## KING PHARMACEUTICALS INC

Form 10-Q August 14, 2001

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

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FORM 10-Q

(MARK ONE)

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001

OR

[ ] 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

 $\mbox{KING PHARMACEUTICALS, INC.} \label{eq:condition} \mbox{(Exact name of registrant as specified in its charter)}$ 

TENNESSEE

(State or other jurisdiction of incorporation or organization)
501 FIFTH STREET, BRISTOL, TN
(Address of principal executive offices)

54-1684963
(I.R.S. Employer
Identification No.)
37620
(Zip Code)

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

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

Number of shares outstanding of Registrant's common stock as of August 14, 2001: 229,274,683

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PART I -- FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

## KING PHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

	JUNE 30, 2001	DECEMBER 31, 2000
	(UNAUDITED)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 254,129	\$ 76 <b>,</b> 395
accounts of \$5,636 and \$5,000	106,044	120,702
Inventories	86,916	65,089
Deferred income taxes	16,862	26,733
Prepaid expenses and other current assets	5 <b>,</b> 836	28 <b>,</b> 324
Total current assets	469,787	317,243
Property, plant and equipment, net	135,722	128,521
Intangible assets, net	771,347	790,324
Other assets	45,918	46,307
Other assets		
Total assets	\$1,422,774	\$1,282,395
	=======	========
LIABILITIES AND SHAREHOLDERS' EQUIT		0 05 010
Accounts payable		\$ 25,010
Accrued expenses	101,705	78 <b>,</b> 545
Income taxes payable	4,486	
Current portion of long-term debt	1,519	1,527
Total current liabilities	128,381	105,082
Long-term debt:		
Senior Subordinated Notes	96,382	96,382
Other	2,362	2,623
Deferred income taxes	17,074	16,989
Other liabilities	69,357	73,586
Other Habilities		
Total liabilities	313 <b>,</b> 556	294,662
Commitments and contingencies (notes 5 and 6)		
Shareholders' equity	1,109,218	987,733
Total liabilities and shareholders' equity	\$1,422,774 ======	\$1,282,395 =======

See accompanying notes.

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KING PHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF INCOME (UNAUDITED) (IN THOUSANDS, EXCEPT PER SHARE DATA)

		30,	SIX MONTHS E JUNE 30,		
	2001	2000	2001	2 	
Revenues:	4102 506	4122 212	<b>6262 406</b>	40.5	
Net sales Royalty revenue		\$133,313 10,129		\$25 2	
Total revenues		143,442	387,826	27	
Operating costs and expenses:					
Cost of revenues, including royalty expense of \$3,270,					
\$2,092, \$6,117 and \$4,517	44,344	37,586	81,760	6	
Selling, general and administrative	30,124	30,803	62,390	6	
Co-promotion fees	20,385		37,849		
Co-promotion marketing expense	4,930		10,459		
Depreciation and amortization	11,421	9,501	22,796	1	
Research and development		6,016	10,515		
Research and development - Special license rights	3,000		3,000		
Merger, restructuring, and other nonrecurring charges		1,505		2	
Total operating costs and expenses		85,411	228,769	18	
Operating income		58,031	159,057	9	
Other income (expense):					
Interest income	3 070	2,983	5 579		
Interest expense			(5,591)	(2	
Other, net	4,515	12	2,944		
Total other income (expense)	4,861	(7,129)	2,932	(1	
Income before income taxes, extraordinary item and					
cumulative effect of change in accounting principle	90 666	50,902	161 989	7	
Income tax expense	(33-818)	(19.782)	(60-422)	(3	
Indome can expende					
Income before extraordinary item and cumulative effect of					
change in accounting principle	56,848	31,120	101,567	4	
Extraordinary item, net of taxes of \$2,847	,	(4,685)		(	
Income before cumulative effect of change in accounting					
principle	56,848	26,435	101,567	3	
Cumulative effect of change in accounting principle, net of			(5.45)		
taxes of \$325			(545)		
Net income	\$ 56,848	\$ 26,435	\$101 <b>,</b> 022	\$ 3	
Income per common share:	======	======	======	===	
Basic:					
Income before extraordinary item and cumulative effect	ć 0.0F	0 0 1 4	<b>6 0 4 6</b>	<u>^</u>	
of change in accounting principle	\$ 0.25	\$ 0.14		\$	
Extraordinary item  Cumulative effect of change in accounting principle		(0.02)			

Net income	\$	0.25	\$	0.12	\$	0.44	\$
	==:		==		==		===
Diluted:							
Income before extraordinary item and cumulative effect							
of change in accounting principle	\$	0.25	\$	0.14	\$	0.44	\$
Extraordinary item				(0.02)			
Cumulative effect of change in accounting principle							
Net income	\$	0.25	\$	0.12	\$	0.44	\$
	===		==		==		===

See accompanying notes.

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## KING PHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY AND OTHER COMPREHENSIVE INCOME (UNAUDITED) (IN THOUSANDS, EXCEPT SHARE DATA)

	SHARES	AMOUNT	RETAINED EARNINGS	TOTAL
Balance at December 31, 2000	170,841,178	\$658,948	\$328,785	\$ 987,73
4 for 3 stock split (Note 10)	56,941,365			_
Net income and total comprehensive income			101,022	101,02
Exercise of stock options  Effect of acceleration of vesting options from	1,412,500	18,281		18,28
restructuring		2,182		2,18
Balance at June 30, 2001	229,195,043	\$679 <b>,</b> 411	\$429,807	\$1,109,21

See accompanying notes.

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## KING PHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) (IN THOUSANDS)

					SIX MONTHS ENDED JUNE 30,			DED
					2001		 _2 	000
Cash	flows	from	operating	activities	\$174,19	93 \$		69 <b>,</b> 255

Cash flows from investing activities: Purchase of investment securities Proceeds from maturity and sale of investment		(50,680)
securities		112,152
Loans receivable	(5,000)	
Purchases of property, plant and equipment	(14,158)	(9,062)
Purchase of intangible assets		(4,000)
Proceeds from sale of product rights	3,332	
Proceeds from sale of assets	1,434	411
Net cash (used in) provided by investing		
activities	(14,392)	•
Cash flows from financing activities:		
Proceeds from revolving credit facility		14,000
Payments on revolving credit facility		(59 <b>,</b> 000)
Proceeds from issuance of common shares and exercise of		
stock options, net	18,281	260,574
Payments of cash dividends-Jones		(2,619)
Payments on other long-term debt and capital lease		
obligations	(269)	(228,502)
Other	(79)	
Net cash provided by financing activities	17,933	(15,547)
Increase in cash and cash equivalents	177,734	102,529
Cash and cash equivalents, beginning of period	76,395	131,723
Cash and cash equivalents, end of period	\$254 <b>,</b> 129	\$ 234,252
		=======

See accompanying notes.

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## KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2001 AND 2000
(IN THOUSANDS)

#### 1. GENERAL

The accompanying unaudited interim condensed consolidated financial statements of King Pharmaceuticals, Inc. (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 six months ended June 30, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001. These interim statements should be read in conjunction with the financial statements and notes thereto included in the Company's latest Annual Report on Form 10-K. The year-end condensed balance sheet was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles.

These consolidated financial statements include the accounts of King and its wholly owned subsidiaries, Monarch Pharmaceuticals, Inc., Parkedale

Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (formerly Medco Research, Inc.), Jones Pharma Incorporated, and King Pharmaceuticals of Nevada, Inc. All intercompany transactions and balances have been eliminated in consolidation.

#### 2. EARNINGS PER SHARE

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

	THREE MONTHS ENDED JUNE 30,		-	MONTHS ENDED JUNE 30,	
	2001	2000	2001	2000	
Basic income per common share: Weighted average common shares	228,718	214,120	228,387	211,571	
Diluted income per common share:	======	======	======	======	
Weighted average common shares.  Effect of stock options	228,718 2,370	214,120 4,643	228,387 2,489	211,571 4,738	
Weighted average common shares plus assumed					
conversions	231 <b>,</b> 088 ======	218,763 ======	230,876 =====	216,309 ======	

#### INVENTORIES

Inventory consists of the following:

	JUNE 30, 2001	DECEMBER 31, 2000
Finished goods (including \$9,236 and \$6,821 of sample		
inventory, respectively)	\$60 <b>,</b> 477	\$49 <b>,</b> 825
Work-in-process	6 <b>,</b> 970	6,662
Raw materials	19,469	8,602
	\$86 <b>,</b> 916	\$65 <b>,</b> 089
		======

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## KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## 4. INTANGIBLE ASSETS

Intangible assets consist of the following:

JUNE 30, DECEMBER 31,

	2001	2000
Trademarks and product rights	\$761 <b>,</b> 690	\$762 <b>,</b> 669
Patents	80,000	80,000
Goodwill	16,251	16,251
Other intangibles	8,648	8,648
	866 <b>,</b> 589	867 <b>,</b> 568
Less accumulated amortization	(95,242)	(77,244)
	\$771 <b>,</b> 347	\$790 <b>,</b> 324
	=======	=======

The intangible assets above relate to the following products:

	JUNE 30, 2001	DECEMBER 31, 2000
Altace(R), Silvadene(R)	\$361 <b>,</b> 450	\$361 <b>,</b> 450
Bicillin(R), Wycillin(R), and Nordette(R)	203,000	203,000
Lorabid(R)	91 <b>,</b> 799	91 <b>,</b> 799
Sterile Products	48,871	48,871
Tapazole (R)	26,065	26,065
Cortisporin(R)	23,694	23,694
Cytomel (R)	21,406	21,406
Septra(R), Proloprim(R), Mantadil(R), Kemadrin(R)	15,425	15,425
Brevital(R)	14,072	14,072
AVC (TM)		1,500
Thrombin-JMI(R)	7,684	7,684
Other product rights and intangible assets	53,123	52,602
	866 <b>,</b> 589	867 <b>,</b> 568
Less accumulated amortization	(95,242)	(77,244)
	\$771 <b>,</b> 347	\$790 <b>,</b> 324
		=======

## 5. MERGERS, RESTRUCTURING AND NONRECURRING CHARGES

#### A. Merger with Medco

On February 25, 2000, the Company completed a merger with Medco Research, Inc. ("Medco"). The Medco merger was accounted for as a pooling of interests. In connection with this transaction the Company charged to expense \$20,789 of merger related costs in the first quarter of 2000. The types of costs incurred and the actual cash payments made in 2001 as well as the remaining accrued balances at June 30, 2001 are summarized below:

	JANUARY 1,	
	2001	
ACCRUED	THROUGH	ACCRUED
BALANCE AT	JUNE 30,	BALANCE AT
DECEMBER 31,	2001	JUNE 30,
2000	PAYMENTS	2001

Transaction costs	•	\$ 116	\$ 797 323
Total	 \$1,236	 \$116	 \$1,120
	======	====	======

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#### KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

### B. Merger with Jones

On August 31, 2000, the Company completed a merger with Jones Pharma Incorporated ("Jones"). The Jones merger was accounted for as a pooling of interests. In connection with the merger with Jones, the Company incurred total merger and restructuring related costs of \$35,317. The types of costs incurred and the actual cash payments made in 2001 as well as the remaining accrued balances at June 30, 2001 are summarized below:

		ACTIVITY JANUARY 1,	
	ACCRUED	2001	ACCRUED
	BALANCE AT	THROUGH	BALANCE AT
	DECEMBER 31,	JUNE 30,	JUNE 30,
	2000	2001	2001
Transaction costs	\$ 620	\$ 468	\$ 152
of vesting of options	3,707	2,800	907
Total	\$4 <b>,</b> 327	\$3 <b>,</b> 268	\$1 <b>,</b> 059
	=====	=====	=====

All activity was paid in cash except for a \$1.3 million reclassification of acceleration of vesting options to shareholders' equity.

