

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

November 14, 2002

**Table of Contents**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2002

**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 number: 39040

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**13-4022871**  
(I.R.S. Employer  
Identification Number)

**100 Painters Drive**  
**Chadds Ford, Pennsylvania 19317**  
(Address of Principal Executive Offices)

**(610) 558-9800**  
(Registrant's Telephone Number, Including Area Code)

Indicate by check  whether the registrant: (1) has filed all reports required to be filed by Sections 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  NO

The aggregate number of shares of the Registrant's common stock outstanding as of November 14, 2002 was 102,064,450.

---

**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

**CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

**Overview**

**Critical Accounting Policies**

**Results of Operations**

**Goodwill and Other Intangibles**

**Compensation Related to Stock Options**

**Other Events**

**Net Sales**

**Three Months Ended September 30, 2002 Compared to the Three Months Ended September 30, 2001**

**Nine Months Ended September 30, 2002 Compared to the Nine Months Ended September 30, 2001**

**Liquidity and Capital Resources**

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

**Item 4. Controls and Procedures**

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

**Item 2. Changes in Securities and Use of Proceeds**

**Item 3. Defaults Upon Senior Securities**

**Item 4. Submission of Matters to a Vote of Security Holders**

**Item 5. Other Information**

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

**SIGNATURES**

**CERTIFICATIONS**

**EXHIBIT INDEX**

**EXHIBIT 11 STATEMENT REGARDING EARNINGS**

**EXHIBIT 99.1 CERTIFICATION OF CEO**

**EXHIBIT 99.2 CERTIFICATION OF CFO**

---

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.  
REPORT ON FORM 10-Q  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002**

**TABLE OF CONTENTS**

		<b>Page</b>
<b>PART I. FINANCIAL INFORMATION</b>		
Item 1.	Financial Statements	
	Consolidated Balance Sheets (Unaudited)	
	September 30, 2002 and December 31, 2001	1
	Consolidated Statements of Operations (Unaudited)	
	Three Months and Nine Months Ended September 30, 2002 and 2001	2
	Consolidated Statements of Cash Flows (Unaudited)	
	Nine Months Ended September 30, 2002 and 2001	3
	Notes to Consolidated Financial Statements (Unaudited)	4
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	12
	Overview	12
	Critical Accounting Policies	12
	Results of Operations	13
	Goodwill and Other Intangibles	13
	Compensation Related to Stock Options	14
	Other Events	15
	Net Sales	16
	Three Months Ended September 30, 2002 Compared to the Three Months Ended September 30, 2001	17
	Nine Months Ended September 30, 2002 Compared to the Nine Months Ended September 30, 2001	18
	Liquidity and Capital Resources	20
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4.	Controls and Procedures	21

**Table of Contents**

**PART II. OTHER INFORMATION**

Item 1.	Legal Proceedings	22
Item 2.	Changes in Securities and Use of Proceeds	23
Item 3.	Defaults Upon Senior Securities	23
Item 4.	Submission of Matters to a Vote of Security Holders	23
Item 5.	Other Information	23
Item 6.	Exhibits and Reports on Form 8-K	24
	Signatures	25
	Certifications	26

---

**Table of Contents**

**Forward Looking Statements**

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales and consolidated EBITDA contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management's Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this Report could affect our future financial results and could cause our actual results to differ materially from those expressed in forward-looking statements contained in this Report. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this Report include, among others:

our ability to successfully develop, commercialize and market new products;

results of clinical trials on new products;

competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;

market acceptance of our future products;

government regulation of the pharmaceutical industry;

our dependence on a small number of products;

our dependence on outside manufacturers for the manufacture of our products;

our dependence on third parties to supply raw materials and to provide services for the core aspects of our business;

new regulatory action or lawsuits relating to the use of narcotics in most of our core products;

our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;

our ability to protect our proprietary technology;

our ability to successfully implement our acquisition strategy;

the availability of controlled substances that constitute the active ingredients of some of our products and products in development;

the availability of third-party reimbursement for our products; and

our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this Report for any reason, even if new information becomes available or other events occur in the future.

**Table of Contents****PART I****FINANCIAL INFORMATION****Item 1. Financial Statements**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED BALANCE SHEETS (UNAUDITED)**  
(In thousands, except share data)

	September 30, 2002	December 31, 2001
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 36,545	\$ 95,357
Accounts receivable, net	111,203	85,329
Inventories	33,259	27,766
Prepaid expenses	4,615	5,527
Deferred income taxes	42,574	26,946
	<u>          </u>	<u>          </u>
Total current assets	228,196	240,925
	<u>          </u>	<u>          </u>
PROPERTY AND EQUIPMENT, Net	10,477	9,883
GOODWILL	181,079	182,318
OTHER INTANGIBLES, Net	11,940	12,495
DEFERRED INCOME TAXES	24,678	23,420
RESTRICTED CASH		150
OTHER ASSETS	1,665	1,804
	<u>          </u>	<u>          </u>
<b>TOTAL ASSETS</b>	<b>\$ 458,035</b>	<b>\$ 470,995</b>
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 46,977	\$ 30,705
Accrued expenses	70,276	50,176
Income taxes payable	2,681	3,526
Current portion of long-term debt		91,259
	<u>          </u>	<u>          </u>
Total current liabilities	119,934	175,666
	<u>          </u>	<u>          </u>
OTHER LIABILITIES	231	207
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		
Preferred Stock, \$.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$.01 par value; 175,000,000 shares authorized; 102,064,450 and 102,063,950 issued and outstanding at September 30, 2002 and December 31, 2001, respectively	1,021	1,021
	<u>          </u>	<u>          </u>
Additional paid-in capital	552,995	519,316
Accumulated deficit	(216,146)	(225,215)
	<u>          </u>	<u>          </u>

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

Total Stockholders Equity	337,870	295,122
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 458,035	\$ 470,995

See Notes to Consolidated Financial Statements

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
(In thousands, except share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
NET SALES	\$ 110,554	\$ 66,268	285,482	\$ 173,507
COST OF SALES	24,392	20,622	71,088	54,303
<b>GROSS PROFIT</b>	<b>86,162</b>	<b>45,646</b>	<b>214,394</b>	<b>119,204</b>
<b>COSTS AND EXPENSES:</b>				
Selling, general and administrative	28,753	19,588	79,898	54,931
Research and development	15,352	7,886	43,890	25,396
Depreciation and amortization	692	12,394	2,168	37,170
Compensation related to stock options - primarily selling, general and administrative	40,406	37,253	40,406	37,253
Purchased in-process research and development	13,334		13,334	
Manufacturing transfer fee	9,000		9,000	
<b>OPERATING (LOSS) INCOME</b>	<b>(21,375)</b>	<b>(31,475)</b>	<b>25,698</b>	<b>(35,546)</b>
INTEREST EXPENSE, Net of interest income of \$376, \$607, \$1,024 and \$2,423 respectively	1,031	2,686	4,302	9,129
<b>(LOSS) INCOME BEFORE INCOME TAX (BENEFIT)</b>	<b>(22,406)</b>	<b>(34,161)</b>	<b>21,396</b>	<b>(44,675)</b>
INCOME TAX (BENEFIT)	(4,098)	(1,168)	12,327	(175)
<b>NET (LOSS) INCOME</b>	<b>\$ (18,308)</b>	<b>\$ (32,993)</b>	<b>\$ 9,069</b>	<b>\$ (44,500)</b>
<b>NET (LOSS) INCOME PER SHARE:</b>				
Basic	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
Diluted	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
<b>NET (LOSS) INCOME PRO FORMA TO EXCLUDE AMORTIZATION OF GOODWILL AND WORKFORCE-IN-PLACE:</b>	<b>\$ (18,308)</b>	<b>\$ (13,868)</b>	<b>\$ 9,069</b>	<b>\$ (5,886)</b>
<b>NET (LOSS) INCOME PER SHARE PRO FORMA TO EXCLUDE AMORTIZATION OF GOODWILL AND WORKFORCE-IN-PLACE:</b>				
Basic	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)
Diluted	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	102,064	89,139	102,064	89,139
Diluted	102,064	89,139	102,245	89,139

See Notes to Consolidated Financial Statements



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**  
(In thousands)

	Nine Months Ended September 30,	
	2002	2001
<b>OPERATING ACTIVITIES:</b>		
Net Income (Loss)	\$ 9,069	\$ (44,500)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	2,168	37,170
Purchased in-process research and development	13,334	
Amortization of deferred financing costs	290	1,165
Accretion of promissory notes	4,627	3,771
Deferred income taxes	(14,304)	(1,100)
Compensation related to stock options	40,406	37,253
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(25,874)	(1,107)
Inventories	(5,493)	9,489
Other assets	925	(2,049)
Accounts payable	16,272	5,515
Accrued expenses	42,639	8,473
Income taxes payable	(845)	(2,364)
Other liabilities		16,266
Net cash provided by operating activities	83,214	67,982
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(2,221)	(4,928)
Acquisition of BML Pharmaceuticals	(14,190)	
Net cash used in investing activities	(16,411)	(4,928)
<b>FINANCING ACTIVITIES:</b>		
Repayments of long-term debt	(118,889)	(32,941)
Exercise of Endo Pharmaceuticals Holdings Inc. stock options	4	
Repurchase of Class A Transferable and Class B Non-Transferable Warrants	(6,730)	
Net cash used in financing activities	(125,615)	(32,941)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(58,812)	30,113
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	95,357	59,196
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 36,545	\$ 89,309
<b>SUPPLEMENTAL INFORMATION:</b>		
Interest Paid	\$ 430	\$ 6,622
Income Taxes Paid	\$ 27,479	\$ 2,189
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Promissory Note issued under Manufacturing & Supply Agreement	\$ 23,000	\$ 21,301
Adjustment to fair value of net assets acquired in the Algos merger due to lease termination		\$ 3,131

See Notes to Consolidated Financial Statements.



