement costs with all relevant governmental parties. This amount includes \$65.4 million accrued for estimated underpayments to Medicaid and other government pricing programs, and an additional \$65.0 million for estimated settlement costs to cover interest, costs, fines, penalties and all other additional amounts. Our current expectation is that the aggregate cost to settle with the governmental authorities should not materially exceed the amounts already accrued.

With respect to the matters being investigated by or discussed with the staff of the SEC, we currently anticipate that we would settle, without admitting or denying, one or more charges that we failed to maintain adequate books and records and internal controls. We anticipate that the action to be settled could also include one or more charges that our public filings contained material misstatements or omissions relating to our financial results for some or all of the periods for which results have been restated. We do not anticipate being required to restate any results for periods prior to 2002.

We expect that we will be required to enter into a Corporate Integrity Agreement with the Department of Health and Human Services, which would require us to submit to audits relating to our Medicaid rebate calculations over a five-year period. We do not expect that the resolution of the pending investigations will result in any prohibitions on our sales to Medicaid or any related state or Federal program, nor do we expect any other material restriction on our ability to conduct our business, although we will be required to incur consultant fees and other expenses in order to comply with the Corporate Integrity Agreement.

We do not expect that any criminal charges will be asserted against the Company or against any present or former director, officer or employee in connection with the matters being investigated.

Our ability to achieve a settlement on these or other terms is subject to substantial uncertainties. Our discussions to date have been conducted with the staffs of various agencies and other governmental authorities. We do not yet have any agreements or understandings with any of them. Even if we were to reach such an agreement or understanding with staff personnel, it would be subject to the approval of numerous more senior representatives of the governmental parties, including the members of the U.S. Securities and Exchange Commission, the United States Attorney for the Eastern District of Pennsylvania, senior officials in the Departments of Justice, Health and Human Services and Veterans Affairs, and senior officials in most or all of the States. We expect that our agreements with the various governmental parties will also require that those governmental parties reach numerous agreements among themselves, and that the consummation of our agreement with each governmental party would be dependent on consummation of our agreements with other governmental parties. We also expect that some aspects of a comprehensive settlement would require court approval.

In light of these uncertainties, we stress that we may not be able to reach a settlement with the governmental parties, whether on the terms described above or at all. As a result, the ultimate amount that we will actually have to pay to resolve these matters could be materially more than the amount accrued to date, and the terms could otherwise be materially less favorable than those described above. Because of these uncertainties and the complexity of completing a comprehensive resolution, we are not yet able to estimate with reasonable confidence the amount of time that will be required to enter into and consummate comprehensive settlement agreements.

The possible settlement described above would not apply to the related pending class actions and derivative suits, or any other claims by private plaintiffs. While we deny any liability, we are unable to predict the outcome of the class actions and derivative suits or reasonably estimate the range of loss, if any.

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

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

On August 12, 2004, the United States District Court for the Eastern District of Tennessee ruled on defendants motions to dismiss. The Court dismissed all claims as to Jones Pharma, Inc., a predecessor to one of our wholly owned subsidiaries, King Research and Development, Inc., and as to defendants Dennis Jones and Henry Richards. The Court also dismissed certain claims as to five other individual defendants. The Court denied the motions to dismiss in all other respects. Following the Court s ruling, on September 20, 2004, we and the other remaining defendants filed answers to plaintiffs consolidated amended complaint. Discovery and other proceedings in the case are continuing, and no trial date has been set.

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. On October 26, 2004, all of the defendants named in this action filed a partial answer to the amended consolidated derivative and class action complaint. Discovery in this action has commenced. No trial date has been set.

Another purported class action complaint was filed on August 16, 2004 in Tennessee state court against us and the members of our board of directors. This new case largely asserts substantially the same claims and seeks the same relief as the class action claim that was recently added to the state derivative action described above. Defendants in that action filed a motion to dismiss on November 30, 2004; that motion is pending and no hearing date has been set.

Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act (ERISA). As amended, the complaint alleges that we and certain of our executive officers, former executive officers, directors, former directors and an employee violated fiduciary duties that they allegedly owed our 401(k) Retirement Savings Plan s participants and beneficiaries under ERISA. The allegations underlying this action are similar in many respects to those in the class action litigation described above. The defendants filed a motion to dismiss the ERISA action on March 5, 2004. The District Court Judge referred the motion to a Magistrate Judge for a report and recommendation. On December 8, 2004, the Magistrate Judge held a hearing on this motion, and, on December 10, 2004, he recommended that the District Court Judge dismiss the action. The District Court Judge accepted the recommendation and dismissed the case on February 4, 2005.

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

Skelaxin[®] Patent Challenge

Eon Labs, Inc., CorePharma, LLC and Mutual Pharmaceutical Company have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. Additionally, Eon Labs ANDA seeks permission to market a generic version of Skelaxin® 800 mg tablets. United States Patent Nos. 6,407,128, the 128 patent, and 6,683,102, the 102 patent two method-of-use patents relating to Skelaxin®, are listed in the FDA s Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications alleging noninfringement and invalidity of the 128 and 102 patents. Mutual has filed a Paragraph IV certification alleging noninfringement and invalidity of the 102 patent. A patent infringement suit was filed against Eon Labs on January 2, 2003 in the District Court for the Eastern District of New York; CorePharma on March 7, 2003 in the District Court for the District of New Jersey (subsequently transferred to the District Court for the Eastern District of New York); and Mutual on March 12, 2004 in the District Court for the Eastern District of Pennsylvania concerning their proposed 400 mg products. Additionally, we filed a separate suit against Eon Labs on December 17, 2004 in the District Court for the Eastern District of New York, concerning its proposed 800 mg product. Pursuant to the Hatch-Waxman Act, the filing of the suit against CorePharma provides us with an automatic stay of FDA approval of CorePharma s ANDA for 30 months from no earlier than January 24, 2003. Also pursuant to the Hatch-Waxman Act, the filing of the suits against Eon Labs provides us with an automatic stay of FDA approval of Eon Labs ANDA for its proposed 400 mg and 800 mg products for 30 months from no earlier than November 18, 2002, and November 3, 2004, respectively. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. We filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004 and on July 21, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information corresponding to the use listed in the Orange Book. We concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated our Citizen Petition.

On March 12, 2004, the FDA sent a letter to us explaining that our proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, we submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of our proposed labeling revision until the FDA has fully evaluated and ruled upon our Citizen Petition, as well as all comments submitted in response to that petition. Discussions with the FDA concerning appropriate labeling are ongoing. CorePharma, Mutual and we have filed responses and supplements to the pending Citizen Petitions.

If our Citizen Petition is rejected, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected. We have entered into an agreement with a generic pharmaceutical company

to launch an authorized generic of Skelaxin® in the event we face generic competition for Skelaxin®. However, we cannot assure to what extent this strategy will be successful.

Altace[®] Patent Challenge

Cobalt Pharmaceuticals, Inc. filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA s *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is known as the Orange Book : U.S. Patent Nos. 4,587,258, the 258 patent, and 5,061,722, the 722 patent, two composition of matter patents related to Altace®, and U.S. Patent No. 5,403,856, the 856 patent, a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the Hatch- Waxman Act, any generic manufacturer may file an ANDA with Paragraph IV certification challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the

722 patent, and we filed suit on March 14, 2003 in the District Court for the District of Massachusetts to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt s ANDA for 30 months from no earlier than February 5, 2003. Should the court find in favor of a Cobalt summary judgment motion on the 722 patent, however, we would not receive the full benefit of that 30 month stay. Subsequent to filing our original complaint, we amended our complaint to add an allegation of infringement of the 856 patent. The 856 patent covers one of Altace® s three indications for use. In response to the amended complaint, Cobalt informed the FDA that it no longer seeks approval to market its proposed product for the indication covered by the 856 patent. On this basis, the court granted Cobalt summary judgment of non-infringement of the 856 patent. The court s decision does not affect Cobalt s infringement of the 722 patent. We intend to vigorously enforce our rights under the 722 and 856 patents.