The following information presents certain unaudited financial data of the separate companies during the three and six months of 2000:

	THREE MONTHS ENDED JUNE 30, 2000	SIX MONTHS ENDED JUNE 30, 2000
Net Revenues:  Medco (through date of acquisition)	\$ 51,632	\$ 9,169 97,366
Total	\$51,632 ======	\$106,535 ======

Net Income:

Total	\$20,137	\$ 46,552
Jones	20,137	39,308
Medco (through date of acquisition)	\$	\$ 7,244

#### C. Discontinuance of Fluogen(R) product

On September 27, 2000, the Company received written notification from the United States Food and Drug Administration ("FDA") that it must cease manufacturing and distributing Fluogen(R), an influenza vaccine, until the Company demonstrated compliance with related FDA regulations. In addition, the notification recommended that the Company properly dispose of Fluogen(R) inventory on hand. As a result of this notification, the Company decided to permanently discontinue Fluogen(R) production and distribution. This restructuring plan resulted in the elimination of approximately 160 employees of which approximately 110 were hourly and 50 were salaried. As a result of these events, the Company recorded extraordinary losses on disposed and impaired assets of \$43.7 million, before tax benefit of \$16.4 million, and a nonrecurring charge of

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#### KING PHARMACEUTICALS, INC.

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#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

\$8.6 million for the year ended December 31, 2000. A summary of the types of costs incurred in 2001 and the remaining accrued balances at June 30, 2001 are summarized below:

	ACCRUED BALANCE AT DECEMBER 31, 2000	PAYMENTS	OTHER(1)	ACCRUED BALANCE AT JUNE 30, 2001
Nonrecurring charges Employee costs, including severance and				
acceleration of vesting of options	\$5 <b>,</b> 270	\$4,412	\$858	\$
Contractual commitments and cleanup activities	1,296	249		1,047
Total	\$6 <b>,</b> 566	\$4,661	\$858	\$1,047 =====

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In September 2000 management decided to discontinue the research and development efforts relating to Pallacor(TM) due to its inability to out-license rights to the product and its assessment of the significance of projected research and development costs relative to the likelihood of the project's

<sup>(1)</sup> Includes reclassification of acceleration of vesting options to shareholders' equity.

D. Discontinuance of Pallacor(TM) Research and Development Efforts

success resulting in a nonrecurring research and development charge of \$6.1 million. At December 31, 2000 and June 30, 2001 the Company has \$4.7 million and \$1.6 million, respectively, accrued for all estimated remaining contractual commitments associated with Pallacor(TM).

#### 6. 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 more than 32 lawsuits which claim damages for personal injury arising from the Company's production of the anorexigenic drug, phentermine, under contract for GlaxoSmithKline. The Company expects to be named in additional lawsuits related to the Company's production of the anorexigenic drug under contract for GlaxoSmithKline.

While the Company cannot predict the outcome of these suits, the Company believes that the claims against it are without merit and intends to vigorously pursue all defenses available to it. The Company is being indemnified in all of these suits by GlaxoSmithKline for which it 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 its 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 lawsuit and be responsible for damages, if any, which are awarded against it or for amounts in excess of the Company's product liability coverage. A reasonable estimate of possible losses related to these suits cannot be made.

In addition, Jones, a wholly-owned subsidiary of the Company is a defendant in more than 1,800 multi-defendant lawsuits involving the manufacture and sale of dexfenfluramine, fenfluramine and phentermine. These suits have been filed in various jurisdictions throughout the United States, and in each of these suits,

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#### KING PHARMACEUTICALS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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

Jones denies any liability incident to the distribution of Obenix or its generic phentermine product and intends to pursue all defenses available to it.

Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. The manufacturers of fenfluramine and dexfenfluramine have settled many of these cases. In the event that Jones' insurance coverage is inadequate to satisfy any resulting liability, Jones will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

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

#### State of Wisconsin Investment Board

On November 30, 1999, the Company entered into an agreement of merger with Medco Research, Inc. ("Medco") pursuant to which the Company acquired Medco in an all stock, tax-free pooling of interests transaction (Note 5), which was subject to approval by the Medco shareholders. On January 5, 2000, Medco issued to its stockholders a proxy statement with respect to the proposed transaction and noticed a meeting to approve the transaction for February 10, 2000.

On January 11, 2000, the State of Wisconsin Investment Board, ("SWIB"), a Medco shareholder which held approximately 11.6% of the outstanding stock of Medco, filed suit on behalf of a proposed class of Medco shareholders in the Court of Chancery for the State of Delaware, New Castle County, against Medco and members of Medco's board of directors to enjoin the shareholder vote on the merger and the consummation of the merger. State of Wisconsin Investment Board v. Bartlett, et al., C.A. No. 17727. SWIB alleged, among other things, that the proxy materials filed by Medco failed to disclose all material information and included misleading statements regarding the transaction, its negotiation, and its approval by the Medco board of directors; that the Medco directors were not adequately informed and did not adequately inform themselves of all reasonably available information before recommending the transaction to Medco shareholders; and that the Medco directors were disloyal and committed waste in allegedly enabling one of the Medco directors to negotiate the transaction purportedly for his own benefit and in agreeing to terms that precluded what the complaint alleged were more beneficial alternative transactions. SWIB also moved for a preliminary injunction to enjoin the shareholder vote and the merger based on the claims asserted in its complaint. Medco and the other defendants denied all allegations and continue to deny them.

After Medco distributed a supplemental proxy statement on January 31, 2000 and the court postponed the February 10, 2000 vote on the merger agreement for 15 days to allow shareholders sufficient time to consider the supplemental disclosures, the court rejected SWIB's claims in a February 24, 2000 Memorandum Opinion and denied preliminary injunctive relief because SWIB had not shown a reasonable likelihood of success following trial on the merits. The court made a number of preliminary findings, including that the

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### KING PHARMACEUTICALS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

Medco board of directors properly delegated to one of its directors the responsibility to negotiate the merger; that the payment of the negotiating fee was a proper exercise of business judgment and did not constitute waste; that

the other merger provisions were also valid; that the Medco directors were adequately informed of all material information reasonably available to them prior to approving the merger agreement; that the Medco directors acted independently and in good faith to benefit the economic interests of the Medco shareholders; that the alleged omissions in the proxy statements were not material; and that the Medco board of directors fully met its duty of complete disclosure with respect to the transaction.

SWIB has filed an Application for a Scheduling Order stating its intention to dismiss the case, before a class has been certified, without prejudice. In the meantime, the action is still pending. While SWIB has indicated that it does not intend to prosecute the merits of the case further, another shareholder could intervene and continue the action. Even though SWIB lost its motion for preliminary injunction, and is going to dismiss the case, SWIB has claimed that its attorneys are entitled to an award of attorney's fees and costs. SWIB has petitioned the court for approximately \$7.26 million in attorney's fees and approximately \$270,000 in costs.

A hearing on SWIB's petition to dismiss and for attorney's fees and costs was held on June 26, 2000 in the Court of Chancery for the State of Delaware. No ruling has yet been issued.

The Company believes that SWIB's case, including SWIB's claim for significant attorney's fees which includes fees based on a formula related to an alleged benefit conferred on Medco shareholders, is meritless, and the Company is vigorously contesting it. The Company believes SWIB's actions did not confer a benefit on the Medco shareholders. The Company also believes it is unlikely that another shareholder will intervene to continue the action, but if that results then the Company will vigorously contest it.

Other

The Parkedale Facility was one of six facilities owned by Pfizer subject to a Consent Decree of Permanent Injunction issued August 1993 in United States of America v. Warner-Lambert Company and Melvin R. Goodes and Lodewijk J.R. DeVink (U.S. Dist. Ct., Dist. of N.J.) (the "Consent Decree"). The Parkedale Facility is currently manufacturing pharmaceutical products subject to the Consent Decree which prohibits the manufacture and delivery of specified drug products unless, among other things, the products conform to current good manufacturing practices and are produced in accordance with an approved abbreviated new drug application or new drug application. The Company intends, when appropriate, to petition for relief from the Consent Decree.

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

Summary

Management believes that the outcome of all pending legal proceedings in the aggregate will not have a material adverse affect on the Company's consolidated financial position, results of operations, or cash flow.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

7. LONG-TERM DEBT

Long-term debt consists of the following:

	JUNE 30, 2001	DECEMBER 31, 2000
Senior subordinated notes  Notes payable to former owners, due in equal annual	\$ 96,382	\$ 96 <b>,</b> 382
installments of principal and interest (at a rate of 6%) of \$1,226 through December 2003	3,276	3,276
to 12.7% and maturing at various times through 2002	604	869
Other notes payable	1	5
Less current portion	100,263 1,519	100,532 1,527
	\$ 98,744	\$ 99 <b>,</b> 005

As of June 30, 2001 the Company has \$100.0 million of availability under the Senior Credit Facility.

#### 8. SEGMENT REPORTING

The Company's business is classified into three reportable segments; Branded Pharmaceuticals, Contract Manufacturing, and Licensed Products. Branded Pharmaceuticals include a variety of branded prescription products over four therapeutic areas, including cardiovascular, anti-infective, critical care and women's health/endocrinology. Contract Manufacturing represents contract manufacturing services provided for pharmaceutical and biotechnology companies. Licensed products represent products for which the Company has transferred the manufacturing and marketing rights to corporate partners in exchange for royalty payments on product sales. The classification "all other" primarily includes generic pharmaceutical products and development services.

The Company primarily evaluates its segments based on gross profit. Reportable segments were separately identified based on revenues, gross profit and total assets.

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#### KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2001	2000	2001	2000
Total Revenues: Branded pharmaceuticals Licensed products Contract manufacturing	\$187,136 13,003 16,170	\$115,608 10,129 17,975	\$348,617 24,420 31,198	\$229,438 22,871 31,667

All other	978 (10,778)	4,916 (5,186)	1,502 (17,911)	5,255 (10,594)
Consolidated total revenues	\$206,509	\$143,442	\$387,826	\$278,637
Gross profit:				
Branded pharmaceuticals	\$155,955	\$ 94,008	\$290,323	\$186,247
Licensed products	10,341	8,517	19,257	19,364
Contract manufacturing	(4,247)	834	(3,668)	2,492
All other	116	2,497	154	2,573
Consolidated gross profit	\$162 <b>,</b> 165	\$105 <b>,</b> 856	\$306 <b>,</b> 066	\$210 <b>,</b> 676
	=======	=======	=======	=======

	AS OF JUNE 30, 2001	AS OF DECEMBER 31, 2000
Total assets:		
Branded pharmaceuticals	\$1 312 463	\$1,189,997
Licensed products		10,723
Contract manufacturing	97,892	82,314
All other	406	720
Eliminations	(2,328)	(1,359)
Consolidated total assets	\$1,422,774	\$1,282,395

#### 9. CO-PROMOTION AGREEMENT WITH AHP

On June 22, 2000, the Company entered into a co-promotion agreement with American Home Products Corporation ("AHP") to promote Altace(R) in the United States and Puerto Rico through October 29, 2008. Under the agreement, AHP and the Company have agreed to share various marketing expenses related to the promotion of Altace(R). The Company's share of these expenses are included in the caption "Co-promotion marketing expense" in the accompanying financial statements. In addition, AHP paid an up front fee of \$75.0 million to King which was classified as other liabilities and is being amortized over the life of the agreement. The amortization is included as a reduction of Co-promotion marketing expense in the accompanying financial statements.