**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2002**

**1. CONSOLIDATED FINANCIAL STATEMENTS**

In the opinion of management, the accompanying condensed consolidated financial statements of Endo Pharmaceuticals Holdings Inc. (the Company or we ) and its subsidiaries, which are unaudited, include all normal and recurring adjustments necessary to present fairly the Company's financial position as of September 30, 2002 and the results of operations and cash flows for the periods presented. The accompanying consolidated balance sheet as of December 31, 2001 is derived from the Company's audited financial statements. Certain information and footnote disclosure normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted as promulgated by Accounting Principles Board Opinion No. 28 and Rule 10.01 of Regulation S-X under the Securities Act of 1933. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto as of and for the year ended December 31, 2001 contained in the Company's Annual Report on Form 10-K. Certain reclassifications have been made to the prior period's financial statements to conform with the classifications used in 2002.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In June 1998, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 133, Accounting for Derivative Instruments and Hedging Activities, which was effective for all fiscal years beginning after June 15, 2000. SFAS No. 133, as amended by SFAS No. 137 and SFAS No. 138, establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities. All derivatives, whether designated in hedging relationships or not, are required to be recorded on the balance sheet at fair value. If the derivative is designated in a fair value hedge, the changes in the fair value of the derivative and the hedged item are recognized in earnings. If the derivative is designated as a cash flow hedge, changes in the fair value of the derivative are recorded in other comprehensive income (OCI) and are recognized in the income statement when the hedged item affects earnings. SFAS No. 133 defines new requirements for designation and documentation of hedging relationships as well as ongoing effectiveness assessments in order to use hedge accounting. A derivative that does not qualify as a hedge is marked to fair value through earnings.

At January 1, 2001, we recorded \$228,000 as an accumulated transition adjustment as a reduction to earnings.

In June 2001, the FASB, issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 was effective for all business combinations completed after June 30, 2001. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. SFAS No. 141 requires that all business combinations be accounted for under the purchase method only and that certain acquired intangible assets in a business combination be recognized as assets apart from goodwill. SFAS No. 142 establishes revised reporting requirements for goodwill and other intangible assets. See notes 3 and 9 to the consolidated financial statements.

**Table of Contents****3. GOODWILL AND OTHER INTANGIBLES**

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, and will no longer amortize goodwill and workforce in place.

Our goodwill and other intangible assets consist of the following (in thousands):

	<b>September 30, 2002</b>	<b>December 31, 2001</b>
Goodwill	\$ 181,079	\$ 182,318
Amortizable Intangibles:		
Licenses	\$ 11,000	\$ 11,000
Patents	3,200	3,200
	14,200	14,200
Less accumulated amortization	(2,260)	(1,705)
Other Intangibles, net	\$ 11,940	\$ 12,495

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of DuPont Pharmaceuticals Company ( DuPont , formerly The DuPont Merck Pharmaceutical Company, DuPont Merck Pharma and Endo Laboratories, L.L.C.) and the July 17, 2000 acquisition of Algos Pharmaceutical Corporation ( Algos ). Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and will be evaluated as such for goodwill impairment. Goodwill will be evaluated for impairment on an annual basis on January 1<sup>st</sup> of each year unless events or circumstances indicate that an impairment has occurred between annual dates. Goodwill has been evaluated for impairment upon the adoption of SFAS No. 142 and no impairment has been identified.

Effective January 1, 2002, the carrying amount of workforce-in-place was reclassified as goodwill. The cost of license fees is capitalized and is being amortized on a straight-line basis over their estimated useful life of twenty years. The cost of acquired patents is capitalized and is being amortized on a straight-line basis over their estimated useful life of seventeen years.

The pro forma effect of the adoption of SFAS No. 141 and SFAS No. 142 is as follows:

	<b>(Unaudited) Three Months Ended September 30,</b>		<b>(Unaudited) Nine Months Ended September 30,</b>	
	<b>2002</b>	<b>2001</b>	<b>2002</b>	<b>2001</b>
	<b>(in thousands, except per share data)</b>			
Reported net (loss) income	\$(18,308)	\$(32,993)	\$9,069	\$(44,500)
Add back: Goodwill amortization		10,225		30,675
Add back: Amortization of workforce-in-place		1,487		4,461
Add back: Pro forma income tax benefit		7,413		3,478
Adjusted net (loss) income	\$(18,308)	\$(13,868)	\$9,069	\$( 5,886)
<b>Basic earnings (loss) per share:</b>				
Reported net (loss) income	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
Add back: Goodwill amortization		.11		.34



**Table of Contents**

	(Unaudited) Three Months Ended September 30,		(Unaudited) Nine Months Ended September 30,	
	2002	2001	2002	2001
(in thousands, except per share data)				
Add back: Amortization of workforce-in-place		.02		.05
Add back: Pro forma income tax benefit		.08		.04
Adjusted net (loss) income	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)
<b>Diluted earnings (loss) per share:</b>				
Reported net (loss) income	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
Add back: Goodwill amortization		.11		.34
Add back: Amortization of workforce-in-place		.02		.05
Add back: Pro forma income tax benefit		.08		.04
Adjusted net (loss) income	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2001 is as follows (in thousands):

2002	\$ 741
2003	741
2004	741
2005	741
2006	741

**4. COMPENSATION RELATED TO STOCK OPTIONS****Endo Pharma LLC 1997 Executive and Employee Stock Option Plans**

On November 25, 1997, the Company established the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, the 1997 Stock Option Plans). Pursuant to the recapitalization of the Company which took place on July 17, 2000 in connection with our acquisition of Algos (the Recapitalization), the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC Amended and Restated 1997 Employee Stock Option Plan and the Endo Pharma LLC Amended and Restated 1997 Executive Stock Option Plan (collectively, the Endo Pharma LLC 1997 Stock Option Plans) reserve an aggregate of 25,615,339 shares of Common Stock of the Company held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest) for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire no later than December 31, 2012 unless an initial public offering of the Company Common Stock held by Endo Pharma LLC occurs, in which case the stock options granted will expire on August 26, 2007. The effect of the Recapitalization has been reflected in the accompanying financial statements. Subsequent to the July 17, 2000 acquisition of Algos, the exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans does not result in the issuance of additional shares in the Company.

The Class C stock options vest in four discrete tranches contingent upon (i) the Common Stock of the Company exceeding a defined closing price threshold for ninety consecutive trading days, (ii) the closing price of the Common Stock of the Company on the last trading day of such ninety consecutive trading day period being greater than or equal to 85% of the defined closing price and (iii) the holder being a director, officer or employee of the Company or any of its subsidiaries on such date. The defined closing price thresholds are as follows:

**Table of Contents**

Option Class	MorphiDex® is Approved On or Prior to December 31, 2002	MorphiDex® is Not Approved On or Prior to December 31, 2002
	Common Stock Closing Price Threshold	Common Stock Closing Price Threshold
C1A and C1B	\$ 6.06	\$ 4.28
C2	\$ 9.38	\$ 6.62
C3	\$ 14.99	\$ 10.58
C4	\$ 24.50	\$ 17.29

If each of these share price targets are achieved resulting in the vesting of each tranche of options, the Company will record non-cash compensation charges related to such vesting. Under performance-based options, the measurement of expense is recorded as a non-cash charge at the time performance is achieved and is calculated as the difference between the market price of the stock and the exercise price of the options. If these charges are recorded by the Company in connection with the above options, they will be significant. They will, however, not result in the issuance of additional shares of Company Common Stock. The aforementioned conditions have been achieved for the Class C1A, Class C1B and Class C2 stock options, and therefore these stock options have vested. Accordingly, a non-cash compensation charge of \$15.3 million was recorded in the fourth quarter of 2000 for the vesting of the Class C1A and Class C1B stock options, and a non-cash compensation charge of \$37.3 million was recorded in the third quarter of 2001 for the vesting of the Class C2 stock options.