Three Months Ended March 31, 2005

We generated net cash from continuing operations of \$23.5 million for the three months ended March 31, 2005. Our net cash provided from operations was primarily the result of \$67.1 million net income from continuing operations, adjusted for non-cash depreciation and amortization from continuing operations of \$41.4 million, a change in deferred taxes from continuing operations of \$25.1 million, and changes in working capital. Changes in working capital include an increase in income taxes payable of \$13.2 million, a decrease in inventory from continuing operations of \$19.0 million, a decrease in accounts payable of \$47.5 million, a decrease in accrued expenses of \$70.7 million, and an increase in accounts receivable of \$25.7 million.

Investing activities reduced cash flow by \$17.1 million primarily due to the purchase of property, plant and equipment of \$9.1 million and an increase in restricted cash of \$8.0 million.

Financing activities contributed \$0.1 million to cash flow due to the exercise of employee stock options.

Certain Indebtedness and Other Matters

As of March 31, 2005, we had \$345.0 million of long-term debt (including current portion) outstanding, up to \$400.0 million available under our revolving credit facility, and \$616.0 million available under our universal shelf registration.

On September 20, 2001, we registered a \$1.3 billion universal shelf registration statement on Form S-3 with the Securities and Exchange Commission. This universal shelf registration statement allows us to sell any combination of debt and/or equity securities in one or more offerings up to a total of \$1.3 billion. During November 2001, we completed the sale of 17,992,000 newly issued shares of common stock for \$38.00 per share (\$36.67 per share net of commissions and expenses) resulting in net proceeds of \$659.8 million. Additionally, during November 2001, we issued \$345.0 million of $2^3/4\%$ Convertible Debentures due November 15, 2021 in a private placement. Holders may require us to repurchase for cash all or part of these debentures on November 15, 2006, November 15, 2011 or November 15, 2016 at a

price equal to 100% of the principal amount of the debentures plus accrued interest up to but not including the date of repurchase.

On April 23, 2002, we established a \$400.0 million five year senior secured revolving credit facility. The facility has been collateralized in general by all real estate with a value of \$5.0 million or more and all of our personal property and that of our significant subsidiaries. Our obligations under the senior secured revolving credit facility are unconditionally guaranteed on a senior basis by most of our subsidiaries. The senior secured revolving credit facility accrues interest at our option, at either (a) the base rate, which is based on the greater of (1) the prime rate or (2) the federal funds rate plus one-half of 1%, plus an applicable spread ranging from 0.0% to 0.75% (based on a leverage ratio) or (b) the applicable LIBOR rate plus an applicable spread ranging from 1.0% to 1.75% (based on a leverage ratio). In addition, the lenders under the senior secured revolving credit facility are entitled to customary facility fees based on (a) unused commitments under the facility and (b) letters of credit outstanding. We incurred \$5.1 million of deferred financing costs, which are being amortized over five years, the life of the senior secured revolving credit facility. This facility requires us to maintain a minimum net worth of no less than \$1.2 billion plus 50% of our consolidated net income for each fiscal quarter after April 23, 2002, excluding any fiscal quarter for which consolidated income is negative; an EBITDA to interest expense ratio of no less than 3.00 to 1.00; and a funded debt to EBITDA ratio of no greater than 3.50 to 1.00 prior to April 24, 2004 and of no greater than 3.00 to 1.00 on or after April 24, 2004. As of March 31, 2005, we have complied with these covenants. As of March 31, 2005, there were no outstanding borrowings under this facility.

Capital Expenditures

Capital expenditures, including capital lease obligations, were \$9.1 million and \$12.6 million for the three months ended March 31, 2005 and 2004, respectively. The principal capital expenditures during the three months ended March 31, 2005 included property and equipment purchases, building improvements for facility upgrades and costs associated with improving our production capabilities, and costs associated with moving production of some of our pharmaceutical products to our facilities in St. Louis, Bristol and Rochester.

Recently Issued Accounting Standards

In December 2004, the FASB issued SFAS No. 123(R), (Share-based Payment) that requires us to expense costs related to share-based payment transactions with employees. The Securities and Exchange Commission issued Amendment 4-01(a) of Regulation S-X, changing the compliance date for SFAS 123(R) to the annual reporting period beginning after June 15, 2005. We are in the process of evaluating the effect that SFAS No. 123(R) will have on our financial reporting.

In November 2004, the FASB issued SFAS No. 151, (Inventory Costs), an amendment of ARB No. 43. SFAS No. 151 requires certain abnormal expenditures to be recognized as expenses in the current period. It also requires that the amount of fixed production overhead allocated to inventory be based on the normal capacity of the production facilities. The standard is effective for the fiscal year beginning January 1, 2006. We are currently evaluating the effect that SFAS No. 151 will have on our financial reporting.

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 generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

Significant estimates for which it is reasonably possible that a material change in estimate could occur in the near term include forecasted future cash flows used in testing for impairments of intangible and

tangible assets and loss accruals for excess inventory and fixed purchase commitments under our supply contracts. Forecasted future cash flows in particular require considerable judgment and are subject to inherent imprecision. In the case of impairment testing, changes in estimates of future cash flows could result in a material impairment charge and, whether or not they result in an immediate impairment charge, could result prospectively in a reduction in the estimated remaining useful life of tangible or intangible assets, which could be material to the financial statements.

Other significant estimates include accruals for Medicaid and other rebates, returns and chargebacks, allowances for doubtful accounts and estimates used in applying the revenue recognition policy and accounting for the Co-Promotion Agreement with Wyeth.

We are subject to risks and uncertainties that may cause actual results to differ from the related estimates, and our estimates may change from time to time in response to actual developments and new information.

Intangible assets, goodwill, and other long-lived assets. When we acquire product rights in conjunction with either business or asset acquisitions, we allocate an appropriate portion of the purchase price to intangible assets, goodwill and other long-lived assets. The purchase price is allocated to product rights and trademarks, patents, acquired research and development, if any, 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. However, patents have specific legal lives over which they are amortized. Conversely, trademarks and product rights have no specific legal lives. Trademarks and product rights will continue to be an asset to us after the expiration of the patent, as their economic value is not tied exclusively to the patent. We believe that by establishing separate lives for the patent versus the trademark and product rights, we are in essence using an accelerated method of amortization for the product as a whole. This results in greater amortization in earlier years when the product is under patent protection, as we are amortizing both the patent and the trademark and product rights, and less amortization after the product has the potential for generic competition, as the amortization on the patent is eliminated. As the pattern of economic benefit cannot be reliably determined, we use the straight-line method of amortization for our intangibles.

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

We may incur impairment charges in the future if prescriptions for, or sales of, our products are less than current expectations and result in a reduction of our estimated undiscounted future cash flows. This may be caused by many factors, including competition from generic substitutes, significant delays in the manufacture of supply of materials, the publication of negative results of studies or clinical trials, or new legislation or regulatory proposals.