In connection with the co-promotion agreement with AHP, the Company has agreed to pay AHP a promotional fee as follows:

- For 2001 and 2002, 20% of net sales up to \$165 million, 50% of net sales from \$165 million to \$465 million and 52.5% of net sales in excess of \$465 million.
- For years subsequent to 2002 through 2008 the fee is based on the same formula, except the fee for the first \$165 million will be 15% of net sales.

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KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

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

#### 10. STOCK SPLIT

On June 20, 2001, the Company's Board of Directors declared a four for three stock split for shareholders of record as of July 3, 2001, to be distributed July 19, 2001. The stock split has been reflected in all share data contained in these consolidated financial statements.

#### 11. OTHER SECOND QUARTER TRANSACTIONS

In the second quarter of 2001, the Company paid \$3.0 million to Novavax, Inc. for the license rights to promote, market and distribute Estrasorb(TM) and Androsorb(TM) in certain countries. Such amount was expensed rather than capitalized because these products have not yet received FDA approval.

In the second quarter, the Company recognized a gain of approximately \$4.0 million on its primary derivative, a \$20.0 million convertible senior note from Novavax, Inc., which has been recognized as other income in the accompanying financial statements.

#### 12. NEW ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards ("SFAS") No. 141, "Business Combinations." SFAS No. 141 requires all business combinations to be accounted for under the purchase method of accounting. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001, as well as all business combinations accounted for under the purchase method of accounting for which the date of acquisition is July 1, 2001, or later.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The Company is in the process of reviewing the impact of this pronouncement on previous acquisitions.

#### 13. GUARANTOR FINANCIAL STATEMENTS

The Company's wholly-owned subsidiaries Monarch Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc., Parkedale Pharmaceuticals, Inc., Jones Pharma Incorporated and King Pharmaceuticals of Nevada, Inc. (the "Guarantor Subsidiaries") have guaranteed the Company's performance under the \$150,000, 10 3/4% Senior Subordinated Notes due 2009 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 notes.

KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## GUARANTOR SUBSIDIARIES

#### CONDENSED CONSOLIDATING BALANCE SHEETS

	JUNE 30, 2001				DECEMBE	R 31,
	KING	GUARANTOR SUBSIDIARIES	ELIMINATING ENTRIES	KING CONSOLIDATED	KING	GUA SUBS
		(UNAU	DITED)			
ASSETS						
Current assets:						
Cash and cash						
equivalents Accounts	\$ 254,810	\$ (681)	\$	\$ 254,129	\$ 82,316	\$
receivable,						
net	9,787	98,585	(2,328)	106,044	7,027	1
Inventories	15,935	70,981		86,916	3,856	
Deferred income taxes	14,234	2,628		16,862	23,939	
Prepaid expenses	14,234	2,020		10,002	23,939	
and other current						
assets	3,219	2,617		5,836	39,637	(
Total						
current						
assets	297,985	174,130	(2,328)	·	156 <b>,</b> 775	1
Duana anti-						
Property, plant, and equipment, net	36.683	99,039		135,722	28,831	
Intangible assets,	,	,			_==, -==	
net	407,879	363,468		771,347	418,895	3
Investment in subsidiaries	1 047 706		(1,047,796)		911,602	
Other assets		18,666	(1,047,796)	45,918	24,940	
Total						
assets	\$1,817,595 ======	•	\$(1,050,124)	\$1,422,774 =======		\$6 ==
LIABILITIES AND SHARE	HOLDERS' EQUIT	Ϋ́				
Current liabilities:			* (0.000)			
Accounts payable Accrued expenses			\$ (2,328)		\$ 2,080 13,048	\$
Income taxes	0,093	93,012		101,703	13,040	
payable	(44,286)	48,772		4,486		
Current portion of						
long-term debt	1,491	28		1,519	1,498	
Total	_	_	_	_	_	
current						
liabilities		164,923	(2,328)		16,626	
Long-term debt	98,744			98 <b>,</b> 744	98 <b>,</b> 992	
Deferred income	50,711			JO, 111	JO <b>,</b> JJZ	
taxes	14,592	2,482		17,074	14,592	

					71 714
Other liabilities Intercompany (receivable)	68,600	757		69 <b>,</b> 357	71,714
payable	560 <b>,</b> 655	(560 <b>,</b> 655)			351 <b>,</b> 386
Total liabilities	708,377	(392,493)	(2,328)	313,556	553 <b>,</b> 310
Shareholders' equity			(1,047,796)		987,733
Total liabilities and					
shareholders' equity			\$(1,050,124) =======		\$1,541,043 ======
	DECEMBER	31, 2000			
	ELIMINATING	KING CONSOLIDATED			
ASSETS Current assets: Cash and cash equivalents	\$	\$ 76 <b>,</b> 395			
Accounts receivable,					
net Inventories Deferred income	(1,359)	120,702 65,089			
taxes Prepaid expenses and other current		26,733			
assets		28,324			
Total current assets	(1,359)	317,243			
Property, plant, and equipment, net Intangible assets,		128,521			
net		790,324			
subsidiaries Other assets	(911,602) 	46,307			
Total assets	\$(912,961) ======	\$1,282,395 =======			
LIABILITIES AND SHARE Current liabilities: Accounts payable Accrued expenses Income taxes		\$ 25,010 78,545			
payable Current portion of					

(3

long-term debt		1,527
Total current liabilities	(1,359)	105,082
ilabilities	(1,339)	105,062
Long-term debt Deferred income		99,005
taxes		16,989
Other liabilities Intercompany (receivable)		73,586
payable		
Total		
liabilities	(1,359)	294,662
Shareholders'		
equity	(911,602)	987 <b>,</b> 733
Total liabilities and shareholders'		
equity	\$(912,961) ======	\$1,282,395 ======

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#### KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

#### GUARANTOR SUBSIDIARIES

#### CONSOLIDATING STATEMENTS OF INCOME

## THREE MONTHS ENDED JUNE 30, 2001 GUARANTOR ELIMINATING KING KING SUBSIDIARIES ENTRIES CONSOLIDATED (UNAUDITED) Revenues: Net sales...... \$ 6,451 \$192,183 \$ (5,128) \$193,506 Royalty revenue...... -- 13,003 -- 13,003 \_\_\_\_\_ \_\_\_\_\_ revenues..... 6,451 205,186 (5,128) ----Operating costs and expenses: Costs of revenues..... 6,748 42,724 (5,128) 44,344 Selling, general and administrative (including co-promotion Depreciation and

amortization Research and	5,362	6,059		11,421	
development	2,500	4,000		6,500	
development-Special license rights Merger, restructuring and other	3,000			3,000	
nonrecurring charges					
Total operating costs and					
expenses	19 <b>,</b> 253	106 <b>,</b> 579	(5,128)	120 <b>,</b> 704	
Operating income	(12,802)	98 <b>,</b> 607		85 <b>,</b> 805	
Other income(expense):					
Interest income	2,748	322		3,070	
Interest expense	(2,893)	169		(2,724)	
Other, net	4,437	78		4,515	
Equity in earnings of	1, 13,	, 0		1,010	
subsidiaries Intercompany interest	59 <b>,</b> 914		(59,914)		
(expense)	3,620	(3,620)			
Total other income					
(expense)	67 - 826	(3,051)	(59,914)	4,861	
(expense)		(3,031)	(33,311)		
<pre>Income before income   taxes and extraordinary   item</pre>	55,024	95 <b>,</b> 556	(59,914)	90 <b>,</b> 666	
<pre>Income tax (expense)</pre>					
benefit	1,824	(35,642)		(33,818)	
<pre>Income before   extraordinary item Extraordinary item</pre>	56,848	59,914	(59 <b>,</b> 914)	56,848	
Encraoramary reem					
Net income	\$ 56,848 ======	\$ 59,914 ======	\$(59,914) ======	\$ 56,848 ======	
		THREE MONTHS EN	NDED JUNE 30, 2	2000	
	KING		ELIMINATING ENTRIES		
	(UNAUDITED)				
Revenues:					
Net sales	\$ 8,319	\$126,593 10,129	\$ (1,599) 	\$133,313 10,129	
Total					
revenues	8,319 	136 <b>,</b> 722	(1,599)	143,442	
Operating costs and expenses:	·				
Costs of revenues Selling, general and	5 <b>,</b> 769	33,416	(1,599)	37,586	

administrative (including co-promotion				
expenses)  Depreciation and	3,909	26,894		30,803
amortization Research and	5,242	4,259		9,501
development  Research and  development-Special	273	5,743		6,016
license rights  Merger, restructuring and other				
nonrecurring charges		1,505		1,505
Total operating costs and				
expenses	15 <b>,</b> 193	71 <b>,</b> 817	(1,599)	85,411 
Operating income	(6,874)	64 <b>,</b> 905		58 <b>,</b> 031
Other income(expense):				
Interest income	391	2,592		2,983
Interest expense	(10,123)	(1)		(10,124)
Other, net Equity in earnings of	6	6		12
subsidiaries Intercompany interest	56,215		(56,215)	
(expense)	1,253 	(1,253)		
Total other income				
(expense)	47 <b>,</b> 742	1,344 	(56,215) 	(7 <b>,</b> 129)
<pre>Income before income   taxes and extraordinary</pre>				
<pre>item Income tax (expense)</pre>	40,868	66,249	(56,215)	50,902
benefit	(9,748) 	(10,034)		(19 <b>,</b> 782)
Income before				
extraordinary item	31,120	56,215	(56,215)	31,120
Extraordinary item	(4,685)			(4,685) 
Net income	\$ 26,435 ======	\$ 56,215 ======	\$ (56,215) ======	\$ 26,435 ======

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## KING PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

GUARANTOR SUBSIDIARIES

CONSOLIDATING STATEMENTS OF INCOME

SIX MONTHS ENDED JUNE 30, 2001

	KING	GUARANTOR SUBSIDIARIES	ELIMINATING ENTRIES	KING CONSOLIDATEI	
		(UNA	UDITED)		
Revenues: Net sales Royalty revenue	\$ 11,758 	\$360,950 24,420	\$ (9,302) 	\$363,406 24,420	
Total revenues	11,758	385,370	(9,302)	387,826	
Operating costs and expenses:					
Costs of revenues Selling, general and administrative (including co- promotion	11,398	79,664	(9,302)	81,760	
expenses)  Depreciation and	3,156	107,542		110,698	
amortization Research and	10,671	12,125		22 <b>,</b> 796	
development Research and development-	2,698	7,817		10,515	
Special license rights  Merger, restructuring and other	3,000			3,000	
nonrecurring charges					
Total operating costs and					
expenses	30 <b>,</b> 923	207,148	(9 <b>,</b> 302)	228 <b>,</b> 769	
Operating income	(19,165)	178 <b>,</b> 222		159 <b>,</b> 057	
Other income(expense):     Interest income     Interest expense     Other, net Equity in earnings	4,769 (5,922) 2,992	810 331 (48)	 	5,579 (5,591) 2,944	
of subsidiaries Intercompany	136,192		(136, 192)		
<pre>interest (expense)</pre>	6 <b>,</b> 532	(6,532)			
Total other income(expense)				2 <b>,</b> 932	
Income before income taxes and cumulative effect of change in					
accounting principle Income tax (expense)	125,398	172 <b>,</b> 783	(136, 192)	161,989	
benefit	(23,831)	(36,591)		(60,422)	
<pre>Income before   extraordinary item</pre>	101,567	136,192	(136, 192)	101,567	