As indicated in the table above, if the U.S. Food and Drug Administration (the FDA) does not approve MorphiDex(®) for any pain indication prior to December 31, 2002, the Common Stock Closing Price Threshold for the Endo Pharma LLC 1997 Stock Option Plans will be adjusted which will result in the vesting of the outstanding Class C3 stock options. This does not result, however, in the issuance of additional shares of Company Common Stock. Under performance-based options, the measurement of expense is recorded as a non-cash charge at the time performance is achieved and is calculated as the difference between the market price of the stock and the exercise price of the options. As previously disclosed, the Company does not believe that MorphiDex(®) will be approved by the FDA for any pain indication prior to December 31, 2002. Accordingly, the Company recorded a non-cash compensation charge of \$40.4 million in the third quarter of 2002 for the probable vesting of the Class C3 stock options. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter when the actual vesting event occurs based on the then market price of the stock. See note 8 to the consolidated financial statements.

The Class C1A, C1B, C2, C3 and C4 stock options are generally exercisable, if vested, upon the earlier of (i) the occurrence of a sale, disposition or transfer of Common Stock, after which neither Kelso & Company nor Endo Pharma LLC any longer own any shares of Common Stock or (ii) January 1, 2006.

**Endo Pharma LLC 2000 Supplemental Executive and Employee Stock Option Plans**

Pursuant to the Merger and Recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of Common Stock of the Company held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are only effective on January 1, 2003 in the event that we have not received the approval from the FDA for MorphiDex(®) for any pain indication prior to December 31, 2002. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire no later than December 31, 2012 unless an initial public offering of the Company Common Stock held by Endo Pharma LLC occurs, in which case the stock options granted will expire on August 26, 2007. The exercise of stock options pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans does not result in the issuance of additional shares in the Company; however, the issuance of

## **Table of Contents**

these stock options and/or attainment of defined common stock price targets may result in additional non-cash compensation charges to the Company. These charges may be substantial. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are not currently effective, therefore no options have been granted. See note 8 to the consolidated financial statements.

### **Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan**

All the options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our stock on the date granted and, under accounting principles generally accepted in the United States, a measurement date had occurred on the date of grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

## **5. WARRANTS**

### **Class A Transferable Warrants and Class B Non-Transferable Warrants**

The Class A Transferable Warrants and Class B Non-Transferable Warrants are exercisable at an exercise price of \$.01 per share into a specified number of shares of Common Stock depending on the timing of the FDA's approval of MorphiDex® for one or more pain indications. If the FDA approves MorphiDex® for any pain indication on or before March 31, 2003, these warrants become exercisable on the fifth business day following the date on which we receive such approval. These warrants will remain exercisable for a period of six months after the exercisability date, at which time they will expire. If the FDA does not approve MorphiDex® by March 31, 2003, each of these warrants expires without any payment therefor. See note 8 to the consolidated financial statements.

If the FDA approves MorphiDex® on or prior to March 31, 2003, then upon exercise of these warrants, each warrant will be exercisable into 0.263158 shares of Common Stock. If the FDA does not approve MorphiDex® before March 31, 2003, each of these warrants becomes void and all rights in respect of these warrants will cease. See note 8 to the consolidated financial statements.

On December 5, 2001, we commenced a tender offer to purchase up to 13,500,000 of our outstanding Class A Transferable Warrants and any and all of our outstanding Class B Non-Transferable Warrants. This tender offer expired at midnight on January 25, 2002. As of December 31, 2001, there were outstanding 17,810,526 of these warrants. We accepted an aggregate of 8,585,262 Class A Transferable Warrants and Class B Non-Transferable Warrants for payment at a purchase price of \$0.75 per warrant. We used cash on hand to finance the purchase of the tendered warrants. Following the purchase by us, there are outstanding 9,225,264 of these warrants. See note 8 to the consolidated financial statements.

### **Pre-Merger Endo Warrants**

The warrants issued to Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest) in connection with the Merger are exercisable at an exercise price of \$.01 per share into a specified number of shares of Common Stock if the FDA does not approve MorphiDex® for any pain indication prior to December 31, 2002. As of September 30, 2002, there were outstanding 71,328,424 of these warrants. If the FDA does not approve MorphiDex® before December 31, 2002, then these warrants become exercisable and upon exercise, each warrant will be exercisable into 0.416667 shares of Common Stock for a total of 29,720,177 shares of Common Stock. See note 8 to the consolidated financial statements.

## **6. RELATED PARTY TRANSACTIONS**

On July 14, 2000, Endo Pharma LLC was formed to ensure that the stock options granted pursuant to the 1997 Employee Stock Option Plan and the 1997 Executive Stock Option Plan (collectively, as amended and restated, the Endo Pharma LLC 1997 Stock Option Plans) diluted only the pre-Merger holders of Endo Common Stock (see note 4 to the consolidated financial statements). Subsequent to the Merger, only currently outstanding shares of Common Stock of the Company held by Endo Pharma LLC will be issued upon the exercise of these stock options.

## **Table of Contents**

Because Endo Pharma LLC, and not the Company, will provide the shares issued upon the exercise of the options, the Company has entered into a tax sharing agreement with Endo Pharma LLC under which the Company will pay to Endo Pharma LLC the amount of the tax benefits it receives as a result of the exercise of these stock options into shares of Common Stock held by Endo Pharma LLC for the years in which these tax benefits arise. As of September 30, 2002, approximately 1.1 million of these stock options have been exercised into shares of Common Stock held by Endo Pharma LLC by former employees. These stock option exercises may permit the Company to deduct for income tax purposes compensation of approximately \$8 million, which may result in a tax benefit amount of approximately \$3 million. Under the terms of the tax sharing agreement discussed above, the Company must pay any such tax benefit amounts to Endo Pharma LLC only upon the occurrence of a liquidity event, which is generally defined as (a) a sale of greater than 20% on a fully diluted basis of the common equity of the Company (either through a primary offering by the Company or a secondary sale by Endo Pharma LLC or a combination of both), (b) a change in control of the Company or (c) a sale of all or substantially all of the assets of the Company. In accordance with the tax sharing agreement, no payments have been made or accrued.

## **7. COMMITMENTS AND CONTINGENCIES**

We have entered into employment agreements with certain members of management.

We have entered into certain collaboration agreements with third parties for the development of pain management products. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If any of our third party partners are unable to fund their portion of the particular collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

As described in note 9 to the consolidated financial statements, upon FDA approval of BML's lead pipeline product, Immunol<sup>TM</sup>, we will pay the former shareholders of BML a \$32 million payment and an earn-out based on a percentage of net sales of certain products in BML's pipeline.

As described in note 10 to the consolidated financial statements, we entered into a license agreement ( License Agreement ) with DURECT Corporation ( DURECT ) to develop and commercialize DURECT's CHRONOGESIC (sufentanil) Pain Therapy System for the U.S. and Canada. Once CHRONOGESIC's clinical trials have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the CHRONOGESIC's ongoing development costs. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to \$52.0 million. In addition, the License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, the License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT \$10.0 million.

We are, and may in the future be, subject to various claims or legal proceedings arising out of the normal course of business with respect to commercial matters, including product liabilities, patent infringement matters, governmental regulation and other actions. We cannot predict the timing or outcome of these claims or proceedings. Currently, the Company is not involved in any claim and/or legal proceeding with respect to which the amount of ultimate liability will, in the opinion of management, materially affect our financial position, results of operations or liquidity.

## **8. OTHER EVENTS**

On June 24, 2002, we announced the results from the first of our three Phase III clinical trials for our development product, MorphiDex®. No statistically significant difference in average daily morphine dose was observed in the morphine sulfate:dextromethorphan group compared to the morphine sulfate group. In addition, we observed no statistically significant difference in the percentage change from baseline in daily morphine dose averaged by week from the commencement of the double-blind study period to the completion of the double-blind study period.

## **Table of Contents**

On October 28, 2002, we announced the results from the second of our three Phase III clinical trials for our development product, Morphidex®. No statistically significant difference in analgesia was observed in the Morphidex® group compared to the morphine sulfate alone group. In addition, the study did not meet its secondary endpoint, a reduction in analgesic tolerance for patients administered Morphidex®.