The gross carrying amount and accumulated amortization as of March 31, 2005 are as follows:

| | | Cost | | Accumulated Amortization | | | | Net Book Value |
|------------------------------------|----|-----------|-------|-----------------------------|----|-----------|--|-------------------|
| | | | (in t | housands) | | | | |
| Branded | | | | | | | | |
| Altace | \$ | 276,150 | \$ | 60,086 | \$ | 216,064 | | |
| Other Cardiovascular | | 94,045 | | 17,840 | | 76,205 | | |
| Cardiovascular | | 370,195 | | 77,926 | | 292,269 | | |
| Anti-infective | | 221,593 | | 53,957 | | 167,636 | | |
| Critical care | | 17,643 | | 7,418 | | 10,225 | | |
| Endocrinology | | 28,841 | | 13,368 | | 15,473 | | |
| Skelaxin | | 203,015 | | 20,970 | | 182,045 | | |
| Sonata | | 181,121 | | 17,021 | | 164,100 | | |
| Neuroscience | | 384,136 | | 37,991 | | 346,145 | | |
| Intal | | 106,192 | | 10,178 | | 96,014 | | |
| Other Respiratory | | 12,397 | | 3,179 | | 9,218 | | |
| Respiratory | | 118,589 | | 13,357 | | 105,232 | | |
| Other | | 81,027 | | 22,060 | | 58,967 | | |
| Total Branded | | 1,222,024 | | 226,077 | | 995,947 | | |
| Meridian Medical Technologies | | 146,217 | | 13,327 | | 132,890 | | |
| Royalties | | 2,470 | | 2,051 | | 419 | | |
| Contract manufacturing | | | | | | | | |
| All other | | | | | | | | |
| Total trademark and product rights | \$ | 1,370,711 | \$ | 241,455 | \$ | 1,129,256 | | |
| | 35 | | | | | | | |

The amounts for impairments and amortization expense and the amortization period used for the three months ended March 31, 2004 and 2005 are as follows:

| | | nths ended 31, 2005 | | Three months ended March 31, 2004 | | | |
|-------------------------------------|-------------|-------------------------|-----------------|--------------------------------------|-------------------------|--|--|
| | Impairments | Amortization Expense | Life (Years) | Impairments | Amortization Expense | | |
| | (in tho | usands) | | (in thousands) | | | |
| Branded | | | | | | | |
| Altace | \$ | \$ 3,225 | 23 | \$ | \$ 2,304 | | |
| Other Cardiovascular | | 1,638 | | | 1,178 | | |
| Cardiovascular | | 4,863 | | | 3,482 | | |
| Anti-infective | | 2,633 | | | 2,632 | | |
| Critical care | | 264 | | | 166 | | |
| Endocrinology | | 238 | | 14,362 | 655 | | |
| Skelaxin | | 3,887 | 13.5 | | 2,550 | | |
| Sonata | | 2,993 | 15.5 | | 3,375 | | |
| Neuroscience | | 6,880 | | | 5,925 | | |
| Intal | | 1,361 | 20 | | 1,065 | | |
| Other respiratory | | 134 | | | 143 | | |
| Respiratory | | 1,495 | | | 1,208 | | |
| Other | | 1,188 | | 20,240 | 1,614 | | |
| Total Branded | | 17,561 | | 34,602 | 15,682 | | |
| Meridian Medical Technologies | | 1,291 | | | 1,531 | | |
| Royalties | | 11 | | | 11 | | |
| Contract manufacturing All other | | | | | | | |
| Au oiner | | | | | | | |
| Total trademark and product | | | | | | | |
| rights | \$ | \$ 18,863 | | \$ 34,602 | \$ 17,224 | | |
| | | 36 | | | | | |

The amounts for impairments and amortization expense for the twelve months ended December 31, 2003 and 2004 are as follows:

| | 2003 | | | | 2004 | | | |
|-------------------------------------|------|-----------|---------|----------------------|----------------|-----------|----|----------------------|
| | Imp | pairments | | ortization xpense | Im | pairments | | ortization xpense |
| | | (in thou | isands) |) | (in thousands) | | | |
| Branded | | | | | | | | |
| Altace | \$ | | \$ | 9,254 | \$ | | \$ | 10,135 |
| Other Cardiovascular | | | | 3,863 | | 3,618 | | 5,117 |
| Cardiovascular | | | | 13,117 | | 3,618 | | 15,252 |
| Anti-infective | | | | 10,019 | | 11,042 | | 10,420 |
| Critical care | | 1,206 | | 832 | | 3,274 | | 760 |
| Endocrinology | | | | 1,640 | | 16,169 | | 1,467 |
| Skelaxin | | | | 5,525 | | | | 11,558 |
| Sonata | | | | 7,313 | | 88,000 | | 12,635 |
| Neuroscience | | | | 12,838 | | 88,000 | | 24,193 |
| Intal | | | | 4,259 | | | | 4,558 |
| Other Respiratory | | 5,015 | | 705 | | 149 | | 564 |
| Respiratory | | 5,015 | | 4,964 | | 149 | | 5,122 |
| Other | | 110,970 | | 5,068 | | 38,529 | | 4,790 |
| Total Branded | | 117,191 | | 48,478 | | 160,781 | | 62,004 |
| Meridian Medical Technologies | | | | 6,125 | | 3,120 | | 5,885 |
| Royalties | | | | 42 | | | | 42 |
| Contract manufacturing All other | | | | | | | | |
| Total trademark and product rights | \$ | 117,191 | \$ | 54,645 | \$ | 163,901 | \$ | 67,931 |

The remaining patent life compared to the life of the trademarks and product rights for significant products is as follows:

Remaining Life at March 31, 2005

| | Patent | Trademark & Product Rights |
|-----------|------------------|-------------------------------|
| Altace | 4 years 1 month | 16 years 9 months |
| Skelaxin* | 3 months | 11 years 9 months |
| Sonata | 3 years 3 months | 13 years 9 months |
| Intal | | 17 years 8 months |

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

- * When we acquired the Skelaxin patent, it was under challenge by third parties. These challenges continue.
 - Considering the existence of these challenges we chose to amortize the patent rights over a shorter period. If we are successful in defending the patent, the remaining legal life may extend well beyond three months.

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

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

Accruals for rebates, returns, and chargebacks. We establish accruals for returns, chargebacks and commercial and Medicaid rebates in the same period we recognize the related sales. The accruals reduce revenues and are included in accrued expenses. At the time a rebate or chargeback payment is made or a product return is received, which 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 differences between estimated and actual payments. Due to estimates and assumptions inherent in determining the amount of returns, chargebacks and rebates, the actual amount of product returns and claims for chargebacks and rebates may be different from our estimates.

Our product returns accrual is primarily based on estimates of future product returns over the period during which customers have a right of return which is in turn based in part on estimates of the remaining shelf life of our products when sold to customers. Future product returns are estimated primarily based on historical sales and return rates. We estimate our Medicaid rebate and commercial contractual rebate accruals based on estimates of usage by rebate-eligible customers, estimates of the level of inventory of our products in the distribution channel that remain potentially subject to those rebates, and the terms of our contractual and regulatory rebate obligations. We estimate our chargeback accrual based on our estimates of the level of inventory of our products in the distribution channel that remain subject to chargebacks, and specific contractual and historical chargeback rates.

Our accruals for returns, chargebacks and rebates are adjusted as appropriate for specific known developments that may result in a change in our product returns or our rebate and chargeback obligations. In the case of product returns, we monitor demand levels for our products and the effects of the introduction of competing products and other factors on this demand. When we identify decreases in demand for products or experience higher than historical rates of returns caused by unexpected discrete events, we further analyze these products for potential additional supplemental reserves. We also monitor wholesale inventory levels and adjust the reserve as appropriate.