Cumulative effect of change in accounting principle	(545)			(545)
Net income	\$101,022 ======	\$136 <b>,</b> 192 ======	\$(136,192) ======	\$101,022 ======
		SIX MONTHS EN	DED JUNE 30, 20	000
	KING	GUARANTOR SUBSIDIARIES		KING CONSOLIDATED
			UDITED)	
Revenues:				
Net sales	\$ 11,854 	\$246,885 22,871	\$ (2,973) 	\$255,766 22,871
Total				
revenues	11,854	269 <b>,</b> 756	(2,973)	278,637
Operating costs and expenses:				
Costs of revenues Selling, general and administrative (including co-	8,929	62,005	(2,973)	67,961
promotion	7 265	E ( 72 (		C4 001
expenses)  Depreciation and	7,265	56 <b>,</b> 736		64,001
	10,476	8,302		18,778
development	533	9,148		9,681
Research and development- Special license rights				
Merger, restructuring and other				
nonrecurring charges	6,225	16,069		22,294
Total operating costs and				
expenses	33,428	152 <b>,</b> 260	(2,973)	182 <b>,</b> 715
Operating income	(21,574)	117,496		95 <b>,</b> 922
Other income(expense):     Interest income     Interest expense     Other, net Equity in earnings	597 (24,154) (86)	6,407 (2) (28)	  	7,004 (24,156) (114)
of subsidiaries Intercompany	85,407		(85,407)	
interest (expense)		(2,355)		
Total other income(expense)	64,119	4,022	(85,407)	(17,266)

Income before income taxes and cumulative effect of change in				
accounting principle Income tax (expense)	42,545	121 <b>,</b> 518	(85,407)	78 <b>,</b> 656
benefit	(1,629)	(36,111)		(37,740)
<pre>Income before   extraordinary item Cumulative effect of   change in accounting</pre>	40,916	85,407	(85,407)	40,916
principle	(4,685)			(4,685)
Net income	\$ 36,231 ======	\$ 85,407 =====	\$ (85,407) ======	\$ 36,231 ======

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## KING PHARMACEUTICALS, INC.

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS -- (CONTINUED)

## GUARANTOR SUBSIDIARIES

## CONSOLIDATING STATEMENTS OF CASH FLOWS

	SIX MONTHS ENDED JUNE 30, 2001				
	KING	GUARANTOR SUBSIDIARIES	ELIMINATING ENTRIES	CONSOLIDATED	
		(UNA			
Net cash flows provided by operating activities	\$(48,615)	\$ 222,808	\$	\$174 <b>,</b> 193	
Cash flows from investing activities: Purchase of investment					
securities  Proceeds from maturity and sale of investment					
securities					
Loans receivable  Purchases of property, plant		(5,000)		(5,000)	
<pre>and equipment Intercompany transfer of   property, plant and</pre>	(8,650)	(5,508)		(14, 158)	
equipment  Purchases of intangible	(223)	223			
assets Proceeds from sale of					
products  Proceeds from sale of	3,332			3 <b>,</b> 332	
assets		1,434		1,434 	
Net cash used in investing activities		(8,851)	 	(14,392)	

Cash flows from financing activities:  Proceeds from revolving credit facility				
Proceeds from issuance of common shares and exercise of stock options, net	18,281			18,281
Payments on other long-term debt	(255)	(14)		(269)
Payments of cash dividends Other Intercompany	(79)	 (208,703)	 	(79) 
Incorompany				
Net cash provided by (used in) financing activities	226,650	(208,717)		17,933
Increase in cash and cash equivalents		5,240		177,734
Cash and cash equivalents, beginning of period	82,316	(5,921)		76 <b>,</b> 395
Cash and cash equivalents, end of period	\$254,810		\$ ====	\$254 <b>,</b> 129
		SIX MONTHS ENI	DED JUNE 30, 2	000
		 GUARANTOR		 KING
		GUANANIUN	PHIMINALING	NIING
	KING	SUBSIDIARIES	ENTRIES	CONSOLIDATED
	KING 			
Net cash flows provided by operating activities	\$(27,772)	JANU)		
operating activities  Cash flows from investing activities:		JANU)		
operating activities  Cash flows from investing activities:  Purchase of investment securities  Proceeds from maturity and	\$(27,772)	JANU)		
operating activities  Cash flows from investing activities:  Purchase of investment securities	\$(27,772)	97,027		\$ 69,255 
operating activities  Cash flows from investing activities:  Purchase of investment securities  Proceeds from maturity and sale of investment securities  Loans receivable	\$(27,772)	97,027 		\$ 69,255 
operating activities  Cash flows from investing activities:  Purchase of investment securities  Proceeds from maturity and sale of investment securities  Loans receivable  Purchases of property, plant and equipment  Intercompany transfer of	\$(27,772)	97,027  (50,680) 112,152		\$ 69,255 
cash flows from investing activities: Purchase of investment securities. Proceeds from maturity and sale of investment securities. Loans receivable. Purchases of property, plant and equipment. Intercompany transfer of property, plant and equipment.	\$(27,772) 	97,027  (50,680) 112,152		\$ 69,255  (50,680) 112,152 
cash flows from investing activities:  Purchase of investment securities.  Proceeds from maturity and sale of investment securities.  Loans receivable.  Purchases of property, plant and equipment.  Intercompany transfer of property, plant and equipment.  Purchases of intangible assets.	\$(27,772) 	97,027  (50,680) 112,152		\$ 69,255  (50,680) 112,152 
operating activities  Cash flows from investing activities: Purchase of investment securities  Proceeds from maturity and sale of investment securities  Loans receivable  Purchases of property, plant and equipment  Intercompany transfer of property, plant and equipment  Purchases of intangible assets  Proceeds from sale of products.	\$(27,772) 	97,027  (50,680) 112,152  (7,771)		\$ 69,255  (50,680) 112,152  (9,062)
cash flows from investing activities:  Purchase of investment securities.  Proceeds from maturity and sale of investment securities.  Loans receivable.  Purchases of property, plant and equipment.  Intercompany transfer of property, plant and equipment.  Purchases of intangible assets  Proceeds from sale of	\$(27,772) 	97,027  (50,680) 112,152  (7,771)		\$ 69,255  (50,680) 112,152  (9,062)
cash flows from investing activities:  Purchase of investment securities.  Proceeds from maturity and sale of investment securities.  Loans receivable.  Purchases of property, plant and equipment.  Intercompany transfer of property, plant and equipment.  Purchases of intangible assets.  Proceeds from sale of products.  Proceeds from sale of	\$(27,772)   (1,291)  	97,027  (50,680) 112,152  (7,771)  (4,000) 		\$ 69,255  (50,680) 112,152  (9,062)  (4,000)
Cash flows from investing activities: Purchase of investment securities. Proceeds from maturity and sale of investment securities. Loans receivable. Purchases of property, plant and equipment. Intercompany transfer of property, plant and equipment. Purchases of intangible assets. Proceeds from sale of products. Proceeds from sale of assets.	\$(27,772)   (1,291)  	97,027  (50,680) 112,152  (7,771)  (4,000) 		\$ 69,255  (50,680) 112,152  (9,062)  (4,000)

activities:				
Proceeds from revolving credit				
facility	14,000			 14,000
Payments on revolving credit				
facility	(59,000)			 (59,000)
Proceeds from issuance of				
common shares and exercise				
of stock options, net	257,841	2,733		 260,574
Payments on other long-term				
debt	(228,489)	(13)		 (228,502)
Payments of cash dividends		(2,619)		 (2,619)
Other				 
Intercompany	103,378	(103 <b>,</b> 378)		 
Net cash provided by (used in)				
financing activities	87 <b>,</b> 730	(103 <b>,</b> 277)		 (15 <b>,</b> 547)
_ , , , ,				 
Increase in cash and cash	50 OS5	40.464		100 500
equivalents	59,065	43,464		 102,529
Cash and cash equivalents,	11 600	100 040		101 700
beginning of period	11,683	120,040		 131,723
Cash and cash equivalents, end				
of period	\$ 70,748	\$163,504	Ś	 \$234,252
or porrou	======	=======	·	 =======

#### 14. SUBSEQUENT EVENTS

On August 8, 2001, the Company acquired three branded pharmaceutical products and a fully paid license to a fourth product from Bristol-Myers Squibb ("BMS") for \$285.0 million. The products acquired include BMS's rights in the United States to Corzide(R), Delestrogen(R), and Florinef(R). King acquired also a fully paid license to and trademark for Corgard(R) in the United States. The acquisition was financed with a combination of borrowings under its senior secured credit facility and cash on hand.

On July 3, 2001, the Company filed a \$1.5 billion universal shelf registration statement on Form S-3 with the Securities and Exchange Commission covering the issuance and sale, from time to time over an extended period, of debt and/or equity securities. The Company may sell any combination of such debt and/or equity securities in one or more offerings up to a total of \$1.3 billion and certain of the Company's executive officers may sell shares of common stock from time to time in an amount up to \$200 million. The Company will not receive any of the proceeds from the sale of shares of the selling shareholders. The shelf registration statement filed with the Securities and Exchange Commission is not yet effective.

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## PART I -- FINANCIAL INFORMATION

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The following discussion contains certain forward-looking statements that reflect management's current views of future events and operations. This discussion should be read in conjunction with the following: (a) "Risk Factors" set out below and other sections of our Annual Report on Form 10-K for the year ended December 31, 2000, 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, 2000; and (c) our unaudited consolidated financial statements and related notes thereto included in this report.

OVERVIEW

General

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

	FOR THE THREE MONTHS ENDED JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
	2001	2000	2001	2000
Branded pharmaceuticals	\$186,670 13,003	\$115,608 10,129	\$347 <b>,</b> 898 24 <b>,</b> 420	\$229 <b>,</b> 438 22 <b>,</b> 871
Contract manufacturing	5,858 978	12,789 4,916	14,006 1,502	21,073 5,255
Total	\$206 <b>,</b> 509	\$143,442	\$387 <b>,</b> 826	\$278,637

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2001 AND 2000

Revenues

Net revenues increased \$63.1 million, or 44.0%, to \$206.5 million in 2001 from \$143.4 million in 2000, due primarily to the acquisition and growth of branded pharmaceutical products.

Net sales from branded pharmaceutical products increased \$71.1 million, or 61.5%, to \$186.7 million in 2001 from \$115.6 million in 2000. This increase was due primarily to growth in net sales of Altace(R), Levoxyl(R), and Thrombin-JMI(R) and net sales attributable to Nordette(R) and Bicillin(R) which were acquired from American Home Products in June 2000. While we expect continued growth in net sales of our branded pharmaceuticals in the future, we refer you to the "Risk Factors" that appear below, particularly those related to Altace(R), Levoxyl(R), and Thrombin-JMI(R), that could cause results to differ.

Revenues from licensed products increased \$2.9 million, or 28.7%, to \$13.0 million in 2001 from \$10.1 million in 2000 primarily due to an increase in the net sales of Adenoscan(R) and Adenocard(R), on which we receive royalty revenues. The increase in revenues from licensed products was affected by a contractual reduction in the percentage royalty we receive on net sales of Adenoscan(R) that became effective during the third quarter of 2000.

Revenues from contract manufacturing and other decreased \$10.9 million, or 61.6%, to \$6.8 million in 2001 from \$17.7 million in 2000, primarily due to (1) the conclusion of two manufacturing and supply agreements during the fourth quarter of 2000; (2) reduced revenues derived under a third manufacturing and supply agreement during the second quarter of 2001 as compared to the second quarter of 2000; and (3) reduced sales of generic private label neomycin and polymyxin B sulfates and hydrocortisone suspension and solution. While contract manufacturing and generic pharmaceutical sales remain a part of our business, we do not consider contract manufacturing and generic pharmaceutical sales as

significant components of our growth strategy.