While we expect to be able to announce the results of the third of these clinical trials in the fourth quarter of this year, the Company believes that the data that has been generated to date would suggest that we will not have enough evidence to support the filing of an amendment to the Morphidex® New Drug Application. Accordingly, it is not likely Morphidex® will receive FDA approval prior to December 31, 2002.

As a result:

As described in note 5 to the consolidated financial statements in this Report, the warrants held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest) will become exercisable on December 31, 2002 into 29,720,177 shares of Company Common Stock, thereby increasing Endo Pharma LLC's ownership of the Company from approximately 68.5% to approximately 75.6%;

As described in note 4 to the consolidated financial statements in this Report, during the 2002 third quarter, we recorded a non-cash compensation charge of \$40.4 million for the probable vesting of the outstanding Class C3 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter when the actual vesting event occurs based on the then market price of the stock. Neither the vesting nor the exercise of these stock options will result, however, in the issuance of additional shares of Company Common Stock because these stock options are exercisable only into shares of Company Common Stock that are held by Endo Pharma LLC. Accordingly, these stock options will not dilute the public shareholders;

In addition, as described in note 4 to the consolidated financial statements in this Report, the Endo Pharma LLC 2000 Supplemental Stock Option Plans will become effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management on such date, approximately 9.2 million of which will be vested upon their issuance resulting in a significant non-cash compensation charge to the Company. These stock options will not result, however, in the issuance of additional shares of Company Common Stock because these stock options are exercisable only into shares of Company Common Stock that are held by Endo Pharma LLC. Accordingly, these stock options will not dilute the public shareholders. The weighted average exercise price of these options is \$2.42 per share; and

Finally, if Morphidex® is not approved prior to March 31, 2003, the Class A Transferable Warrants and Class B Non-Transferable Warrants will expire and have no economic value.

## **9. BML ACQUISITION**

On July 29, 2002, our wholly owned subsidiary, Endo Pharmaceuticals Inc., acquired BML Pharmaceuticals, Inc. ( BML ), a privately held company, for an up-front payment of \$14 million. In addition, upon FDA approval of BML's lead pipeline product, Immuno™, Endo Pharmaceuticals Inc. will pay the former shareholders of BML a \$32 million payment and an earn-out based on a percentage of net sales of certain products in BML's pipeline. BML will operate as a wholly owned subsidiary of Endo Pharmaceuticals Inc. We have accounted for the acquisition using the purchase method of accounting. In accordance with the purchase method of accounting, the purchase price is allocated to BML's assets and liabilities based on their respective fair values on the date of the acquisition. The acquisition included an on-going project to research and develop a new pharmaceutical product. Based on preliminary estimates, the allocation of the fair value of the assets acquired and liabilities assumed included an allocation to purchased in-process research and development ( IPRD ) of \$13.3 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The Company expects to finalize the purchase price allocation in the fourth quarter of 2002, which may result in an adjustment to the preliminary allocation. The assets acquired and liabilities assumed, results of operations and cash flows of BML have been

**Table of Contents**

included in the Company's financial statements and Management's Discussion and Analysis of Financial Conditions and Results of Operations prospectively for reporting periods beginning July 29, 2002.

**10. CHRONOGESIC™ LICENSE AGREEMENT**

On November 8, 2002, our wholly owned subsidiary, Endo Pharmaceuticals Inc., entered into a Development, Commercialization and Supply License Agreement ( License Agreement ) with DURECT Corporation ( DURECT ). Under the terms of the agreement we have agreed to collaborate on the development and commercialization of DURECT's CHRONOGESIC™ (sufentanil) Pain Therapy System for the U.S. and Canada. Under the terms of the agreement, we will have no obligation to fund any of the development costs until the clinical trials are restarted (which are currently anticipated to begin in the second half of 2003). In the event that the clinical trials have not restarted by December 31, 2003, then during the six-month period from January 1, 2004 until the earlier of (a) the recommencement of the clinical trials and (b) June 30, 2004, we will be responsible for 25% of the development costs actually incurred each month, up to an aggregate of \$3.0 million of development costs for such period.

Once the CHRONOGESIC's clinical trials have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the CHRONOGESIC's ongoing development costs. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to \$52.0 million.

In addition, under the License Agreement, DURECT licensed to Endo the exclusive promotional rights to the Product in the U.S. and Canada. Endo will be responsible for marketing, sales and distribution, including providing specialty sales representatives dedicated to supplying technical and training support. DURECT will be responsible for the manufacture of the Product. Endo and DURECT will share profits equally, based on projected financial performance of the Product.

Further, the License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, the License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT \$10.0 million.

Finally, in connection with the License Agreement, Endo has purchased approximately 1.5 million newly issued common shares of DURECT for approximately \$5.0 million, representing approximately 3% of DURECT's outstanding common stock.

## **Table of Contents**

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

Except for the historical information contained in this Report, this Report, including the following discussion, contains forward-looking statements that involve risks and uncertainties.

#### **Overview**

We, through our wholly owned subsidiary, Endo Pharmaceuticals Inc., are engaged in the research, development, sales and marketing of branded and generic prescription pharmaceuticals used primarily for the treatment and management of pain. Branded products comprised approximately 76%, 67% and 62% of net sales for the years ended December 31, 2000, 2001 and the nine months ended September 30, 2002, respectively. On August 26, 1997, an affiliate of Kelso & Company and the then members of management entered into an asset purchase agreement with the then DuPont Merck Pharmaceutical Company to acquire certain branded and generic pharmaceutical products and exclusive worldwide rights to a number of new chemical entities in the DuPont research and development pipeline from DuPont Merck through the newly-formed Endo Pharmaceuticals Inc.

On July 17, 2000, we completed our merger with Algos Pharmaceutical Corporation ( Algos ). In the merger, we issued to the former Algos stockholders, in the aggregate, 17,810,526 shares of our common stock and 17,810,526 warrants to purchase in the aggregate up to 20,575,507 additional shares of our common stock in certain circumstances as more fully described under notes 5 and 8 to the consolidated financial statements in this Report. In the merger, we also issued to our pre-merger stockholders, in the aggregate, 71,328,424 warrants to purchase in the aggregate up to 29,720,177 additional shares of common stock in certain other circumstances as more fully described under notes 5 and 8 to the consolidated financial statements in this Report.

The stock of Endo Pharmaceuticals Inc. is our only asset, and we have no other operations or business.

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., whereby Novartis has agreed to manufacture certain of our commercial products and products in development. We have incurred and expect to continue to incur significant costs associated with the preparation of Novartis' manufacturing operations under this agreement. These costs primarily relate to the preparation of test batches of drug product for FDA approval and our own quality assessment and administrative costs relating to the shifting of existing production to Novartis.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products and the impact of competitive products and pricing.

#### **Critical Accounting Policies**

To understand our financial statements, it is important to understand our accounting policies. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States (generally accepted accounting principles) requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. We believe, however, that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on our consolidated results of operations, financial position or cash flows for the periods represented in this Report.

Our most critical accounting policies include the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses, the utilization of deferred tax assets and the assessment of impairment of goodwill and other intangible assets. Note 2 to our consolidated financial statements contained in our Annual Report on Form 10-K describes our significant accounting policies.

**Table of Contents****Results of Operations***Goodwill and Other Intangibles*

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets and will no longer amortize goodwill and workforce in place.

Goodwill represents a significant portion of our assets and stockholders' equity. As of September 30, 2002, goodwill comprised approximately 40% of our total assets and 54% of our stockholders' equity. We assess the potential impairment of goodwill by comparing the fair value of goodwill to its carrying value for our one reporting unit. An impairment loss would be recognized when the estimated fair value is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of DuPont Pharmaceuticals Company ( DuPont Pharmaceuticals , formerly The DuPont Merck Pharmaceutical Company, DuPont Merck Pharma and Endo Laboratories, L.L.C.) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and will be evaluated as such for goodwill impairment. Goodwill will be evaluated for impairment on an annual basis on January 1<sup>st</sup> of each year unless events or circumstances indicate that an impairment has occurred between annual dates. Goodwill has been evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit, no impairment has been identified.

Our goodwill and other intangible assets consist of the following (in thousands):

	<b>September 30,2002</b>	<b>December 31, 2001</b>
Goodwill	\$ 181,079	\$ 182,318
Amortizable Intangibles:		
Licenses	\$ 11,000	\$ 11,000
Patents	3,200	3,200
	14,200	14,200
Less accumulated amortization	(2,260)	(1,705)
Other Intangibles, net	\$ 11,940	\$ 12,495

Effective January 1, 2002, we reclassified the carrying amount of workforce-in-place as goodwill. The cost of license fees is capitalized and is being amortized on a straight-line basis over their estimated useful life of twenty years. The cost of acquired patents is capitalized and is being amortized on a straight-line basis over their estimated useful life of seventeen years.