Accrual for Rebates (in thousands):

| | 2005 | (r | 2004 restated) |
|---|---------------|----|-------------------|
| Balance at January 1, net of prepaid amounts | \$ 172,161 | \$ | 213,893 |
| Current provision related to sales made in current period | 55,456 | | 72,717 |
| Current provision related to sales made in prior periods | (9,202) | | (1,397) |
| Actual rebates | (77,083) | | (74,701) |
| Balance at March 31, net of prepaid amounts | \$ 141,332 | \$ | 210,512 |

Accrual for Returns (in thousands):

| | 2005 | 2004 estated) |
|------------------------|---------------|------------------|
| Balance at January 1 | \$ 122,863 | \$ 82,477 |
| Current provision | (5,867) | 36,797 |
| Supplemental provision | 1,429 | |

| | Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q | | | | | | |
|---------------------|--|----|----------|----|----------|--|--|
| Actual returns | | | (45,394) | | (30,636) | | |
| Balance at March 31 | | \$ | 73,031 | \$ | 88,638 | | |
| | 38 | | | | | | |

Accrual for Chargebacks (in thousands):

| | 2005 | 2004 estated) |
|----------------------|--------------|------------------|
| Balance at January 1 | \$ 27,953 | \$ 25,349 |
| Current provision | 33,298 | 27,606 |
| Actual chargebacks | (36,788) | (29,169) |
| | | |
| Balance at March 31 | \$ 24,463 | \$ 23,786 |

Based on data received from our inventory management agreements with our three key wholesale customers, during the first quarter of 2005, there was a significant reduction of wholesale inventory levels of our products. While our calculation for returns reserves is based on historical sales and return rates over the period which customers have a right of return, it gives consideration to the amount of wholesale inventory levels. The significant reduction in wholesale inventories of our products during the first quarter of 2005 resulted in a decrease of approximately \$25 million in our reserve for returns and a corresponding increase in net sales from branded pharmaceuticals. This reduction has been netted in the current provision in the table for Accrual for Returns above.

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.

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, 2004, 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, 2004 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 Securities and Exchange Commission and Office of Inspector General of the Department of Health and Human Services, other possible governmental investigations, and securities, derivative and ERISA litigation could have a material adverse effect on our business.

As previously reported, in March 2003 the SEC initiated a formal investigation of King relating to, among other topics, sales of our products to VitaRx and Prison Health Services, our best price lists, the pricing of our pharmaceutical products provided to governmental Medicaid agencies, the accrual and payment of rebates on the product Altace®, the products Fluogen® and Lorabid®, the King Benevolent Fund, Inc., our calculations related to Medicaid rebates, and the Audit Committee s internal review of issues raised by the SEC investigation. As also previously reported, on November 13, 2003, we received a subpoena duces tecum from the Office of Inspector General at the Department of Health and Human Services requesting the production of documents relating to some of the matters being investigated by the SEC and to our sales, marketing and other business practices for Altace®, Aplisol® and Levoxyl®. We have also reviewed with the staff of the SEC the circumstances giving rise to the restatement of our previously issued financial statements for 2002, 2003 and the first two quarters of 2004.

In connection with our determination that we underpaid amounts due to Medicaid and other government pricing programs from 1998 through 2002, we have continued to engage in discussions with representatives of the U.S. Securities and Exchange Commission, the United States Attorney for the Eastern District of Pennsylvania, the Department of Justice, the National Association of Medicaid Fraud Control Units, the Office of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs, the Centers for Medicare & Medicaid Services, and the Public Health Service. Our objective in these discussions has been to achieve a comprehensive settlement relating to all the matters being investigated by or discussed with all the governmental authorities.

We have not yet reached any agreements or understandings with respect to the terms of such a settlement, and we cannot assure you that we will ever be able to reach such an agreement. Based on the status of the discussions to date, however, we now believe that it is reasonably likely that we will be able to achieve a comprehensive settlement with all relevant governmental parties on the terms described in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations under the heading Governmental Investigations and Securities Litigation.

Our ability to achieve a settlement on these or other terms is subject to substantial uncertainties. Our discussions to date have been conducted with the staffs of various agencies and other governmental authorities. We do not yet have any agreements or understandings with any of them. Even if we were to reach such an agreement or understanding with staff personnel, it would be subject to the approval of numerous more senior representatives of the governmental parties, including the members of the U.S. Securities and Exchange Commission, the United States Attorney for the Eastern District of Pennsylvania, senior officials in the Departments of Justice, Health and Human Services and Veterans Affairs, and senior officials in most or all of the States. We expect that our agreements with the various governmental parties will also require that the governmental parties reach numerous agreements among themselves, and that the consummation of our agreement with each governmental party would be

dependent on consummation of our agreements with other governmental parties. We also expect that some aspects of a comprehensive settlement would require court approval.

In light of these uncertainties, we stress that we may not be able to reach a settlement with the governmental parties, whether on the terms described above or at all. As a result, the ultimate amount that we will actually have to pay to resolve these matters could be materially more than the amount accrued to date, and the terms could otherwise be materially less favorable than those described above. Because of these uncertainties and the complexity of completing a comprehensive resolution, we are not yet able to estimate with reasonable confidence the amount of time that will be required to enter into and consummate comprehensive settlement agreements.

The possible settlement described above would not apply to the related pending class actions and derivative suits or any other claims by private plaintiffs. While we deny any liability, we are unable to predict the outcome of the class actions and derivative suits or reasonably estimate the range of loss, if any.

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

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

On August 12, 2004, the United States District Court for the Eastern District of Tennessee ruled on defendants motions to dismiss. The Court dismissed all claims as to Jones Pharma, Inc., a predecessor to one of our wholly owned subsidiaries, King Research and Development, Inc., and as to defendants Dennis Jones and Henry Richards. The Court also dismissed certain claims as to five other individual defendants. The Court denied the motions to dismiss in all other respects. Following the Court s ruling, on September 20, 2004, we and the other remaining defendants filed answers to plaintiffs consolidated amended complaint. Discovery and other proceedings in the case are continuing, and no trial date has been set.

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. On October 26, 2004, all of the defendants named in this action filed an answer to the amended consolidated derivative and class action complaint. Discovery in this action has commenced. No trial date has been set.

Another purported class action complaint was filed on August 16, 2004 in Tennessee state court against us and the members of our board of directors. This new case largely asserts substantially the same claims and seeks the same relief as the class action claim that was recently added to the state derivative action described above. Defendants in that action filed a motion to dismiss on November 30, 2004; that motion is pending and no hearing date has been set.

Additionally, a class action complaint was filed in the United States District Court for the Eastern District of Tennessee under the Employee Retirement Income Security Act, which we refer to as ERISA. As amended, the complaint alleges that we and certain of our executive officers, former executive officers, directors, former directors and an employee violated fiduciary duties that they allegedly owed our 401(k) Retirement Savings Plan s participants and beneficiaries under ERISA. The allegations underlying this action are similar in many respects to those in the class action litigation described above. The defendants filed a motion to dismiss the ERISA action on March 5, 2004. The District Court Judge referred the motion to a Magistrate Judge for a report and recommendation. On December 8, 2004, the Magistrate Judge held a hearing on this motion, and, on December 10, 2004, he recommended that the District Court Judge dismiss the action. The District Court Judge accepted the recommendation and dismissed the case on February 4, 2005.

We intend to defend all of these lawsuits vigorously but are unable currently to predict the outcome or reasonably estimate the range of potential loss, if any. If any governmental sanctions are imposed, or if we were not to prevail in the pending litigation, neither of which we can predict or reasonably estimate at this time, our business, financial condition, results of operations and cash flows could be materially adversely affected. Responding to the governmental investigations, resolving the amounts owed to governmental agencies in connection with the underpayments and defending us in the pending litigation has resulted, and is expected to continue to result, in a significant diversion of management s attention and resources and the payment of additional professional fees.

If we cannot successfully enforce our rights under the patents relating to two of our largest products, Altace® and Skelaxin®, or if we are unable to secure or enforce our rights under other patents, trademarks, trade secrets or other intellectual property, our results of operations could be materially adversely affected.