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Operating Costs and Expenses

Total operating costs and expenses increased \$35.3 million, or 41.3%, to \$120.7 million in 2001 from \$85.4 million in 2000. The increase was primarily due to an increase in cost of revenues of \$6.7 million in 2001 and \$25.3 million in co-promotion fees and marketing expense in 2001 related to the co-promotion agreement with American Home Products for the promotion of Altace(R) in the United States and Puerto Rico, offset by \$1.5 million of merger, restructuring and other nonrecurring charges related to merger charges recognized during the second quarter of 2000.

Cost of revenues increased \$6.7 million, or 17.8% to \$44.3 million in 2001 from \$37.6 million in 2000. The increase resulted from cost of revenues associated with the increase in net sales of branded pharmaceutical products described above. As a percentage of revenues, cost of revenues decreased to 21.5% in 2001 from 26.2% in 2000 due to the increase in sales of higher margin products.

Selling, general and administrative expenses remained relatively flat at \$30.1 million in 2001 as compared to \$30.8 million in 2000. As a percentage of revenues, selling, general, and administrative expenses decreased to 14.6% in 2001 from 21.5% in 2000 due to increased revenues, realization of cost synergies from the Medco and Jones mergers, and the classification of all Altace(R) related marketing expenses as co-promotion marketing expense rather than selling, general and administrative during the three months ended June 30, 2001.

During the three months ended June 30, 2001, the Company incurred \$20.4 million in co-promotion fees and \$4.9 million in co-promotion marketing expense pursuant to the June 2000 co-promotion agreement with American Home Products for the promotion of Altace(R) in the United States and Puerto Rico.

Depreciation and amortization expense increased \$1.9 million, or 20.0%, to \$11.4 million in 2001 from \$9.5 million in 2000. The increase was due primarily to additional amortization expense resulting from the acquisition of Nordette(R), Bicillin(R), and Wycillin(R) in July 2000.

Research and development expense increased to \$6.5 million in 2001 from \$6.0 million in 2000.

In June of 2001, we incurred \$3.0 million of "research and development -- special license rights" for fees we paid Novavax, Inc. as consideration for an agreement which (1) expands our exclusive license to promote, market, distribute and sell Estrasorb(TM) worldwide, following approval, except in the United States and Puerto Rico where the parties will co-market the product; and (2) grants us an additional exclusive worldwide license to promote, market and distribute Androsorb(TM), following approval, except in the United States and Puerto Rico where the parties will co-market the product.

Operating Income

Operating income increased \$27.8 million, or 47.9%, to \$85.8 million in 2001 from \$58.0 million in 2000. This increase was due primarily to the increase in branded pharmaceutical sales during the three months ended June 30, 2001 as compared to the three months ended June 30, 2000.

Other Income (Expense)

Interest income equaled \$3.1 million in 2001 compared to \$3.0 million in 2000.

Interest expense decreased \$7.4 million, or 73.3%, to \$2.7 million in 2001 from \$10.1 million in 2000. This decrease is due to the reduced average debt balance in 2001 resulting from our prepayment of debt obligations during 2000.

Other income increased \$4.5 million to \$4.5 million in 2001, from \$12 thousand in 2000, primarily due to an unrealized gain of approximately \$4.0 million on our primary derivative, a \$20 million convertible senior note from Novayax.

Income Tax Expense

The effective tax rate in 2001 of 37.3% and 2000 of 38.9% was higher than the federal statutory rate of 35% primarily due to state income taxes.

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Extraordinary Item

During the second quarter of 2000, we repaid outstanding debt under our senior credit facility prior to maturity. The early repayment caused us to recognize in the second quarter of 2000 an extraordinary loss of \$4.7 million, net of related tax benefits of \$2.8 million, from the write-off of related deferred financing costs.

Net Income

Due to the factors set forth above, net income increased \$30.4\$ million, or 115.2%, to \$56.8 million in 2001 from \$26.4 million in 2000.

SIX MONTHS ENDED JUNE 30, 2001 AND 2000

Revenues

Net revenues increased \$109.2 million, or 39.2%, to \$387.8 million in 2001 from \$278.6 million in 2000, due primarily to the acquisition and growth of branded pharmaceutical products.

Net sales from branded pharmaceutical products increased \$118.5 million, or 51.7%, to \$347.9 million in 2001 from \$229.4 million in 2000. This increase was due primarily to growth in net sales of Altace(R), Levoxyl(R), and Thrombin-JMI(R) and net sales attributable to Nordette(R) and Bicillin(R) which were acquired from American Home Products in June 2000. While we expect continued growth in net sales of our branded pharmaceuticals in the future, we refer you to the "Risk Factors" that appear below, particularly those related to Altace(R), Levoxyl(R), and Thrombin-JMI(R), that could cause results to differ.

Revenues from licensed products increased \$1.5 million, or 6.6%, to \$24.4 million in 2001 from \$22.9 million in 2000, primarily due to an increase in the net sales of Adenoscan(R) and Adenocard(R), on which we receive royalty revenues. The increase in revenues from licensed products was affected by a contractual reduction in the percentage royalty we receive on net sales of Adenoscan(R) that became effective during the third quarter of 2000.

Revenues from contract manufacturing and other decreased \$10.8 million, or 41.1%, to \$15.5 million in 2001 from \$26.3 million in 2000, primarily due to (1) the conclusion of two manufacturing and supply agreements during the fourth quarter of 2000; (2) reduced revenues derived under a third manufacturing and supply agreement during the six months ended June 30, 2001, as compared to the

same period of the prior year; and (3) reduced sales of generic private label neomycin and polymyxin B sulfates and hydrocortisone suspension and solution. While contract manufacturing and generic pharmaceutical sales remain a part of our business, we do not consider contract manufacturing and generic pharmaceutical sales as significant components of our growth strategy.

Operating Costs and Expenses

Total operating costs and expenses increased \$46.1 million, or 25.2%, to \$228.8 million in 2001 from \$182.7 million in 2000. The increase was primarily due to an increase in cost of revenues of \$13.8 million in 2001 and \$48.3 million in co-promotion fees and marketing expense in 2001 related to the co-promotion agreement with American Home Products for the promotion of Altace(R) in the United States and Puerto Rico, offset by \$22.3 million of merger related expenses in 2000.

Cost of revenues increased \$13.8 million, or 20.3% to \$81.8 million in 2001 from \$68.0 million in 2000. The increase resulted from cost of revenues associated with the increase in net sales of branded pharmaceutical products described above. As a percentage of revenues, cost of revenues decreased to 21.1% in 2001 from 24.4% in 2000 due to the increase in sales of higher margin products.

Selling, general and administrative expenses remained relatively flat at \$62.4 million in 2001 as compared to \$64.0 million in 2000. As a percentage of revenues, selling, general, and administrative expenses decreased to 16.1% in 2001 from 23.0% in 2000 due to increased revenues and the classification of all Altace(R) related marketing expenses as co-promotion marketing expense rather than selling, general and administrative during the six months ended June 30, 2001, and realization of cost synergies from the Medco and Jones mergers in 2000.

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During the six months ended June 30, 2001, the Company incurred \$37.8 million in co-promotion fees and \$10.5 million in co-promotion marketing expense pursuant to the June 2000 co-promotion agreement with American Home Products for the promotion of Altace(R) in the United States and Puerto Rico.

Depreciation and amortization expense increased \$4.0 million, or 21.3%, to \$22.8 million in 2001 from \$18.8 million in 2000. The increase was due primarily to additional amortization expense resulting from the acquisition of Nordette(R), Bicillin(R), and Wycillin(R) in July 2000.

Research and development expense increased to \$10.5 million in 2001 from \$9.7 million in 2000.

In June of 2001, we incurred \$3.0 million of "research and development -- special license rights" for fees we paid Novavax as consideration for an agreement which (1) expands our exclusive license to promote, market, distribute and sell Estrasorb(TM) worldwide, following approval, except in the United States and Puerto Rico where the parties will co-market the product; and (2) grants us an additional exclusive worldwide license to promote, market and distribute Androsorb(TM), following approval, except in the United States and Puerto Rico where the parties will co-market the product.

Operating Income

Operating income increased \$63.2 million, or 65.9%, to \$159.1 million in 2001 from \$95.9 million in 2000. This increase was due primarily to the increase in branded pharmaceutical sales during the six months ended June 30, 2001 as

compared to the six months ended June 30, 2000 as well as \$22.3 million of merger, restructuring and other non-recurring charges related primarily to the Medco merger in 2000.

Other Income (Expense)

Interest income decreased \$1.4 million from \$7.0 million in 2000 to \$5.6 million in 2001 due to lower balances of invested cash and cash equivalents during the six months ended June 30, 2001 as compared to the six months ended June 30, 2000.

Interest expense decreased \$18.6 million, or 76.9%, to \$5.6 million in 2001 from \$24.2 million in 2000. This decrease is due to the reduced average debt balance in 2001 resulting from the Company's prepayment of debt obligations during 2000.

Other income/expense increased from \$0.1 million expense in 2000 to \$2.9 million income in 2001 primarily due to unrealized gains on our derivatives.

Income Tax Expense

The effective tax rate in 2000 of 48.0% was reduced to 37.3% in 2001 due primarily to nondeductible merger, restructuring and other non-recurring charges related to the Medco merger in 2000.

Extraordinary Item

During the second quarter of 2000, we repaid outstanding debt under our senior credit facility prior to maturity. The early repayment caused us to recognize an extraordinary loss of \$4.7 million, net of related tax benefits of \$2.8 million, from the write-off of related deferred financing costs.

Cumulative Effect of Accounting Change

The Company recognized an expense of \$0.5 million, net of income taxes of \$0.3 million, in 2001 due to the cumulative effect of a change in accounting principle as a result of the adoption of SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", as amended by SFAS No. 138, which establishes accounting and reporting standards for derivative instruments and hedging activities.

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Net Income

Due to the factors set forth above, net income increased \$64.8 million, or 179.0%, to \$101.0 million in 2001 from \$36.2 million in 2000.

LIQUIDITY AND CAPITAL RESOURCES

General

We believe that existing credit facilities and cash generated from operations are sufficient to finance our current operations and working capital requirements. However, in the event we make significant future acquisitions or change our capital structure, we may be required to raise funds through additional borrowings or the issuance of additional debt or equity securities.

On August 8, 2001, we acquired three branded pharmaceutical products and a fully-paid license to a fourth product from Bristol-Myers Squibb ("BMS") for \$285.0 million. The products acquired include BMS's rights in the United States

to Corzide(R), Delestrogen(R), and Florinef(R). We also acquired a fully paid license to and trademark for Corgard(R) in the United States. The acquisition was financed with a combination of borrowings under our senior secured credit facility and cash on hand.

At present, we are actively pursuing additional acquisitions that may require the use of substantial capital resources.

SIX MONTHS ENDED JUNE 30, 2001

As of June 30, 2001 we had available up to  $$100.0\ \text{million}$  under a revolving line of credit.

We generated net cash from operations of \$174.2 million for the six months ended June 30, 2001. Our net cash provided from operations was primarily the result of \$101.0 million in net income, adjusted for non-cash depreciation and amortization of \$22.8 million, an adjustment to deferred income taxes of \$10.0 million, a change in income taxes payable of \$24.5 million, and an increase in accrued expenses of \$23.7 million. Additionally, we decreased accounts receivable by \$13.9 million and prepaid expenses and other current assets by \$3.0 million. An increase in inventory of \$14.9 million, a decrease in accounts payable of \$4.1 million, amortization of deferred revenue of \$4.5 million, and an unrealized gain on derivative instruments of \$2.8 million offset the items previously described.