**Table of Contents**

The pro forma effect of the adoption of SFAS No. 141 and SFAS No. 142 is as follows:

	(Unaudited) Three Months Ended September 30,		(Unaudited) Nine Months Ended September 30,	
	2002	2001	2002	2001
(in thousands, except per share data)				
Reported net (loss) income	\$ (18,308)	\$ (32,993)	\$ 9,069	\$ (44,500)
Add back: Goodwill amortization		10,225		30,675
Add back: Amortization of workforce-in-place		1,487		4,461
Add back: Pro forma income tax benefit		7,413		3,478
Adjusted net (loss) income	\$ (18,308)	\$ (13,868)	\$ 9,069	\$ (5,886)
<b>Basic earnings (loss) per share:</b>				
Reported net (loss) income	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
Add back: Goodwill amortization		.11		.34
Add back: Amortization of workforce-in-place		.02		.05
Add back: Pro forma income tax benefit		.08		.04
Adjusted net (loss) income	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)
<b>Diluted earnings (loss) per share:</b>				
Reported net (loss) income	\$ (.18)	\$ (.37)	\$ .09	\$ (.50)
Add back: Goodwill amortization		.11		.34
Add back: Amortization of workforce-in-place		.02		.05
Add back: Pro forma income tax		.08		.04
Adjusted net (loss) income	\$ (.18)	\$ (.16)	\$ .09	\$ (.07)

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2001 is as follows (in thousands):

2002	\$741
2003	741
2004	741
2005	741
2006	741

**Compensation Related to Stock Options**

During our fourth quarter ended December 31, 2000, we incurred a non-cash charge of \$15.3 million, and during our third quarter ended September 30, 2001, we recorded a non-cash charge of \$37.3 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC stock option plans. In addition, during our third quarter ended September 30, 2002, we recorded a non-cash compensation charge of \$40.4 million for the probable vesting of the Class C3 stock options. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter of 2002 when the vesting event actually occurs based on the then market price of the stock. Under these plans, tranches of options vest when we attain certain stock price targets. As each tranche vests, we incur a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. We may in the future incur additional charges in relation to the Endo Pharma LLC options as a result of the attainment of other common stock price targets. These charges may be substantial. These options are exercisable into shares of common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock.

**Table of Contents**

In connection with the Algos merger and our related recapitalization on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Employee Stock Option Plan and the Endo Pharma LLC 2000 Supplemental Executive Stock Option Plan (collectively, the Endo Pharma LLC 2000 Supplemental Stock Option Plans ) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are only effective on January 1, 2003 in the event that we have not received the approval from the FDA of MorphiDex® for the treatment of pain by December 31, 2002. The exercise of stock options pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans does not result in the issuance of additional shares in the Company, however, the issuance of these stock options and/or attainment of defined common stock price targets may result in additional non-cash compensation charges to the Company. These charges may be substantial. The Endo Pharma LLC 2000 Supplemental Stock Option Plans are not currently effective, therefore no options have been granted.

All the options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan have exercise prices equal to the market price of our stock on the date granted and, under accounting principles generally accepted in the United States, a measurement date had occurred on the date of grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

*Other Events*

On June 24, 2002, we announced the results from the first of our three Phase III clinical trials for our development product, MorphiDex®. No statistically significant difference in average daily morphine dose was observed in the morphine sulfate:dextromethorphan group compared to the morphine sulfate group. In addition, we observed no statistically significant difference in the percentage change from baseline in daily morphine dose averaged by week from the commencement of the double-blind study period to the completion of the double-blind study period.

On October 28, 2002, we announced the results from the second of our three Phase III clinical trials for our development product, MorphiDex®. No statistically significant difference in analgesia was observed in the MorphiDex® group compared to the morphine sulfate alone group. In addition, the study did not meet its secondary endpoint, a reduction in analgesic tolerance for patients administered MorphiDex®.

While we expect to be able to announce the results of the third of these clinical trials in the fourth quarter of this year, the Company believes that the data that has been generated to date would suggest that we will not have enough evidence to support the filing of an amendment to the MorphiDex® New Drug Application. Accordingly, it is not likely MorphiDex® will receive FDA approval prior to December 31, 2002. As a result:

As described under note 5 to the consolidated financial statements in this Report, the warrants held by Endo Pharma LLC (an affiliate of Kelso & Company in which certain members of management have an interest) will become exercisable on December 31, 2002 into 29,720,177 shares of Company common stock, thereby increasing Endo Pharma LLC's ownership of the Company from approximately 68.5% to approximately 75.6%;

As described under note 4 to the consolidated financial statements in this Report, during the 2002 third quarter, we recorded a non-cash compensation charge of \$40.4 million for the probable vesting of the outstanding Class C3 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter when the actual vesting event occurs based on the then market price of the stock. Neither the vesting nor the exercise of these stock options will result, however, in the issuance of additional shares of Company common stock because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, these stock options will not dilute the public shareholders;

**Table of Contents**

In addition, as described under note 4 to the consolidated financial statements in this Report, the Endo Pharma LLC 2000 Supplemental Stock Option Plans will become effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management on such date, approximately 9.2 million of which will be vested upon their issuance resulting in a significant non-cash compensation charge to the Company. These stock options will not result, however, in the issuance of additional shares of Company common stock because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, these stock options will not dilute the public shareholders. The weighted average exercise price of these options is \$2.42 per share; and

Finally, if MorphiDex® is not approved prior to March 31, 2003, the Class A Transferable Warrants and Class B Non-Transferable Warrants will expire and have no economic value.

*Net Sales*

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, rebates, sales incentives and allowances, royalties and the cost of returns and losses. We estimate the accrual for sales deductions based on historical data, estimated future trends and other competitive factors. Net sales are recognized when products are shipped.

The following table presents our unaudited net sales by product category for the three months and nine months ended September 30, 2002 and 2001.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
(in thousands, unaudited)				
Percocet®	\$ 36,585	\$ 16,430	\$ 100,663	\$ 72,831
Lidoderm®	24,080	16,268	59,916	26,993
Other brands	6,048	8,087	15,669	16,678
Total brands	\$ 66,713	\$ 40,785	\$ 176,248	\$ 116,442
Total generics	\$ 43,841	\$ 25,483	\$ 109,234	\$ 57,065
Total net sales	\$ 110,554	\$ 66,268	\$ 285,482	\$ 173,507

The following table presents our unaudited net sales of select products as a percentage of total net sales for the three months and nine months ended September 30, 2002 and 2001.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
(unaudited)				
Percocet®	33%	25%	35%	42%
Lidoderm®	22%	25%	21%	16%
Other brands	5%	12%	6%	9%
Total brands	60%	62%	62%	67%
Total generics	40%	38%	38%	33%
Total net sales	100%	100%	100%	100%

**Table of Contents**

*Three Months Ended September 30, 2002 Compared to the Three Months Ended September 30, 2001*

Net sales for the three months ended September 30, 2002 increased by 67% to \$110.6 million from \$66.3 million in the comparable 2001 period. This increase in net sales was primarily due to the increase in the net sales of the new strengths of Percocet®, certain generic products and Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. Percocet® net sales increased to \$36.6 million from \$16.4 million in the comparable 2001 period due to the new strengths of Percocet® launched in November 2001. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325 which do not currently have generic equivalents. Net sales of our generic products increased 72% to \$43.8 million from \$25.5 million in the comparable 2001 period primarily due to the growth of our generic morphine sulfate extended release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended release tablets. These products continue to gain market share. In April 2001, we launched two new strengths of our generic product Endocet®. Net sales of Lidoderm® increased to \$24.1 million from \$16.3 million in the comparable 2001 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

Gross profit for the three months ended September 30, 2002 increased by 89% to \$86.2 million from \$45.6 million in the comparable 2001 period. Gross profit margins increased to 78% from 69% due to a more favorable mix of higher margin brand and generic products resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also due to the existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits to continue.

Selling, general and administrative expenses for the three months ended September 30, 2002 increased by 47% to \$28.8 million from \$19.6 million in the comparable 2001 period. This increase was due to a \$5.3 million increase in sales and promotional efforts in 2002 over the comparable 2001 period to support Lidoderm® and Percocet®. In addition, we experienced an increase in costs in the general and administrative functions in order to support our new product marketing and new product development.