Cobalt Pharmaceuticals, Inc., a generic drug manufacturer located in Mississauga, Ontario, Canada, filed an ANDA with the FDA seeking permission to market a generic version of Altace®. The following U.S. patents are listed for Altace® in the FDA s Orange Book: United States Patent Nos. 4,587,258 (the 258 patent), and 5,061,722 (the

722) patent, two composition of matter patents related to Altace®, and United States Patent No. 5,403,856, (the 856 patent), a method-of-use patent related to Altace®, with expiration dates of January 2005, October 2008, and April 2012, respectively. Under the Hatch-Waxman Act, any generic manufacturer may file an ANDA with a certification, known as a Paragraph IV certification, challenging the validity or infringement of a patent listed in the FDA s Orange Book four years after the pioneer company obtains approval of its NDA. Cobalt has filed a Paragraph IV certification alleging invalidity of the 722 patent, and we filed suit on March 14, 2003 in the District Court for the District of Massachusetts to enforce our rights under that patent. Pursuant to the Hatch-Waxman Act, the filing of that suit provides us an automatic stay of FDA approval of Cobalt s ANDA for 30 months from no earlier than February 5, 2003. In March 2004, Cobalt stipulated to infringement of the 722 patent. Should the court find in favor of a Cobalt summary judgment motion on the validity of the 722 patent, we would not receive the full benefit of that 30 month stay. Subsequent to filing our original complaint, we amended our complaint to add an allegation of infringement of the 856 patent. The 856 patent covers one of Altace® s three indications for use. In response to the amended complaint, Cobalt informed the FDA that it no longer seeks approval to market its proposed product for the indication covered by the 856 patent. On this basis, the court granted Cobalt summary judgment of non-infringement of the % for a patent is proposed product for the indication for the sector a decision does not affect Cobalt summary judgment of non-infringement of the % for a patent.

856 patent. The court s decision does not affect Cobalt s infringement of the 722 patent. We intend to vigorously enforce our rights under the 722 and 856 patents.

Eon Labs, Inc., CorePharma, LLC and Mutual Pharmaceutical Co., Inc. have each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. Additionally,

Eon Labs ANDA seeks permission to market a generic version of Skelaxin® 800 mg tablets. United States Patent Nos. 6,407,128 (the 128 patent) and 6,683,102 (the 102 patent), two method-of-use patents relating to Skelaxin®, are listed in the FDA s Orange Book and do not expire until December 3, 2021. Eon Labs and CorePharma have each filed Paragraph IV certifications against the 128 patent and the 102 patent alleging noninfringement and invalidity of these patents. Mutual has filed a Paragraph IV certification against the 102 patent alleging noninfringement and invalidity of that patent. A patent infringement suit was filed against Eon Labs on January 2, 2003 in the District Court for the Eastern District of New York; CorePharma on March 7, 2003 in the District Court for the District of New Jersey (subsequently transferred to the District Court for the Eastern District of New York); and Mutual on March 12, 2004 in the District Court for the Eastern District of Pennsylvania concerning their proposed 400 mg products. Additionally, we filed a separate suit against Eon Labs on December 17, 2004, in the District Court for the Eastern District of New York concerning its proposed 800 mg product. Pursuant to the Hatch-Waxman Act, the filing of the suit against CorePharma provides us with an automatic stay of FDA approval of CorePharma s ANDA for 30 months from no earlier than January 24, 2003. Also pursuant to the Hatch-Waxman Act, the filing of the suits against Eon Labs provides us with an automatic stay of FDA approval of Eon Labs ANDA for its proposed 400 mg and 800 mg products for 30 months from no earlier than November 18, 2002, and November 3, 2004, respectively. We intend to vigorously enforce our rights under the 128 and 102 patents to the full extent of the law.

On March 9, 2004, we received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. We believe that this decision is arbitrary, capricious, and inconsistent with the FDA s previous position on this issue. We filed a Citizen Petition on March 18, 2004 (supplemented on April 15, 2004 and on July 21, 2004), requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information corresponding to the use listed in the Orange Book. King concurrently filed a Petition for Stay of Action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated our Citizen Petition.

On March 12, 2004, the FDA sent a letter to us explaining that our proposed labeling revision, which includes references to additional clinical studies relating to food, age, and gender effects, was approvable and only required certain formatting changes. On April 5, 2004, we submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a Petition for Stay of Action requesting the FDA to stay approval of our proposed labeling revision until the FDA has fully evaluated and ruled upon our Citizen Petition, as well as all comments submitted in response to that petition. Discussions with the FDA concerning appropriate labeling are ongoing. CorePharma, Mutual and we have filed responses and supplements to the pending Citizen Petitions.

If our Citizen Petition is rejected, there is a substantial likelihood that a generic version of Skelaxin® will enter the market, and our business, financial condition, results of operations and cash flows could be materially adversely affected. In an attempt to mitigate this risk, we have entered into an agreement with a generic pharmaceutical company to launch an authorized generic of Skelaxin® in the event of generic competition. However, we cannot assure to what extent this strategy will be successful.

We may not be successful in securing or maintaining proprietary patent protection for other of our products or for 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.

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.

We are subject to the risk of additional litigation and regulatory proceedings or actions in connection with the restatement of prior period financial statements.

We have restated our previously issued financial statements for the fiscal years 2002 and 2003, including interim periods in 2003, and the first two quarters of 2004. We may in the future be subject to class action suits, other litigation or regulatory proceedings or actions arising in relation to the restatement of our prior period financial statements. Any expenses incurred in connection with this potential litigation or regulatory proceeding or action not covered by available insurance or any adverse resolution of this potential litigation or regulatory proceeding or action could have a material adverse effect on our business, results of operations, cash flows and financial condition. Further, any litigation or regulatory proceeding or action may be time consuming, and it may distract our management from the conduct of our business.

Management has concluded that we did not have a sufficient number of finance and accounting resources performing supervisory review and monitoring activities as of year-end 2004 and, accordingly, that we did not maintain effective controls over the period-end financial reporting process. We cannot assure you that we will be able to remediate this material weakness and conclude that our internal control over financial reporting is effective as of the end of 2005 or that the material weakness will not result in material misstatements of our financial statements.

Under the Sarbanes-Oxley Act of 2002 and the rules issued thereunder, management is required to conduct an evaluation of the effectiveness of its internal control over financial reporting as of each year-end. We are also required to include in our Annual Reports on Form 10-K a report on management s assessment of the effectiveness of our internal control over financial reporting. Our registered public accounting firm also issues an audit report on management s assessment and our internal controls over financial reporting.

Management concluded that, as a result of the loss of certain finance personnel, the challenges of hiring new personnel while a merger was pending and the resource requirements to address the restatement of our financial statements, we did not have a sufficient number of finance and accounting resources performing supervisory review and monitoring activities as of the end of 2004. We are in the process of addressing this material weakness by actively recruiting additional managerial level finance and accounting resources.

We cannot assure you that management will not identify one or more additional significant deficiencies or material weaknesses in our internal control over financial reporting during 2005, that the steps we take to address any significant deficiencies or material weaknesses will be successful, that a significant deficiency or material weakness will not result in material errors before it is remediated, that management will be able to complete its assessment of internal control over financial reporting in a timely fashion in 2005, or that management will be able to conclude on the basis of its evaluation that our internal control over financial reporting was effective as of the end of 2005.

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

Altace®, Skelaxin®, Thrombin-JMI®, Sonata®, Levoxyl® and royalty revenues for the last twelve months ended March 31, 2005 accounted for 26.7%, 19.1%, 14.4%, 4.6%, 8.4% and 5.8% of our total revenues from continuing operations, respectively, or 79.0% in total. We believe that these sources of revenue may constitute a significant portion of our revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of any of these products or products for which we receive royalty payments could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

As of March 31, 2005, we had \$1.4 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. A significant decline in future sales of a product could result in an impairment of the declining product s net book value, resulting in a non-cash impairment charge. Demand for some of our non-key products, including Intal®, Tilade®, Synercid® and Corzide®, has been declining. The net intangible assets associated with these four products totals approximately \$248.6 million. 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 and results of operations. In evaluating goodwill for impairment, we estimate the fair value of our individual business reporting units on a discounted cash flow basis. In the event the value of an individual business reporting unit declines significantly, it could result in a non-cash impairment charge.