Cash flows used in investing activities for the six months ended June 30, 2001 was \$14.4 million due to \$14.2 million of capital expenditures, and \$5.0 million of loans receivable offset by \$3.3 million received as proceeds from the sale of product rights and \$1.4 million received as proceeds from the sale of assets.

Financing activities for the six months ended June 30, 2001 provided \$17.9 million comprised principally of \$18.3 million from the exercise of employee stock options.

As of August 10, 2001, cash and cash equivalents total approximately \$69.8 million and we have available up to \$25.0 million under a revolving line of credit.

Certain Indebtedness and Other Matters

As of August 10, 2001, we have \$175.2 million of long-term debt (including current portion) and we have available up to \$25.0 million under our revolving credit facility. Our financing arrangements require us to maintain minimum net worth, debt to equity, cash flow and current ratio requirements. As of June 30, 2001, we were in compliance with these covenants.

On June 20, 2001, the board of directors declared a four for three stock split for shareholders of record as of July 3, 2001, to be distributed July 19, 2001. The stock split has been reflected in all share data contained in this Form 10-Q.

On July 3, 2001, we filed a \$1.5 billion universal shelf registration statement on Form S-3 with the Securities and Exchange Commission covering the issuance and sale, from time to time over an extended

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period, of debt and/or equity securities. We may sell any combination of such debt and/or equity securities in one or more offerings up to a total of \$1.3 billion and certain of our executive officers may sell shares of common stock

from time to time in an amount up to \$200 million. We will not receive any of the proceeds from the sale of shares of the selling shareholders. The shelf registration statement filed with the Securities and Exchange Commission is not yet effective.

#### Capital Expenditures

Capital expenditures, including capital lease obligations, were \$7.1 million and \$3.9 million for the three months ended June 30, 2001 and 2000, respectively, and \$14.2 million and \$9.1 million for the six months ended June 30, 2001 and 2000, respectively. The principal capital expenditures included property and equipment purchases and building improvements.

#### IMPACT OF INFLATION

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

#### RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, "Business Combinations." SFAS No. 141 requires all business combinations to be accounted for under the purchase method of accounting. SFAS No. 141 is effective for all business combinations initiated after June 30, 2001, as well as all business combinations accounted for under the purchase method of accounting for which the date of acquisition is July 1, 2001, or later.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. We are in the process of reviewing the impact of this pronouncement on previous acquisitions.

#### RISK FACTORS

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 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

IF SALES OF OUR MAJOR PRODUCTS OR ROYALTY PAYMENTS TO US DECREASE, OUR RESULTS OF OPERATIONS COULD BE ADVERSELY AFFECTED.

Altace(R) accounted for approximately 32% of our net sales for the six months ended June 30, 2001, and Altace(R), Lorabid(R), Levoxyl(R), Thrombin-JMI(R), and royalty revenues collectively accounted for approximately 61% of our net sales during the same period. We believe that sales of these products will continue to constitute a significant portion of our total revenues for the foreseeable future. Accordingly, any factor adversely affecting sales of any of these products or products for which we receive royalty payments could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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WE MAY NOT ACHIEVE OUR INTENDED BENEFITS FROM THE MARKETING ALLIANCE WITH AMERICAN HOME PRODUCTS CORPORATION FOR THE PROMOTION OF ALTACE(R).

We entered into a marketing alliance with American Home Products Corporation for Altace(R). We call this marketing alliance the "Co-Promotion Agreement." We entered into this alliance partially because we believed a larger pharmaceutical company with more sales representatives and, in our opinion, with substantial experience in the promotion of pharmaceutical products to physicians would significantly increase the sales revenue potential of Altace(R). By efficiently co-marketing the new indications for Altace(R) which were approved by the U.S. Food and Drug Administration, which we refer to as the "FDA," on October 4, 2000, we intend to increase the demand for the product. In the agreement, both of us have incentives to maximize the sales and profits of Altace(R) and to optimize the marketing of the product by coordinating our promotional activities.

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

It is possible that we or American Home Products or both of us will not be successful in effectively promoting Altace(R) or in optimizing its sales. The content of agreed-upon promotional messages for Altace(R) may not sufficiently convey the merits of Altace(R) and may not be successful in convincing physicians to prescribe Altace(R) instead of other angiotensin converting enzyme, or "ACE," inhibitors or competing therapies. The targets for sales force staffing, the number and frequency of details to physicians and the physicians who are called upon may be inadequate to realize our expectations for the revenues from Altace(R). Neither we nor American Home Products may be able to overcome the perception by physicians of a class effect, which we discuss below. Further, developments in technologies, the introduction of other products or new therapies may make it more attractive for American Home Products to concentrate on the promotion of a product or products other than Altace(R) or to lessen its emphasis on the marketing of Altace(R). Our strategic decisions in dealing with managed health care organizations may not prove to be correct and we could consequently lose sales in this market to competing ACE inhibitor products or alternative therapies. If any of these situations occurred, they could have a material adverse effect on our business, financial condition, results of operations and cash flows.

IF OUR BRISTOL FACILITY IS NOT QUALIFIED AS A MANUFACTURING AND PACKAGING SITE FOR ALTACE(R) OR IF THERE IS AN INTERRUPTION IN THE SUPPLY OF RAW MATERIAL FOR ALTACE(R), THE DISTRIBUTION, MARKETING AND SUBSEQUENT SALES OF THE PRODUCT COULD BE ADVERSELY AFFECTED.

We are currently working to qualify our Bristol facility as a manufacturing and packaging site for Altace(R). While Aventis Pharmaceuticals, Inc. (USA), successor to Hoechst Marion Roussel, Inc. from which we purchased Altace(R), will remain as a supplier of the finished Altace(R) product to us, we intend our

Bristol facility to ultimately be the primary source for the manufacture and packaging of Altace(R) for us. If we are unable to secure the approval of our Bristol facility as a manufacturing and packaging site or do not do so in a timely manner, we may not be able to meet the anticipated demand for Altace(R). While Aventis (USA) will remain an alternative or back-up supplier of Altace(R), if we encounter delays or difficulties with the approval of our Bristol facility as a site for the manufacture and packaging of Altace(R), the distribution, marketing and subsequent sales of Altace(R) nonetheless could be adversely affected. If we are delayed or unsuccessful in securing approval of the Bristol facility as a supplier, we might not be able to make alternative supply arrangements for additional amounts of the finished product at commercially reasonable rates, if at all.

When we have qualified our Bristol facility as a manufacturing and packaging site for Altace(R), Aventis Pharma Deutscheland GmbH (Germany) will continue to be our single supplier of ramipril, the active

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ingredient in Altace(R). Because the manufacture of ramipril is a patented process, we cannot secure the raw material from another source. Aventis (USA) currently manufactures and packages Altace(R) for us for sales in the United States and for itself for distribution outside of the United States. Any interruptions or delays in receiving the finished product or raw material used for the future production of Altace(R) could have a material adverse effect on our business, financial condition, results of operations and cash flows. We have entered into a supply agreement with Aventis (Germany) and we believe that it adequately protects our supply of raw material, but there can be no guarantee that there will not be interruptions or delays in the supply of the raw material.

SALES OF ALTACE(R) MAY BE AFFECTED BY THE PERCEPTION OF A CLASS EFFECT, AND ALTACE(R) AND OUR OTHER PRODUCTS MAY BE SUBJECT TO VARIOUS SOURCES OF COMPETITION FROM ALTERNATE THERAPIES.

Although the FDA has approved new indications for Altace(R), we may be unable to meet investors' expectations regarding sales of Altace(R) due to a perceived class effect or the inability to market Altace(R)'s new uses and indications effectively.

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

When one drug from a class is demonstrated to have a particularly beneficial or previously undemonstrated effect (e.g., the benefit of Altace(R) as shown by the Heart Outcomes Prevention Evaluation, which we refer to as the "HOPE trial"), marketers of other drugs in the same class (for example, other ACE inhibitors) will represent that their products offer the same benefit simply by virtue of membership in the same drug class. Consequently, other companies with ACE inhibitors that compete with Altace(R) will represent that their products are equivalent to Altace(R). By doing so, these companies will represent that their products offer the same efficacious results demonstrated by the HOPE trial. Regulatory agencies do not decide whether products within a class are quantitatively equivalent in terms of efficacy or safety. Because comparative data among products in the same drug class are rare, marketing forces often dictate a physician's decision to use one ACE inhibitor over

another. We may not be able to overcome other companies' representations that their ACE inhibitors will offer the same benefits as Altace(R) as demonstrated by the HOPE trial. As a result, sales of Altace(R) may suffer from the perception of a class effect.

Currently, there is no generic form of Altace(R) available. That is, there is no product that has the same active ingredient as Altace(R). Although no generic substitute for Altace(R) has been approved by the FDA, there are other ACE inhibitors whose patents have expired or will expire in the next few years and there are generic forms of other ACE inhibitors. Also, there are different therapeutic agents that may be used to treat certain conditions treated by Altace(R). For example, the group of products known as beta-blockers, calcium channel blockers and diuretics, may be prescribed to treat certain conditions that Altace(R) is used to treat. New ACE inhibitors, increased sales of generic forms of other ACE inhibitors or of other therapeutic agents that compete with Altace(R) may adversely affect the sales of Altace(R).

OUR MARKETING ALLIANCE WITH AMERICAN HOME PRODUCTS FOR ALTACE(R) COULD BE TERMINATED BEFORE WE REALIZE ALL OF THE BENEFITS OF THE AGREEMENT OR IT COULD BE ASSIGNED TO ANOTHER COMPANY BY AMERICAN HOME PRODUCTS OR AMERICAN HOME PRODUCTS COULD MARKET A COMPETING PRODUCT.

Our exclusive Co-Promotion Agreement for Altace(R) with Wyeth-Ayerst Laboratories, a division of American Home Products Corporation, could be terminated before we realize all of the benefits of the agreement. American Home Products and we each have the right to terminate the agreement if annualized net sales of Altace(R) have not reached \$300.0 million by October 4, 2003. There are other reasons why either American Home Products or we could terminate the Co-Promotion Agreement. If the Co-Promotion Agreement is terminated for any reason, we may not realize increased sales which we believe may result from

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the expanded promotion of Altace(R). If we must unwind our marketing alliance efforts because of the reasons mentioned above, there may be a material adverse effect on the sales of Altace(R).

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

When feasible, American Home Products must give us six months' written notice of its intent to sell, market or distribute any product competitive with Altace(R). Under the Co-Promotion Agreement, a product competes with Altace(R) if it is an ACE inhibitor, an angiotensin II receptor blocker, which we refer to as an "ARB," or an ACE inhibitor or ARB in combination with other cardiovascular agents in a single product. However, an ARB alone or in combination with other cardiovascular agents competes with Altace(R) only if the level of promotional effort used by American Home Products for the ARB is greater than 50% of that applied to Altace(R). A product would not compete with Altace(R) if in the last

12 months it had net sales of less than \$100.0 million or 15% of net sales of Altace(R), whichever was higher. Also, a product would not compete with Altace(R) under the Co-Promotion Agreement if the product were acquired by American Home Products through a merger with or acquisition by a third party and the product was no longer actively promoted by American Home Products or its successor through detailing the product to physicians.