Research and development expenses for the three months ended September 30, 2002 increased by 95% to \$15.4 million from \$7.9 million in the comparable 2001 period. This increase was due to our increased spending on new products under development that are focused in pain management. During the third quarter, we were conducting Phase III clinical trials on MorphoDex® and on both an oral extended-release and oral immediate-release version of oxymorphone.

Depreciation and amortization for the three months ended September 30, 2002 decreased to \$.7 million from \$12.4 million in the comparable 2001 period. Effective January 1, 2002, we have adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, and will no longer amortize goodwill unless evidence of an impairment exists. If SFAS No. 142 had been adopted as of January 1, 2001, depreciation and amortization for the three months ended September 30, 2001 would have been \$.7 million.

Compensation related to stock options increased to \$40.4 million from \$37.3 million in the comparable 2001 period. During the three months ended September 30, 2002, the Company recorded a non-cash compensation charge of \$40.4 million for the probable vesting of the outstanding Class C3 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter of 2002 when the vesting event actually occurs based on the then market price of the stock. During the three months ended September 30, 2001, the Company recorded a non-cash compensation charge of \$37.3 million arising from the vesting of the outstanding Class C2 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under these plans, tranches of options vest when the Company attains certain common stock price targets. As each tranche vests, the Company incurs a non-cash charge representing the

**Table of Contents**

difference between the market price of the shares of common stock underlying the options and the exercise price of such options. The Company may in the future incur additional charges in relation to the Endo Pharma LLC options. These charges may be substantial. These options are exercisable into shares of common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock and will not dilute the public stockholders of Endo.

Purchased in-process research and development for the three months ended September 30, 2002 of \$13.3 million resulted from the preliminary estimate of fair value of the product under development that the Company acquired in its acquisition of BML Pharmaceuticals, Inc. The Company expects to finalize the purchase price allocation in the fourth quarter of 2002, which may result in an adjustment to the preliminary allocation.

Manufacturing transfer fee is the consideration paid to Bristol-Myers Squibb Pharma Company which allowed Endo to transfer up to 100% of any Endo product out of any Bristol-Myers Squibb facility at any time, and for the assistance of Bristol-Myers Squibb Pharma Company in the transfer.

Interest expense, net for the three months ended September 30, 2002 decreased by 63% to \$1.0 million from \$2.7 million in the comparable 2001 period. This decrease is substantially due to the repayment on October 29, 2001 of the term loans outstanding under our credit facility and the repayment on August 26, 2002 of promissory notes issued to Bristol-Myers Squibb. Interest expense for the three months ended September 30, 2002 substantially represents the accretion of promissory notes issued to Bristol-Myers Squibb which bore no interest and therefore had been discounted in the accompanying financial statements.

Income tax benefit for the three months ended September 30, 2002 increased to \$4.1 million from \$1.2 million in the comparable 2001 period. The preliminary estimate of the purchased in-process research development of \$13.3 million is not a tax deductible item which reduced the effective income tax benefit rate in 2002. For the three months ended September 30, 2001, we recorded a valuation allowance on our existing deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it is more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets.

*Nine Months Ended September 30, 2002 Compared to the Nine Months Ended September 30, 2001*

Net sales for the nine months ended September 30, 2002 increased by 65% to \$285.5 million from \$173.5 million in the comparable 2001 period. This increase in net sales was primarily due to the increase in net sales of certain generic products, Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and the new strengths of Percocet®. Net sales of our generic products increased 91% to \$109.2 million from \$57.1 million in the comparable 2001 period primarily due to the growth of our generic morphine sulfate extended release tablets and Endocet®. In November 1998, we launched the 15mg, 30mg and 60mg strengths, in May 2001, we launched the 100mg strength and in September 2001, we launched the 200mg strength of our generic morphine sulfate extended release tablets. These products continue to gain market share. In April 2001, we launched two new strengths of our generic product Endocet®. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of Lidoderm® increased to \$59.9 million from \$27.0 million in the comparable 2001 period. Percocet® net sales increased 38% to \$100.7 million from \$72.8 million in the comparable 2001 period due to the new strengths of Percocet® launched in November 2001. In April 2001, generic equivalents of Percocet® 7.5/500 and Percocet® 10.0/650 were introduced. In November 2001, we launched Percocet® 7.5/325 and Percocet® 10.0/325 which do not currently have generic equivalents. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

Gross profit for the nine months ended September 30, 2002 increased by 80% to \$214.4 million from \$119.2 million in the comparable 2001 period. Gross profit margins increased to 75% from 69% due to a more favorable mix of higher margin brand and generic products resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also

**Table of Contents**

due to the existing fixed cost nature of our manufacturing relationship with Bristol-Myers Squibb Pharma Company (formerly DuPont Pharmaceuticals), currently our most significant contract manufacturing relationship. If we achieve our forecast for revenue and product mix, we expect the increase in gross profits and gross profit margins to continue.

Selling, general and administrative expenses for the nine months ended September 30, 2002 increased by 46% to \$79.9 million from \$54.9 million in the comparable 2001 period. This increase was due to a \$12.9 million increase in sales and promotional efforts in 2002 over the comparable 2001 period to support Lidoderm® and Percocet®. In addition, we experienced an increase in costs in the general and administrative functions in order to support our new product marketing and new product development.

Research and development expenses for the nine months ended September 30, 2002 increased by 73% to \$43.9 million from \$25.4 million in the comparable 2001 period. This increase was due to our increased spending on new products under development that are focused in pain management. During the nine months ended September 30, 2002, we were conducting Phase III clinical trials on MorphiDex® and on both an oral extended-release and oral immediate-release version of oxymorphone.

Depreciation and amortization for the nine months ended September 30, 2002 decreased to \$2.2 million from \$37.2 million in the comparable 2001 period. Effective January 1, 2002, we have adopted the provisions of SFAS No. 142, Goodwill and Other Intangible Assets, and will no longer amortize goodwill unless evidence of an impairment exists. If SFAS No. 142 had been adopted as of January 1, 2001, depreciation and amortization for the nine months ended September 30, 2001 would have been \$2.0 million.

Compensation related to stock options increased to \$40.4 million from \$37.3 million in the comparable 2001 period. During the nine months ended September 30, 2002, the Company recorded a non-cash compensation charge of \$40.4 million for the probable vesting of the outstanding Class C3 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under variable plan accounting, this non-cash compensation charge will be adjusted during the fourth quarter of 2002 when the vesting event actually occurs based on the then market price of the stock. During the nine months ended September 30, 2001, the Company recorded a non-cash compensation charge of \$37.3 million arising from the vesting of the outstanding Class C2 stock options granted under the Endo Pharma LLC 1997 Stock Option Plans. Under these plans, tranches of options vest when the Company attains certain common stock price targets. As each tranche vests, the Company incurs a non-cash charge representing the difference between the market price of the shares of common stock underlying the options and the exercise price of such options. The Company may in the future incur additional charges in relation to the Endo Pharma LLC options. These charges may be substantial. These options are exercisable into shares of common stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of common stock and will not dilute the public stockholders of Endo.

Purchased in-process research and development for the nine months ended September 30, 2002 of \$13.3 million resulted from the preliminary estimate of fair value of the product under development that the Company acquired in its acquisition of BML Pharmaceuticals. The Company expects to finalize the purchase price allocation in the fourth quarter of 2002, which may result in an adjustment to the preliminary allocation.

Manufacturing transfer fee is the consideration paid to Bristol-Myers Squibb which allowed Endo to transfer up to 100% of any Endo product out of any Bristol-Myers Squibb facility at any time, and for BMS assistance in the transfer.

Interest expense, net for the nine months ended September 30, 2002 decreased by 53% to \$4.3 million from \$9.1 million in the comparable 2001 period. This decrease is substantially due to the repayment on October 29, 2001 of the term loans outstanding under our credit facility. Interest expense for the six months ended June 30, 2002 substantially represents the accretion of promissory notes issued to Bristol-Myers Squibb which bear no interest and therefore have been discounted in the accompanying financial statements. For the nine months ended September 30, 2001, due to the adoption of SFAS No. 133 on January 1, 2001, the Company recorded a \$.2 million charge for the accumulated transition adjustment relating to derivative instruments that do not qualify as a hedge under SFAS No. 133.

**Table of Contents**

Income tax for the nine months ended September 30, 2002 increased to \$12.3 million from an income tax benefit of \$.2 million in the comparable 2001 period. This increase is due to the increase in income before income tax for the nine months ended September 30, 2002. The preliminary estimate of the purchased in-process research development of \$13.3 million is not a tax deductible item which increased the effective income tax rate in 2002. For the nine months ended September 30, 2001, we recorded a valuation allowance on our existing deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future. During the fourth quarter of 2001, we evaluated our anticipated future taxable income based upon the repayment of our outstanding term loans, new product approvals and other existing and estimated future product performance and determined that it is more likely than not that we will utilize our deferred tax benefits. Accordingly, we reversed our valuation reserves that had been recorded against those deferred tax assets.