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

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

We are engaged in the development and licensing of new products. For example, we are engaged in the development of binodenoson, a myocardial pharmacologic stress imaging agent;

engaged in the development of PT-141, an investigational new drug for the treatment of ED and FSD;

engaged in the development of T-62, an investigational drug for the treatment of neuropathic pain;

engaged in the development of MRE0094, an investigational drug for the topical treatment of chronic diabetic foot ulcers;

engaged in the development of a new inhaler for Intal[®] using the alternative propellant HFA for which the FDA has issued an approvable letter;

engaged in the development of an Altace®/diuretic combination product; and

engaged in the development of a diazepam-filled auto-injector.

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

Table of Contents

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

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

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

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

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

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

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

develop or license their products more rapidly than we can,

complete any applicable regulatory approval process sooner than we can,

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

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

and thereby have a negative impact on the sales of our newly developed or licensed products. The inability to effect acquisitions or licenses of additional branded products in development and FDA-approved products could limit the overall growth of our business. Furthermore, even if we obtain rights to a pharmaceutical product or acquire a company, we may not be able to generate sales sufficient to create a profit or otherwise avoid a loss. Technological developments or the FDA s approval of new products or of new therapeutic indications for existing products may make our existing products or those products we are licensing or developing obsolete or may make them more difficult to market successfully, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

The integration of acquisitions into our business requires significant management attention and may require the further expansion of our sales force. In order to manage our acquisitions effectively, we must maintain adequate operational, financial and management information systems and motivate and effectively manage an increasing number of employees. Our acquisitions have significantly expanded our product offerings, operations and number of employees. Our future success will also depend in part on our ability to retain or hire qualified employees to operate our expanding facilities efficiently in accordance with applicable regulatory standards. If we cannot integrate our acquisitions successfully, these changes and acquisitions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

Although most of our revenue is generated by products not subject to competition from generic products, there is no proprietary protection for most of our branded pharmaceutical products, and generic substitutes for many of these products are sold by other pharmaceutical companies. Even our products that currently have no generic substitute could face generic competition if generics are developed by other companies and approved by the FDA. The entry of

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

generic substitutes for any of our products could adversely affect our business, financial condition, results of operations and cash flows. 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.

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

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

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

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

We manufacture many of our products in facilities we own and operate. These products include Altace®, Thrombin-JMI® and Levoxyl®, which together represent approximately 49.5% of our revenues for the last twelve months ended March 31, 2005. 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®, Intal®, Tilade®, Synercid® and Cortisporin®, are currently manufactured by third parties. Our dependence upon third parties for the manufacture of our products may adversely impact our profit margins or may result in unforeseen delays or other problems beyond our control. For example, if any of these third parties are not in compliance with applicable regulations, the manufacture of our products could be adversely affected. If for any reason we are unable to obtain or retain third-party manufacturers on commercially acceptable terms, we may not be able to distribute our products as planned. If we encounter delays or difficulties with contract manufacturers in producing or packaging our products, the distribution, marketing and subsequent sales of these products would be adversely affected, and we may have to seek alternative sources of supply or abandon or sell product lines on unsatisfactory terms. We might not be able to enter into alternative supply arrangements at commercially acceptable rates, if at all. We also cannot assure you that the manufacturers we utilize will be able to provide us with sufficient quantities of our products or that the products supplied to us will meet our specifications.

We have begun construction of facilities to produce Bicillin® at our Rochester facility. The third party manufacturer that produced Bicillin® for us recently closed its plant. If our inventory of Bicillin® is not sufficient to sustain demand during the period we are constructing our Bicillin® manufacturing facility, or if we experience delays in obtaining regulatory authorizations or experience production difficulties at our Bicillin® manufacturing facility, sales of this product may be reduced or the market for the product may be permanently diminished, either of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. For the last twelve months ended March 31, 2005, net sales of Bicillin® were \$34.2 million representing 2.5% of total revenues.

We are also in the process of transferring to our manufacturing facilities some of our other products that are currently manufactured by third parties. We expect to complete these transfers prior to the expiration of the agreements concerning supply of these products. However, we cannot assure that we will complete the transfers prior to the expiration of the supply agreements, which could have a material adverse effect 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. Some of the contracts we have for the supply of raw materials have short terms, and there is no assurance that we will be able to secure extension of the terms of such agreements. However, if we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to distribute our products as planned.

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

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

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

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

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

may otherwise breach or terminate their agreements with us.

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

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

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

The Rochester facility was inspected by the FDA in November/ December 2004. When an FDA inspector completes an authorized inspection of a manufacturing facility, the inspector typically provides the owner/operator of

the facility with a written report listing the inspector s observations of objectionable

conditions and practices. This written report is known as an FDA Form 483 or simply as a 483. The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a pharmaceutical manufacturer receives a 483 after an inspection and our Rochester facility received a 483 following the November/ December 2004 inspection. While no law or regulation requires us to respond to a 483, we have submitted a written response detailing our plan of action with respect to each of the observations made on the 483 and our commitment to correct any objectionable practice or condition. The risk to us of a 483, if left uncorrected, could include, among other things, the imposition of civil monetary penalties, the commencement of actions to seize or prohibit the sale of unapproved or non-complying products, or the cessation of manufacturing operations at the Rochester facility that are not in compliance with cGMPs. While we believe the receipt of the 483 will not have a material adverse effect on our business, financial condition, results of operations and cash flows, we cannot assure you that future inspections may not result in adverse regulatory actions which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

We are currently working to expand our production capacity for Thrombin-JMI®. 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.

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

Our results of operations, including, in particular, product sales revenue, may vary from quarter to quarter due to many factors. Wholesalers and distributors represent a substantial portion of our sales. Buying patterns of our wholesalers and distributors may vary from time to time. In the event wholesalers and distributors with whom we do business determine to limit their purchases of our inventory, sales of our products could be adversely affected. For example, in advance of an anticipated price increase, many of our customers may order pharmaceutical products in larger than normal quantities. The ordering of excess quantities in any quarter could cause sales of some of our branded pharmaceutical products to be lower in subsequent quarters than they would have been otherwise. As part of our ongoing efforts to facilitate improved management of wholesale inventory levels of our branded pharmaceutical products, we entered into inventory management agreements with each of our three key wholesale customers during the second quarter of 2004. To a great extent, we rely on the accuracy of the data that each customer provides to us on a regular basis. Other factors that may affect quarterly results 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.

The insolvency of any of our principal customers, wholesale pharmaceutical distributors, could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Similar to other pharmaceutical companies, our principal customers are primarily wholesale pharmaceutical distributors. The wholesale distributor network for pharmaceutical products has in recent years been subject to increasing consolidation, which has increased our, and other industry participants , customer concentration. Accordingly, three key customers account for approximately 70.0% of our revenues and a significant portion of our accounts receivable. The insolvency of any of our principal customers could have a material adverse effect on our business, financial condition, results of operations and cash flows.