Once we have been notified in writing of American Home Products' intent to market, sell or distribute a competing product, then American Home Products has 90 days to inform us as to whether it intends to divest its interest in the competing product. If American Home Products elects to divest the competing product, it must try to identify a purchaser and to enter into a definitive agreement with the purchaser as soon as practicable. If American Home Products 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 together market the competing product for the remaining term of our Altace(R) Co-Promotion Agreement. Alternatively, American Home Products and we could agree upon another commercial relationship, such as royalties payable to us for the sale of the competing product, or we could agree to adjust the promotion fee we pay to American Home Products for the its marketing of Altace(R). If American Home Products and we are unable to establish acceptable terms under any of these options, then we have the option at our sole discretion to reacquire all the marketing rights to Altace(R) and terminate the Co-Promotion Agreement upon 180 days' prior written notice to American Home Products. In the event we decided to reacquire all the marketing rights to Altace(R) we would be obligated to pay American Home Products an amount of cash equal to twice the net sales of Altace(R) in the United States for the 12 month period preceding the reacquisition. Such a decision could have a material effect on our business, financial condition, the results of our operations and cash flows.

OUR SALES OF LEVOXYL(R) COULD BE AFFECTED BY FUTURE ACTIONS OF THE FDA AND BY UNCERTAINTY IN THE LEVOTHYROXINE SODIUM PRODUCT MARKET.

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

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On May 25, 2001, the FDA approved our previously filed New Drug Application for Levoxyl(R), our levothyroxine sodium drug product. It is possible that other manufacturers of levothyroxine sodium drug products have filed or will file other New Drug Applications for their levothyroxine sodium products. Jerome Stevens, Inc. has also received approval for its levothyroxine sodium product Unithroid. After August 14, 2001, the FDA will refuse to accept a New Drug Application for a levothyroxine sodium drug product that is pharmaceutically equivalent to an approved product. However, the treatment of applications which are submitted prior to August 14, 2001, but not approved by August 14, 2001 is uncertain. The FDA has stated it will continue to review these applications. Other manufacturers who wish to submit an application for an equivalent product after August 14, 2001 must submit an Abbreviated New Drug Application. Also, since the Jerome Stevens product has been approved, a manufacturer could submit an Abbreviated New Drug Application demonstrating in vivo bioequivalence (in other words, the two products produce identical effects on the body) to the Jerome Stevens product. If the FDA were to determine that another levothyroxine sodium product is bioequivalent to Levoxyl(R), generic substitution for

Levoxyl(R) may become possible which could result in a decrease in sales of our product Levoxyl(R).

WE CANNOT ASSURE YOU THAT SALES OF LORABID(R) WILL INCREASE IN THE FUTURE. IF SALES DO NOT INCREASE, THERE MAY BE A MATERIAL ADVERSE EFFECT UPON OUR RESULTS OF OPERATIONS.

Prior to our acquisition of Lorabid(R), sales of that product were on the decline because we believe that the prior owner was not actively promoting the product. Increased sales of Lorabid(R) depend upon effective marketing to physicians which leads them to write prescriptions for our product. Since the antibiotic market is very competitive, we cannot assure you that sales of Lorabid(R) will increase in the future. If Lorabid(R) sales do not increase or if they decrease, there may be a material adverse effect upon our results of operations and cash flow.

IF WE CANNOT IMPLEMENT OUR STRATEGY TO GROW OUR BUSINESS THROUGH INCREASED SALES AND ACQUISITIONS, OUR COMPETITIVE POSITION IN THE PHARMACEUTICAL INDUSTRY MAY SUFFER.

We have historically increased our sales and net income through strategic acquisitions and related internal growth initiatives intended to develop marketing opportunities with respect to acquired product lines. Our strategy is focused on increasing sales and enhancing our competitive standing through acquisitions 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 product development, we rely heavily on purchasing product lines from other companies.

Other companies, many of which have substantially greater financial, marketing and sales resources than we do, may compete with us for the acquisition of products or companies. We may not be able to acquire rights to additional products or companies on acceptable terms, if at all, or be able to obtain future financing for acquisitions on acceptable terms, if at all. The inability to effect acquisitions of additional branded products 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. For example, our marketing strategy, distribution channels and levels of competition with respect to acquired products may be different than those of our current products, limiting our ability to compete favorably in those product categories.

IF WE CANNOT INTEGRATE THE BUSINESS OF COMPANIES OR PRODUCTS WE ACQUIRE, OUR BUSINESS MAY SUFFER.

We anticipate that the integration of newly acquired companies and products into our business will require significant management attention and 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 recent acquisitions, including the acquisition of Jones Pharma Incorporated, 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

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we cannot integrate our acquisitions successfully, these changes and acquisitions could have a material adverse effect on our business, financial condition, results of operations and cash flows.

IF WE ARE NOT ABLE TO DEVELOP OR LICENSE NEW PRODUCTS, OUR BUSINESS MAY SUFFER.

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

- engage in product life cycle management to develop new indications and line extensions for existing and acquired products;
- develop, license or successfully commercialize new products on a timely basis or at all; or
- develop or license new products in a cost effective manner.

### For example, we are

- engaged in the development of Binodisine (MRE0470), a myocardial pharmacologic stress imaging agent;
- under a licensing agreement with Novavax developing recombinant human papillomavirus (HPV) virus-like particle (VLP) vaccines; and
- under an exclusive license with Novavax we anticipate promoting, marketing, distributing and selling Estrasorb(TM), a topical transdermal estrogen replacement therapy, and Androsorb(TM), a topical testosterone replacement therapy for testosterone deficient women, upon their approval by the FDA.

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

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

- develop or license their products more rapidly than we can,
- complete any applicable regulatory approval process sooner than we can,
- market or license their products before we can market or license our products, or
- offer their newly developed or licensed products at prices lower than our prices,

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

WE DO NOT HAVE PROPRIETARY PROTECTION FOR MOST OF OUR BRANDED PHARMACEUTICAL PRODUCTS, AND OUR SALES COULD SUFFER FROM COMPETITION BY GENERIC SUBSTITUTES.

Although most of our revenue is generated by products not subject to competition from generic products, there is no proprietary protection for most of our branded pharmaceutical products, and generic substitutes for most of

these products are sold by other pharmaceutical companies. In addition, governmental and other pressure to reduce pharmaceutical costs may result in physicians prescribing products for which there are generic substitutes. Increased competition from the sale of generic pharmaceutical products may cause a decrease in revenue from our branded products and could have a material adverse effect on our business, financial condition and results of operations. For example, Tapazole(R), with net sales of \$26.5 million in 1999, began to face generic competition in 2000 and had net sales of \$29.0 million in 2000 although net sales declined in the last six months of 2000. In addition, our branded products for which there is no generic form

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available may face competition from different therapeutic agents used for the same indications for which our branded products are used.

THIRD PARTIES MANUFACTURE OR SUPPLY MATERIALS FOR MANY OF OUR PRODUCTS, AND ANY DELAYS OR DIFFICULTIES EXPERIENCED BY THEM MAY REDUCE OUR PROFIT MARGINS AND REVENUES OR HARM OUR REPUTATION.

Many of our product lines, including Altace(R), Lorabid(R) and Cortisporin(R), 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. 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 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. Generally, we have not had difficulty obtaining raw materials and components from suppliers in the past. Currently, we rely on over 500 suppliers to deliver the necessary raw materials and components. We have no reason to believe that we will be unable to procure adequate supplies of raw materials and components on a timely basis. However, if we are unable to obtain sufficient quantities of any of the raw materials or components required to produce and package our products, we may not be able to distribute our products as planned. In this case, our business, financial condition and results of operations could be materially and adversely affected.

OUR PARKEDALE FACILITY HAS BEEN THE SUBJECT OF FDA CONCERNS. IF WE CANNOT ADEQUATELY ADDRESS THE FDA'S CONCERNS, WE MAY BE UNABLE TO OPERATE THE PARKEDALE FACILITY AND, ACCORDINGLY, OUR BUSINESS MAY SUFFER.

Our Parkedale facility, located in Rochester, Michigan, manufactures both drug and biological pharmaceutical products. Prior to our acquisition of the Parkedale facility in February 1998, it was one of six Pfizer facilities subject to a consent decree issued by the U.S. District Court of New Jersey in August 1993 as a result of FDA concerns about compliance issues within Pfizer facilities in the period before the decree was entered.

The Parkedale facility was inspected by the FDA in February 2001. When an FDA inspector completes an authorized inspection of a manufacturing facility,

the FDC Act mandates that the inspector give to the owner/operator of the facility a written report listing the inspector's observations of objectionable conditions and practices. This written report is known as an "FDA Form 483" or simply as a "483." The observations in a 483 are reported to the manufacturer in order to assist the manufacturer in complying with the FDC Act and the regulations enforced by the FDA. Often a pharmaceutical manufacturer receives a 483 after an inspection and our Parkedale facility received a 483 following the February 2001 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 February 483 and our commitment to correct the objectionable practice or condition. The risk to us of a 483, if left uncorrected, could include, among other things, the imposition of civil monetary penalties, the commencement of actions to seize or prohibit the sale of unapproved or non-complying products, or the cessation of manufacturing operations at the Parkedale facility that are not in compliance with current Good Manufacturing Practices, generally known as "cGMP." While we believe the receipt of the 483 will not have a material adverse effect on our business, financial condition, results of operation and cash flows, we cannot assure you that future inspections may not result in adverse regulatory actions. The 483 from February 2001 does not require us to delay or discontinue the production of any products made at the Parkedale facility.

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AN INCREASE IN PRODUCT LIABILITY CLAIMS, PRODUCT RECALLS OR PRODUCT RETURNS COULD HARM OUR BUSINESS.

We face an inherent business risk of exposure to product liability claims in the event that the use of our technologies or products are alleged to have resulted in adverse effects. These risks will exist for those products in clinical development and with respect to those products that receive regulatory approval for commercial sale. While we have taken, and will continue to take, what we believe are appropriate precautions, we may not be able to avoid significant product liability exposure. We currently have product liability insurance in the amount of \$75.0 million for aggregate annual claims with a \$50,000 deductible per incident and a \$500,000 aggregate annual deductible; however, we cannot assure you that the level or breadth of any insurance coverage will be sufficient to cover fully all potential claims. Also, adequate insurance coverage might not be available in the future at acceptable costs, if at all

Product recalls may be issued at our discretion, at the discretion of the FDA, or at the discretion of other government agencies or other companies having regulatory authority for pharmaceutical product sales. From time to time, we may recall products for various reasons. To date, however, 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.

Although product returns were approximately 2.4% of gross sales for the year ended December 31, 2000, we cannot assure you that actual levels of returns will not increase or significantly exceed the amounts we have anticipated.

OUR WHOLLY OWNED SUBSIDIARY, JONES PHARMA, IS A DEFENDANT IN LITIGATION WHICH IS CURRENTLY BEING HANDLED BY ITS INSURANCE CARRIERS. SHOULD THIS COVERAGE BE INADEQUATE OR SUBSEQUENTLY DENIED OR WERE WE TO LOSE SOME OF THESE LAWSUITS, OUR RESULTS OF OPERATIONS COULD BE ADVERSELY AFFECTED.

Our wholly owned subsidiary, Jones Pharma, is a defendant in more than 1,800 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(R), a branded phentermine product. Jones also distributed a generic phentermine product. Jones believes that its phentermine products have been identified in less than 100 of the foregoing cases. The plaintiffs in these cases claim injury as a result of ingesting a combination of these weight-loss drugs. They seek compensatory and punitive damages as well as medical care and court-supervised medical monitoring. The plaintiffs claim liability based on a variety of theories including but not limited to, product liability, strict liability, negligence, breach of warranties and misrepresentation. These suits are filed in various jurisdictions throughout the United States, and in each of these suits Jones is one of many defendants, including manufacturers and other distributors of these drugs. Jones denies any liability incident to the distribution of its phentermine product and intends to pursue all defenses available to it. Jones has tendered defense of these lawsuits to its insurance carriers for handling and they are currently defending Jones in these suits. In the event that insurance coverage is inadequate to satisfy any resulting liability, Jones will have to resume defense of these lawsuits and be responsible for the damages, if any, that are awarded against it.