*Liquidity and Capital Resources*

Net cash provided by operating activities increased by \$15.2 million to \$83.2 million for the nine months ended September 30, 2002 from \$68.0 million for the nine months ended September 30, 2001. This increase was due to the cash provided by the increase in net sales and gross profit for the nine months ended September 30, 2002 compared to the nine months ended September 30, 2001 offset by an increase in selling, general and administrative expenses and research and development expenses for the nine months ended September 30, 2002 as compared to the nine months ended September 30, 2001.

Net cash utilized in investing activities increased by \$11.5 million to \$16.4 million for the nine months ended September 30, 2002 from \$4.9 million for the nine months ended September 30, 2001. During the nine months ended September 30, 2002, the Company utilized cash on hand totaling approximately \$14.2 million to purchase BML Pharmaceuticals. Capital expenditures for the nine months ended September 30, 2002 decreased by \$2.7 million to \$2.2 million from \$4.9 million in the comparable 2001 period due to the purchase in 2001 of leasehold improvements and other furniture and fixtures related to our new principal executive offices and the implementation of an electronic document management system during 2001.

Net cash utilized in financing activities increased by \$92.7 million to \$125.6 million for the nine months ended September 30, 2002 from \$32.9 million for the nine months ended September 30, 2001. During the nine months ended September 30, 2002, we repaid all of the promissory notes issued to Bristol-Myers Squibb which totaled \$118.9 million and utilized \$6.7 million of cash, including fees, to repurchase 8.6 million Class A Transferable Warrants and Class B Non-Transferable Warrants. During the nine months ended September 30, 2001, we made the scheduled principal payments on our term loans which were repaid in full on October 29, 2001.

In its annual report filed on Form 10-K for the year ended December 31, 2001, Penwest Pharmaceuticals Co., a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing one of its pipeline projects, stated that its existing capital resources, will enable Penwest to maintain currently planned operations at least through March 31, 2003. If Penwest is unable to fund their portion of the collaboration project with Endo, this may adversely affect our results of operations and cash flows in the foreseeable future.

Our cash and cash equivalents totaled \$36.5 million at September 30, 2002. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of \$75 million) will be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline projects in the event that our collaboration partners are unable to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions or licensing opportunities.

In December 2001, we amended and restated our senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters of our recent public offering. This amended and restated credit facility provided for a line of credit of \$75.0 million and a delayed draw term loan of \$25.0 million. On August 27, 2002, the delayed draw term loan of \$25.0 million expired unused. The line of credit of \$75.0 million matures December 21, 2006. Any loans outstanding under the credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, events of default and other provisions customarily found in similar agreements.

**Table of Contents**

On July 29, 2002, we announced that our wholly owned subsidiary, Endo Pharmaceuticals Inc., acquired BML Pharmaceuticals, Inc., a privately held company, for an up-front payment of \$14 million. In addition, upon FDA approval of BML's lead pipeline product, Immunō<sup>TM</sup>, Endo Pharmaceuticals Inc. will pay the former shareholders of BML a \$32 million payment and an earn-out based on a percentage of net sales of certain products in BML's pipeline.

On November 8, 2002, we entered into a license agreement ( License Agreement ) with DURECT Corporation ( DURECT ) to develop and commercialize DURECT's CHRONOGESIC<sup>TM</sup> (sufentanil) Pain Therapy System for the U.S. and Canada. Once CHRONOGESIC's clinical trials have restarted or beginning on June 30, 2004 (whichever is earlier), Endo will be obligated to fund 50% of the CHRONOGESIC's ongoing development costs. Endo will also reimburse DURECT for a portion of its prior development costs upon the achievement of certain milestones. Milestone payments made by Endo under the License Agreement could total up to \$52.0 million. In addition, the License Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, the License Agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require Endo to pay DURECT \$10.0 million.

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

During the fourth quarter of 2001, we repaid the remaining outstanding balance of our variable rate term loans. Prior to the repayment of our variable rate term loans, our primary market risk exposure was to changes in interest rates (LIBOR) on our variable rate borrowings. As of September 30, 2002, we do not have any outstanding borrowings. On December 21, 2001, we entered into a new credit facility that provided for a line of credit of \$75.0 million and a delayed draw term loan of \$25.0 million. On August 27, 2002, the delayed draw term loan of \$25.0 million expired unused. Borrowings under the \$75.0 million line of credit are variable rate borrowings. There are no amounts outstanding under the line of credit. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

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

Within 90 days prior to the filing of this Report, an evaluation was carried out by our Chief Executive Officer and Chief Financial Officer, with the assistance of other members of management, of the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 15d-14(c) under the Securities Exchange Act of 1934). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the date of such evaluation, the disclosure controls and procedures were effective in ensuring that all material information relating to the Company required to be included in the Company's reports filed or submitted under the Exchange Act was gathered, analyzed and reported or otherwise made known to them in a timely fashion. There have been no significant changes in our internal controls, or in other factors that could significantly affect these controls, subsequent to the date the evaluation was completed.

**Table of Contents**

**PART II**

**OTHER INFORMATION**

**Item 1. Legal Proceedings.**

*Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 00 Civ. 8029 (SHS) (S.D.N.Y.);  
Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 2109 (SHS) (S.D.N.Y.);  
Purdue Pharma L.P., et al. v. Endo Pharmaceuticals Inc., et al., Index No. 01 Civ. 8177 (SHS) (S.D.N.Y.)*

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue Frederick's OxyContin® (oxycodone hydrochloride extended-release tablets), 40mg strength, infringes three of its patents. This suit arose after EPI provided the plaintiffs with notice that its ANDA submission for a bioequivalent version of Purdue Frederick's OxyContin®, 40mg strength, challenged the listed patents for OxyContin® 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent versions of Purdue Frederick's OxyContin®, 10mg and 20mg strengths, infringe the same three patents. This suit arose from EPI having amended its earlier ANDA on February 9, 2001 to add bioequivalent versions of the 10mg and 20mg strengths of OxyContin®. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue Frederick's OxyContin®, 80mg strength, infringes the same three patents. This suit arose from EPI having amended its earlier ANDA on July 30, 2001 to add the bioequivalent version of the 80mg strength of OxyContin®.

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA's Orange Book as covering these strengths of OxyContin®. EPI has pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI has also counterclaimed for antitrust damages based on allegations that Purdue Frederick obtained the patents through fraud on the United States Patent and Trademark Office and is asserting them while aware of their invalidity and unenforceability. However, we cannot make any assurances as to the outcome of this patent challenge. Purdue Frederick was granted a preliminary injunction (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362 (SDNY 2000)), which decision was affirmed on appeal (*Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359 (Fed. Cir. 2001)), against a different manufacturer based on the same patents that are being asserted against us and EPI, and in the same court in which Purdue Frederick sued. We believe the defenses rejected in the preliminary injunction decision and in the appellate decision do not substantially impact the principal defenses raised by us and EPI.

*SmithKline Beecham Corporation, et al. v. Endo Pharmaceuticals Inc., Index No. 01 Civ. 5770 (E.D. Pa.)*

On November 15, 2001, SmithKline Beecham Corporation (and related companies) filed suit against EPI in the U.S. District Court for the Eastern District of Pennsylvania alleging that EPI's bioequivalent version of SmithKline's Paxil®, 40 mg strength, infringes five of its patents. The FDA accepted EPI's ANDA submission for a bioequivalent version of SmithKline's Paxil®, 40 mg strength, earlier in 2001. In this ANDA, EPI made the required Paragraph IV certification against all of the SmithKline patents listed in the FDA's Orange Book as covering Paxil®. Paxil® is indicated for the treatment of depression, obsessive compulsive disorder and panic disorder. For strategic reasons, on May 9, 2002, we submitted to the FDA a request to withdraw of this ANDA. As a result, Endo has sought to have the pending action dismissed. On August 2, 2002, the parties filed with the court a Stipulation and Consent Order dismissing this action, with each party bearing its own legal costs. On September 3, 2002, the court entered a Final Stipulation and Consent Order dismissing this action.