Our wholly owned subsidiary, King Research and Development, successor to 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, King Research and Development, successor to Jones Pharma Incorporated, is a defendant in 380 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine, which is usually referred to as fen/phen. In 1996, Jones acted as a distributor of Obenix®, a branded phentermine product. Jones also distributed a generic phentermine product. We believe that Jones phentermine products have been identified in less than 100 of the foregoing cases. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs. They seek compensatory and punitive damages as well as medical care and court-supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to, product liability, strict liability, negligence, breach of warranties and misrepresentation. These suits are filed in various jurisdictions throughout the United States, and in each of these drugs. King Research and Development denies any liability incident to the distribution of Jones phentermine products and intends to pursue all defenses available to it. King Research and Development has tendered defense of these lawsuits to its insurance coverage is inadequate to satisfy any resulting liability, King Research and Development will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

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

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

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

The FDA expects manufacturers of biological products to have validated processes capable of removing extraneous viral contaminants to a high level of assurance. As a result, many manufacturers of biologics are currently engaged in developing procedures to remove potential extraneous viral contaminants

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

Table of Contents

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

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

During the fourth quarter of 2001 we issued 2³/4% Convertible Debentures due November 15, 2021 in an aggregate amount of \$345.0 million. The price at which the debentures are convertible into common stock is \$50.16, subject to adjustments spelled out in the documents governing the debentures. If the price of our stock has not reached that amount by November 15, 2006, we may be required to repurchase all or a portion of the debentures representing the \$345.0 million on November 15, 2006 if some or all of the holders of the debentures request that we repurchase their debentures. We cannot assure you that a significant repurchase requirement at that time would not have a material adverse effect on our business, financial condition, results of operations or cash flows.

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

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

Our relationship with the DoD 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. Our Meridian Medical Technologies segment has pharmaceutical products that are presently sold primarily to the DoD under an Industrial Base Maintenance Contract which we refer to as IBMC. The current IBMC expires in September 2005. Although we have reason to believe the DoD will renew the IBMC based on our relationship over many years, we cannot assure you that they will. In the event the DoD does not renew the IBMC, our business, financial condition, results of operations and cash flows could be materially adversely affected. Additionally, 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 DoD are subject to post-award audit and potential price determination. These audits may include a review of our performance on the contract, our pricing practices, our cost structure and our compliance with applicable laws, regulations and standards. 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 DoD makes claims for pricing adjustments with respect to completed contracts. If a government audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including termination of contracts, forfeitures of profits, suspension of payments, fines and suspension or disqualification from doing business with the government.

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

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.

Medicaid reporting and payment obligations are highly complex and in certain respects ambiguous. If we fail to comply with these obligations, 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 Securities and Exchange Commission and Office of Inspector General at the Department of Health and Human Services, other possible governmental investigations, and securities and ERISA litigation could have a material adverse effect on our business, and elsewhere in this report, we have determined that we underpaid amounts due under Medicaid and other governmental pricing programs during the period from 1998 to 2002. We have previously accrued \$130.4 million in respect of our estimated underpayments to Medicaid and other government pricing programs and estimated settlement costs with all relevant governmental parties. Our ability to achieve a settlement on these or other terms is subject to substantial uncertainties.

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

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.

When feasible, Wyeth must give us six months written notice of its intent to sell, market or distribute any product competitive with Altace[®]. Once we have been notified in writing of Wyeth s intent to market, sell or distribute a competing product, Wyeth has 90 days to inform us as to whether it intends to divest its interest in the competing product. 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 the Co-Promotion Agreement. Alternatively, we and Wyeth could agree upon another commercial relationship. If we and Wyeth are unable to establish acceptable terms, then we have the option at our 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.

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

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

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

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

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

We are highly dependent on the principal members of our management staff, the loss of whose services might impede the achievement of our strategic objectives. We cannot assure you that we will be able to attract and retain key personnel in sufficient numbers, with the requisite skills or on acceptable terms necessary or advisable to support growth and integration. The loss of the services of key personnel or the failure to attract such personnel could have a material adverse effect on us. Our Chief Financial Officer, James R. Lattanzi, will retire on June 1, 2005. If we are unable to attract, and retain in a timely manner, a qualified person to fill this position, the achievement of our strategic objectives may be impeded.

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

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

a classified Board of Directors;

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

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

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

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

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

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

variations in our results of operations;

perceived risks and uncertainties concerning our business;

announcements of earnings;

developments in the governmental investigations or securities litigation;

failure to meet or exceed our own 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 pharmaceutical 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 sholdings of our common stock.

Risks Related to Our Industry

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

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

Noncompliance with applicable FDA policies or requirements could subject us to enforcement actions, such as suspensions of manufacturing or distribution, seizure of products, product recalls, fines, criminal penalties,

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

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

All manufacturers of human pharmaceutical products are subject to regulation by the FDA under the authority of the Food, Drug and Cosmetics Act, which we refer to as the FDC Act, or the Public Health Service Act, which we refer to as 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 current Good Manufacturing Practices, which we refer to as cGMPs, and drug products subject to an approved application must be manufactured, processed, packaged, held and labeled in accordance with information contained in the approved application.

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

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

An increase in product liability claims or product recalls 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 exist for products in clinical development and with respect to products that have regulatory approval for commercial sale. While we have taken, and will continue to take, what we believe are appropriate precautions, we may not be able to avoid significant product liability exposure. We currently have product liability insurance in the

amount of \$80.0 million for aggregate annual claims including a \$20.0 million self-insured retention; however, we cannot assure you that the level or breadth of any insurance coverage will be sufficient to cover fully all potential claims. Also, adequate insurance coverage might not be available in the future at acceptable costs, if at all. For example, we are now not able to obtain product liability insurance with respect to our products Menest®, Delestrogen® and Pitocin®, each a women s healthcare product. With respect to any product liability claims relating to these products, we could be responsible for any monetary damages awarded by any court or any voluntary monetary settlements. Significant judgments against us for product liability for which we have no insurance could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

Commercial success in producing, marketing and selling of branded prescription pharmaceutical products depends, in part, on the availability of adequate reimbursement from third-party health care payors, such as the government, private health insurers and managed care organizations. Third-party payors are increasingly challenging whether to reimburse certain pharmaceutical products and medical services. For example, many managed health care organizations limit reimbursement of pharmaceutical products. These limits may take the form of formularies with differential co-pay tiers. The resulting competition among pharmaceutical companies to maximize their product reimbursement has generally reduced growth in average selling prices across the industry. We cannot assure you that our products will be appropriately reimbursed or included on the formulary lists of managed care organizations or that downward pricing pressures in the industry generally will not negatively impact our operations.

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, pharmacies and patients. Third-party payors include state and federal governments, under programs such as Medicaid and other entitlement programs, as well as managed care organizations, private insurance plans and health maintenance organizations. Because of the growing size of the patient population covered by third party reimbursement, it is important to our business that we market our products to reimbursers 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, retail pharmacies 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 reimbursement coverage strategies, including formularies, to reduce their cost for medications. Formularies can be based on the prices and/or therapeutic benefits of the available products. Due to their lower costs, generics receive more favorable reimbursement. The breadth of the products reimbursed 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. Denial of a product from reimbursement 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 addressed our contract relationship with managed care organizations in an effort to increase the attractiveness of reimbursements for our products. 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 business, financial condition, results of operations or cash flows.

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

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

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

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

From time to time studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study. The publication of negative results of studies or clinical trials related to our products or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products compete, our business, financial condition, results of operations and cash flows could be materially adversely affected. Additionally, potential write-offs of the intangible assets associated with the affected products could materially adversely affect our results of operations.

New legislation or regulatory proposals may adversely affect our revenues.