SALES OF THROMBIN-JMI(R) MAY BE AFFECTED BY THE PERCEPTION OF RISKS ASSOCIATED WITH SOME OF THE RAW MATERIALS USED IN ITS MANUFACTURE.

The source material for our product Thrombin-JMI(R) comes from bovine plasma and lung tissue. Bovine-sourced materials from outside the United States may be of some concern because of potential transmission of Bovine Spongiform Encephalopathy, or BSE. However, we have taken precautions to minimize the risks of contamination from BSE in our source materials including, primarily, the use of bovine materials only from FDA-approved sources in the United States. Although no BSE has been documented in the United States, the United States is considered a Category II BSE-risk country, meaning that the United States is probably BSE-free but has some history of importing cattle from the United Kingdom.

We receive the bovine raw materials from a single vendor and any interruption or delay in the supply of that material could adversely affect the sales of Thrombin-JMI(R). In addition to other actions taken by us and  $$^{30}$$ 

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our vendor to minimize the risk of BSE, we are developing steps to further purify the material of other contaminants. 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. We will continue surveillance of the source and believe that the risk of BSE-contamination in the source materials for Thrombin-JMI(R) is very low. There are high levels of global public concern about BSE. Physicians could determine not to administer Thrombin-JMI(R) 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(R). If BSE spreads to the United States, the manufacture and sale of Thrombin-JMI(R) and our business, financial condition and results of operations could be materially and adversely affected.

THE LOSS OF OUR KEY 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 acquisition and development objectives. Although we believe that we are adequately staffed in key positions and that we will be successful in retaining skilled and

experienced management, operational, scientific and development personnel, we cannot assure you that we will be able to attract and retain key personnel on acceptable terms. The loss of the services of key personnel could have a material adverse effect on us, especially in light of our recent growth. We do not maintain key-person life insurance on any of our employees. In addition, we do not have employment agreements with any of our key employees.

IF WE ARE UNABLE TO SECURE OR ENFORCE PATENT RIGHTS, TRADEMARKS, TRADE SECRETS OR OTHER INTELLECTUAL PROPERTY, OUR BUSINESS COULD BE HARMED.

We may not be successful in securing or maintaining proprietary patent protection for products we develop or technologies we license. In addition, our competitors may develop products similar to ours using methods and technologies that are beyond the scope of our intellectual property protection, which could reduce our sales. The validity of patents can be subject to expensive litigation. We can give you no assurance that our patents will not be challenged. Competitors may be able to develop similar or competitive products outside the scope of our patents which could have a material adverse effect on sales of our products or the amounts of royalty revenues we receive.

We also rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable, 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 or disclose the technology, or that we can adequately protect our trade secrets.

OUR SHAREHOLDER RIGHTS PLAN AND BYLAWS DISCOURAGE UNSOLICITED TAKEOVER PROPOSALS AND COULD ENTRENCH CURRENT MANAGEMENT AND 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, thereby entrenching current management and possibly depressing the market price of our common stock. 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 the board of directors to designate the terms of and issue new series of preferred stock,
- advance notice requirements for nominations for election to the board of directors, and
- special voting requirements for the amendment of our charter and bylaws.

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

RISKS RELATED TO OUR INDUSTRY

FAILURE TO COMPLY WITH GOVERNMENT REGULATIONS COULD AFFECT OUR ABILITY TO

OPERATE OUR BUSINESS.

Virtually all aspects of our activities are regulated by federal and state statutes and government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution and advertising of our products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies, including the FDA, the Drug Enforcement Administration, or "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, or "EPA," as well as by foreign governments in countries where we distribute some of our products.

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

All manufacturers of human pharmaceutical products are subject to regulation by the FDA under the authority of 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 and results of operations.

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 and results of operations.

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 cGMP requirements, 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. In addition, modifications, enhancements, or changes in

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manufacturing sites of approved products are in many circumstances subject to additional FDA approvals which may or may not be received and which may be subject to a lengthy FDA review process. Our manufacturing facilities and those of our third-party manufacturers are continually subject to inspection by governmental agencies. Manufacturing operations could be interrupted or halted in any of those facilities if a government or regulatory authority is unsatisfied with the results of an inspection. Any interruptions of this type could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

ANY REDUCTION IN REIMBURSEMENT LEVELS BY MANAGED CARE ORGANIZATIONS OR OTHER THIRD-PARTY PAYORS MAY HAVE AN ADVERSE EFFECT ON OUR REVENUES.

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

NEW LEGISLATION OR REGULATORY PROPOSALS MAY ADVERSELY AFFECT OUR ABILITY TO RAISE CAPITAL AND OUR REVENUES.

A number of legislative and regulatory proposals aimed at changing the health care system, including the cost of prescription products, reimportation of prescription products and changes in the levels at which pharmaceutical companies are reimbursed for sales of their products, have been proposed. While we cannot predict when or whether any of these proposals will be adopted or the effect these proposals may have on our business, the pending nature of these proposals, as well as the adoption of any proposal, may harm our ability to raise capital, may exacerbate industry-wide pricing pressures and could have a material adverse effect on our financial condition, results of operations or cash flows.

THE INDUSTRY IS HIGHLY COMPETITIVE, AND OTHER COMPANIES IN OUR INDUSTRY HAVE MUCH GREATER RESOURCES THEN WE DO.

In the industry, comparatively smaller pharmaceutical companies like us compete with large, global pharmaceutical companies with substantially greater financial resources for the acquisition of products, technologies and companies.

COMPETITION FOR ACQUISITIONS. We compete with other pharmaceutical companies for product and product line acquisitions. These competitors include Forest Laboratories, Inc., Shire Pharmaceuticals Group plc, Biovail Corporation, Watson Pharmaceuticals, Inc., Medicis Pharmaceutical Corporation and other companies which also acquire branded pharmaceutical products and product lines from other pharmaceutical companies. We cannot assure you that

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

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- additional competitors will not enter the market; or
- competition for acquisition of products, companies, technologies and product lines will not have a material adverse effect on our business, financial condition and results of operations.

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

Our largest product Altace(R) competes in the market with other cardiovascular therapies, including in particular, the following ACE inhibitors:

- Zestril(R) (AstraZeneca PLC),
- Acupril(R) (Pfizer Inc.),
- Prinivil(R) (Merck & Co., Inc.),

Our second largest product Levoxyl(R) competes with the following levothyroxine sodium products:

- Synthroid(R) (Abbott Laboratories),
- Levothroid(R) (Forest Laboratories, Inc.), and
- Unithroid(R) (Watson Pharmaceuticals, Inc.)

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

- detailing and sampling to the primary prescribing physician groups
- sponsoring physician symposiums, including continuing medical education seminars, and
- conducting a planned direct-to-consumer advertising campaign for  $\mbox{\sc Altace}\,(\mbox{\sc R})\,.$

Our branded pharmaceutical products may be subject to competition from alternate therapies and from generic equivalents.

Many of our branded pharmaceutical products have either a strong market

niche or competitive position. Some of our branded pharmaceutical products face competition from generic substitutes. For example, during 2000 the FDA approved for sale generic substitutes for Tapazole(R). Of our branded pharmaceutical products that have generic substitutes, we believe that only a small number face significant competition because many of our branded pharmaceutical products are too difficult to manufacture or prove bioequivalence (i.e., the two products produce identical effects on the body) or have sales levels that are too low to attract competition.

The manufacturers of generic products typically do not bear the related research and development costs and, consequently, are able to offer such products at considerably lower prices than the branded equivalents. There are, however, a number of factors which enable products to remain profitable once patent protection has ceased. For a manufacturer to launch a generic substitute, it must prove to the FDA when filing an application to make a generic substitute that the branded pharmaceutical and the generic substitute have bioequivalence. We believe it typically takes two or three years to prove bioequivalence and receive FDA approval for many generic substitutes. By focusing our efforts in part on products with bioequivalence or complex manufacturing requirements and products with a strong brand image with the prescriber or the consumer, supported by the development of a broader range of alternative product formulations or dosage forms, we are better able to protect market share and produce sustainable high margins and cash flows.

### FORWARD-LOOKING STATEMENTS

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

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These forward-looking statements are identified by their use of terms and phrases, such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will" and similar terms and phrases, including references to assumptions. These statements are contained in sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" in our Annual Report on Form 10-K for the year ended December 31, 2000 and in sections of this report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" which includes a section entitled "Risk Factors.".

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

- the future growth potential of, and prescription trends for our branded pharmaceutical products, particularly Altace(R), Levoxyl(R) and Thrombin-JMI(R);
- expected trends with respect to particular income and expense line items;
- the development and potential commercialization of HPV vaccines and Estrasorb(TM) by Novavax and King;
- the development by King Pharmaceuticals Research and Development of Binodisine, pre-clinical programs, and product life cycle development projects;
- our continued successful execution of our growth strategies;
- anticipated developments and expansions of our business;

- increases in sales of recently acquired products or royalty payments;
- the success of existing co-promotion agreements and the development of future co-promotion agreements;
- the high cost and uncertainty of research, clinical trials and other development activities involving pharmaceutical products;
- development of product line extensions;
- the unpredictability of the duration or future findings and determinations of the FDA and other regulatory agencies worldwide;
- debt service and leverage requirements;
- the products which we expect to offer;
- the intent to market and distribute certain of our products internationally;
- the intent to manufacture certain products in our own facilities which are currently manufactured for us by third parties;
- 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; 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 other factors include, but are not limited to, the following:

- changes in general economic and business conditions;
- dependence on continued acquisition of products;
- management of growth of business and integration of product acquisitions;
- changes in current pricing levels;

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- development of new competitive products;
- changes in economic conditions and federal and state regulations;
- competition for acquisition of products;
- manufacturing capacity constraints; and
- the availability, terms and deployment of capital.

#### 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 June 30, 2001, there were no significant changes in our qualitative or quantitative market risk since the prior reporting period.

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### PART II -- OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

The information required by this Item is incorporated by reference to Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this document.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the annual meeting of shareholders on June 22, 2001, the shareholders voted on the following proposals with the results as indicated:

1. Elected three directors to serve in office for a three-year terms as follows:

		WITHHOLD
	FOR	AUTHORITY
Jefferson J. Gregory	123,721,315	28,118,713
Ernest C. Bourne	124,314,890	27,525,138
Gregory D. Jordan	150,165,234	1,674,794

Elected one director to serve in office for a one-year terms as follows:

			FOR	WITHHOLD AUTHORITY
R.	Charles Moyer,	Ph.D	150,229,238	1,610,790

Directors continuing in service include: John M. Gregory, Joseph R. Gregory, Earnest W. Deavenport, Jr., Frank W. DeFriece, Jr., D. Greg Rooker.

2. Ratified the appointment of PricewaterhouseCoopers LLP as the independent accountants and auditors for 2001 as follows:

For:	150,326,652
Against:	992,918
Abstention:	520,458

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

None

(b) Reports on Form 8-K

None

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### SIGNATURES

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

KING PHARMACEUTICALS, INC.

Date: August 14, 2001 By: /s/ JOHN M. GREGORY

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John M. Gregory

Chairman and Chief Executive Officer

Date: August 14, 2001 By: /s/ JAMES R. LATTANZI

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James R. Lattanzi Chief Financial Officer

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