Litigation similar to that described above may also result from products we currently have in development, as

**Table of Contents**

well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

*Rowe, et al. v. Bayer Corp., et al.*, No. 02-1833 (E.D. La.); **In Re: PPA Products Liability Litigation**, MDL No. 1407 (W.D. Wash.);  
*Landry, et al. v. Bayer Corp., et al.*, No. 02-1835, (E.D. La.); **In Re: PPA Products Liability Litigation**, MDL No. 1407 (W.D. Wash.);  
*Everidge, et al. v. Bayer Corp., et al.*, No. 02-1834 (E.D. La.); **In Re: PPA Products Liability Litigation**, MDL No. 1407 (W.D. Wash.);  
*Ackel, et al. v. Bayer Corp., et al.*, No. 02-1831 (E.D. La.); **In Re: PPA Products Liability Litigation**, MDL No. 1407 (W.D. Wash.);  
*Ashton, et al. v. Bayer Corp., et al.*, No. 02-598 (M.D. La.); **In Re: PPA Products Liability Litigation**, MDL No. 1407 (W.D. Wash.);  
*McCullough, et al. v. American Home Products Corp., et al.*, No. CV02-1295-S (W.D. La.)

On June 17, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in four lawsuits filed by groups of 28, 34, 37, and 43 individual plaintiffs, respectively, in the United States District Court for the Eastern District of Louisiana. On June 18, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Ellen McCullough and Brenda Businelle in the United States District Court for the Western District of Louisiana. On June 21, 2002, EPI was named, along with ten other pharmaceutical companies, as a defendant in a lawsuit filed by Joyce Ashton and Bernadine Johnson in the United States District Court for the Middle District of Louisiana. According to each of these six complaints, each of the defendant pharmaceutical companies allegedly manufactured and sold products containing phenylpropanolamine (PPA). Each complaint alleges that the defendants failed to adequately warn plaintiff of the hazards of the use of the subject products containing PPA and that as a result of this failure to warn, plaintiffs suffered injury. On October 16, 2002, EPI was served with process in three of these six cases (the *Ackel*, *Landry* and *Everidge* cases). To date, EPI has not been served with a summons in *Rowe*, *McCullough*, or *Ashton*. Each of these six cases except *McCullough, et al. v. American Home Products Corp., et al.*, has been transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation, where discovery is underway. It is likely that the *McCullough* case will also be transferred to the United States District Court for the Western District of Washington at some point. EPI intends to defend itself vigorously in each of these cases.

**General**

In addition to the above, the Company is involved in, or has been involved in, arbitrations or legal proceedings that arise from the normal course of its business. The Company cannot predict the timing or outcome of these claims and proceedings. Currently, the Company is not involved in any arbitration and/or legal proceeding that it expects to have a material adverse effect on its business, financial condition or results of operations and cash flows.

**Item 2. Changes in Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None.

**Item 5. Other Information.**

None.

**Table of Contents**

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

(a) *Exhibits.*

The information called for by this item is incorporated by reference to the Exhibit Index of this Report.

(b) *Reports on Form 8-K.*

We filed the following Form 8-Ks in the quarter ended September 30, 2002:

<u>Dates</u>	<u>Items</u>
July 25, 2002	Items 7 & 9
July 31, 2002	Items 7 & 9
August 1, 2002	Items 5 & 7
August 23, 2002	Items 7 & 9
August 28, 2002	Items 5 & 7
September 17, 2002	Items 7 & 9

No financial statements were filed in connection with any such Form 8-K.

**Table of Contents**

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/S/ CAROL A. AMMON  
\_\_\_\_\_

Name: Carol A. Ammon  
Title: *Chairman and Chief Executive Officer*

/S/ JEFFREY R. BLACK  
\_\_\_\_\_

Name: Jeffrey R. Black  
Title: *Senior Vice President and Chief Financial Officer*

Date: November 14, 2002

**Table of Contents**

**CERTIFICATIONS**

I, Carol A. Ammon, as Chairman and Chief Executive Officer of the Company, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endo Pharmaceuticals Holdings Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c. Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/S/ CAROL A. AMMON  
Carol A. Ammon  
Chairman & Chief Executive Officer

**Table of Contents**

**CERTIFICATIONS**

I, Jeffrey R. Black, as Chief Financial Officer of the Company, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Endo Pharmaceuticals Holdings Inc.
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a. Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and
  - c. Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/S/ JEFFREY R. BLACK  
Jeffrey R. Black  
Chief Financial Officer

**Table of Contents****Exhibit Index**

Exhibit No.	Title
2.1	Amended and Restated Agreement and Plan of Merger, dated as of March 3, 2000 (the Merger Agreement ), by and among Endo Pharmaceuticals Holdings Inc. ( Endo ), Endo Inc. and Algos Pharmaceutical Corporation ( Algos ) (incorporated herein by reference to Exhibit 2.1 of the Registration Statement on Form S-4 of the Registrant (Registration No. 333-39040) (the Registration Statement ), filed with the Securities and Exchange Commission (the Commission ) on June 9, 2000)
2.2	Amendment, dated as of April 17, 2000, to the Merger Agreement, by and between Endo, Endo Inc. and Algos (incorporated herein by reference to Exhibit 2.2 of the Registration Statement filed with the Commission on June 9, 2000)
2.3	Asset Purchase Agreement, dated as of August 27, 1997, by and between Endo Pharmaceuticals Inc. ( Endo Pharmaceuticals ) and The DuPont Merck Pharmaceutical Company ( DuPont Merck Pharmaceutical ) (incorporated here in by reference to Exhibit 2.3 of the Registration Statement filed with the Commission on June 9, 2000)
3.1	Amended and Restated Certificate of Incorporation of Endo (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 14, 2000, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of July 14, 2000, by and among Endo, Endo LLC, KIA V, KEPV and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.3	Form of Stock Certificate of Endo Common Stock (incorporated herein by reference to Exhibit 4.3 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.1	Endo Warrant Agreement, dated as of July 17, 2000, by and

**Table of Contents**

Exhibit No.	Title
	between Endo and United States Trust Company of New York(incorporated herein by reference to Exhibit 10.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.2	Algos Warrant Agreement, dated as of July 17, 2000, by and between Endo and United States Trust Company of New York(incorporated herein by reference to Exhibit 10.2 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.3	Form of Series A Warrant to Purchase Shares of Common Stock and Warrants of Endo (incorporated herein by reference to Exhibit 10.3 of the Registration Statement filed with the Commission on June 9, 2000)
10.4	Letter Agreement, dated as of November 26, 1999, by and among Algos, Endo, KIA V and KEP V (incorporated herein by reference to Exhibit 10.4 of the Registration Statement filed with the Commission on June 9, 2000)
10.5	Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein byreference to Exhibit 10.5 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.6	[Intentionally Omitted.]
10.7	Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
10.8	[Intentionally Omitted.]
10.9	[Intentionally Omitted.]
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
10.11	Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
10.12	Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)

- 10.15 Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.16 Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and

**Table of Contents**

Exhibit No.	Title
	Mallinckrodt (incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.17	Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
10.18	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)
10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Management, Inc.(f/k/a/ Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
*10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan(incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
*10.26	Employment Agreement, dated as of July 17, 2000, by and between Endo and John W. Lyle (incorporated herein by reference to Exhibit 10.26 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 14, 2000)

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

\*10.27 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated August 31, 2001)

30

---

**Table of Contents**

Exhibit No.	Title
*10.28	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
*10.29	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
*10.30	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
10.31	Separation and Release Agreement, dated as of March 22, 2000, by and between Endo Pharmaceuticals, Endo and Osagie O. Imasogie (incorporated herein by reference to Exhibit 10.31 of the Registration Statement filed with the Commission on June 9, 2000)
10.32	Separation and Release Agreement, dated as of April 20, 2000, by and between Endo Pharmaceuticals, Endo and Louis J. Vollmer (incorporated herein by reference to Exhibit 10.32 of the Registration Statement filed with the Commission on June 9, 2000)
10.33	Office Lease, dated as of August 26, 1997, by and between Endo Pharmaceuticals and Northstar Development Company (incorporated herein by reference to Exhibit 10.33 of the Registration Statement filed with the Commission on June 9, 2000)
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
*10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
*10.36	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36 of the Current Report on Form 8-K dated August 31, 2001)
10.37	License Agreement, dated as of August 16, 1993, by and between Endo Pharmaceuticals (as successor in interest to Algos Pharmaceutical Corporation) and The Medical College of Virginia (incorporated herein by reference to Exhibit 10.4.1 of the registration statement on Form S-1 of Algos Pharmaceutical Corporation declared effective on September 25, 1996)
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the

Edgar Filing: ENDO PHARMACEUTICALS HOLDINGS INC - Form 10-Q

Form 10-Q for the Quarter Ended June 30, 2001 filed with the  
Commission on August 14, 2001)

31

---

**Table of Contents**

**Exhibit  
No.**

**Title**

---

\* A management contract or compensatory plan or arrangement required to be filed as an Exhibit pursuant to Item 14(c) of Form 10-K.