A number of legislative and regulatory proposals aimed at changing the health care system, including the cost of prescription products, importation and reimportation of prescription products from countries outside the United States and changes in the levels at which pharmaceutical companies are reimbursed for

sales of their products, have been proposed. While we cannot predict when or whether any of these proposals will be adopted or the effect these proposals may have on our business, the pending nature of these proposals, as well as the adoption of any proposal, may exacerbate industry-wide pricing pressures and could have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, in 2000, Congress directed the FDA to adopt regulations allowing the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs were sold at a lower price. Although the Secretary of Health and Human Services has refused to implement this directive, in July 2003 the House of Representatives passed a similar bill that does not require the Secretary of Health and Human Services to act. The reimportation bills have not yet resulted in any new laws or regulations; however, these and other initiatives could decrease the price we receive for our products. Additionally sales of our products in the United States could be adversely affected by the importation of products that some may deem to be equivalent to ours that are manufactured by others and are available outside the United States. Many States have implemented or are in the process of implementing regulations requiring pharmaceutical companies to provide them with certain marketing and pricing information. While we intend to comply with these regulations, we are unable at this time to predict or estimate the effect of these regulations, if any.

Changes in the Medicare, Medicaid or similar governmental programs or the amounts paid by those programs for our services may adversely affect our earnings. These programs are highly regulated and subject to frequent and substantial changes and cost containment measures. In recent years, changes in these programs have limited and reduced reimbursement to providers. *The Medicare Prescription Drug, Improvement and Modernization Act of 2003*, creates a new, voluntary prescription drug benefit under the Social Security Act, which we refer to as Medicare Drug Benefit. Beginning in 2006, Medicare beneficiaries entitled to Part A or enrolled in Part B, as well as certain other Medicare enrollees, will be eligible for the Medicare Drug Benefit. Regulations implementing the Medicare Drug Benefit were published January 28, 2005. The Medicare Drug Act requires that the Federal Trade Commission conduct a study and make recommendations regarding additional legislation that may be needed concerning the Medicare Drug Benefit. We are unable at this time to predict or estimate the financial effect of this new legislation.

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

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

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

additional competitors will not enter the market; or

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

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

Competition for Acquisitions. We compete with other pharmaceutical companies for product and product line acquisitions. These competitors include Biovail Corporation, Forest Laboratories, Inc., Galen Holdings plc, Medicis Pharmaceutical Corporation, Shire Pharmaceuticals Group plc, Watson Pharmaceuticals, Inc., and other companies which also acquire branded pharmaceutical products and

product lines, including those in development, from other pharmaceutical companies. We cannot assure you that

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

additional competitors will not enter the market; or

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

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

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

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

Our product Sonata® competes with other insomnia treatments in a highly competitive market. Additionally, other potential competitive insomnia products are in development and could enter the market over the next couple of years.

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

We intend to market these products aggressively by, among other things detailing and sampling to the primary prescribing physician groups, and

sponsoring physician symposiums, including continuing medical education seminars.

Many of our branded pharmaceutical products have either a strong market niche or competitive position. Some of our branded pharmaceutical products face competition from generic substitutes.

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. 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, references to assumptions. These statements are contained in the Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations sections, as well as other sections of this report.

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

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

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

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

the adequacy of our liquidity and capital resources;

anticipated capital expenditures;

the development and approval of binodenoson, our next generation cardiac pharmacologic stress-imaging agent; PT-141, an investigational new drug for the treatment of erectile dysfunction and female sexual dysfunction; T-62, an investigational drug for the treatment of neuropathic pain; MRE0094, an investigational drug for the topical treatment of chronic diabetic foot ulcers; pre- clinical programs; and product life-cycle development projects;

the development and approval of a diazepam-filled auto-injector, new inhaler for Intal® and Tilade® using the alternative propellant HFA, and an Altace®/diuretic combination product;

our successful execution of our growth strategies;

anticipated developments and expansions of our business;

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

anticipated increases in sales of acquired products or royalty revenues;

the success of our Co-Promotion Agreement with Wyeth;

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

the development of product line extensions;

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

the products which we expect to offer;

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

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

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

Edgar Filing: KING PHARMACEUTICALS INC - Form 10-Q

Item 3. Quantitative and Qualitative Disclosure about Market Risk

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

As of March 31, 2005, 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 would be impacted by our stock price.

Item 4. Controls and Procedures

Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems have inherent limitations. Therefore, internal control over financial reporting, no matter how well-designed, may not prevent or detect misstatements. Also, controls may become inadequate in future periods because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

As required by the Sarbanes-Oxley Act of 2002 and the rules issued thereunder, management previously conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004, based on the framework and criteria established in *Internal Control Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. That previous evaluation concluded that, as of December 31, 2004, we did not maintain effective controls over the period-end financial reporting process because we did not have a sufficient number of finance and accounting resources performing supervisory review and monitoring activities as a result of the loss of certain finance personnel, the challenges of hiring new personnel while a merger was pending and the resource requirements to address the previous restatement of our financial statements.

Although this deficiency resulted in certain errors during 2004 that were not detected by the period-end monitoring activities, it did not result in any audit adjustments or material misstatements of our financial statements as of year-end. However, the significance of a deficiency in internal control over financial reporting depends on the potential for a misstatement, not on whether a misstatement actually occurred. A material weakness is defined as a significant deficiency or combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Considering the above, management concluded that as of December 31, 2004 the finance and accounting resource constraints constituted a material weakness in supervisory review and monitoring activities in connection with the period-end financial reporting process. Because of this material weakness, management concluded that our internal control over financial reporting was not effective as of December 31, 2004.

Remediation of Material Weakness

We are in the process of increasing the number of finance and accounting resources performing supervisory review and monitoring activities during the period-end financial reporting process by actively recruiting additional managerial level finance and accounting resources. This material weakness did not result in any adjustments or material misstatements of our financial statements as of March 31, 2005, although we are still in the process of its remediation.

Changes in Internal Control Over Financial Reporting

Except as discussed above, there have been no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2005, that have materially affected, or are reasonably likely to affect, our internal control over financial reporting.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our

management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure.

Management, with the participation of the Chief Executive Officer and Chief Financial Officer, carried out an evaluation, as required by Rule 13a-15(b) under the Exchange Act of the effectiveness of the design and operation of the disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of March 31, 2005.

In making this evaluation, management considered the material weakness discussed above, together with the remedial steps we have taken.

Based on this evaluation by management, the Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2005, due to the material weakness discussed above, our disclosure controls and procedures were not effective at the reasonable assurance level. It should be noted that disclosure controls and procedures cannot provide absolute assurance of achieving the objectives of disclosure controls and procedures.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated by reference to Note 10 to the condensed consolidated financial statements included elsewhere in this report.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

| 31.1 | Certification of Brian A. Markison, President and Chief Executive Officer of King |
|------|--|
| | Pharmaceuticals, Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, |
| | Inc. Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1 | Certification of Brian A. Markison, President and Chief Executive Officer of King |
| | Pharmaceuticals, Inc., Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of James R. Lattanzi, Chief Financial Officer of King Pharmaceuticals, |
| | Inc. Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| | Inc. Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

(b) Reports on Form 8-K

We filed the following Current Reports on Form 8-K during the quarter ended March 31, 2005:

(1) On February 22, 2005, we furnished under Item 2.02 a press release regarding the completion of a previously announced review of the reserve for product returns.

(2) On March 1, 2005, we furnished under Item 1.02 a press release announcing the mutual agreement to terminate the Agreement and Plan of Merger by and among Mylan Laboratories, Inc., Summit Merger Corporation and King, and the related Termination Agreement.

(3) On March 17, 2005 we furnished under Item 2.02 a press release announcing our financial results for the fourth quarter and year ended December 31, 2004.

(4) On March 21, 2005 we filed under Item 1.01 a material definitive agreement, the King Pharmaceuticals, Inc. Severance Pay Plan: Tier I as effective March 15, 2005.

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. By: /s/ Brian A. Markison

Brian A. Markison President and Chief Executive Officer

Date: May 10, 2005

By: /s/ James R. Lattanzi

James R. Lattanzi Chief Financial Officer

Date: May 10, 2005