

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

November 14, 2003

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**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, 2003

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: 001-15989

**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  
(Address of Principal Executive Offices)

19317  
(Zip Code)

(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 Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES  NO

Indicate by check  whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES  NO

The aggregate number of shares of the Registrant's common stock outstanding as of November 14, 2003 was 131,769,766.



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**ENDO PHARMACEUTICALS HOLDINGS INC.**

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FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003**

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**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.

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

	September 30, 2003	December 31, 2002
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 195,430	\$ 56,902
Accounts receivable, net	126,254	119,496
Inventories	46,004	35,516
Prepaid expenses	11,923	4,354
Deferred income taxes	62,517	41,219
	<u>442,128</u>	<u>257,487</u>
PROPERTY AND EQUIPMENT, Net	13,620	11,810
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	35,096	36,755
DEFERRED INCOME TAXES	15,796	21,184
OTHER ASSETS	6,184	4,657
	<u>693,903</u>	<u>512,972</u>
<b>TOTAL ASSETS</b>		
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 56,082	\$ 75,443
Accrued expenses	122,462	68,627
Income taxes payable	3,807	8,359
	<u>182,351</u>	<u>152,429</u>
OTHER LIABILITIES	7,639	7,851
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS EQUITY</b>		
Preferred Stock, \$.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$.01 par value; 175,000,000 shares authorized; 131,765,621 and 102,064,450 issued and outstanding at September 30, 2003 and December 31, 2002, respectively	1,318	1,021
Additional paid-in capital	595,596	547,249
Accumulated deficit	(92,951)	(194,402)
Accumulated other comprehensive loss	(50)	(1,176)
	<u>503,913</u>	<u>352,692</u>
<b>Total Stockholders Equity</b>		



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TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 693,903	\$ 512,972
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See Notes to Consolidated Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
NET SALES	\$ 149,355	\$ 110,554	\$ 453,656	\$ 285,482
COST OF SALES	27,050	24,392	80,885	71,088
<b>GROSS PROFIT</b>	<b>122,305</b>	<b>86,162</b>	<b>372,771</b>	<b>214,394</b>
<b>COSTS AND EXPENSES:</b>				
Selling, general and administrative	35,764	28,753	113,681	79,898
Research and development	20,651	15,352	42,153	43,890
Depreciation and amortization	1,578	692	4,295	2,168
Compensation related to stock options Primarily selling, general and administrative		40,406	48,514	40,406
Purchased in-process research and development		13,334		13,334
Manufacturing transfer fee		9,000		9,000
<b>OPERATING (LOSS) INCOME</b>	<b>64,312</b>	<b>(21,375)</b>	<b>164,128</b>	<b>25,698</b>
INTEREST EXPENSE, Net of interest income of \$209, \$376, \$496 and \$1,024, respectively	12	1,031	165	4,302
<b>INCOME (LOSS) BEFORE INCOME TAX</b>	<b>64,300</b>	<b>(22,406)</b>	<b>163,963</b>	<b>21,396</b>
INCOME TAX (BENEFIT)	24,376	(4,098)	62,512	12,327
<b>NET INCOME (LOSS)</b>	<b>\$ 39,924</b>	<b>\$ (18,308)</b>	<b>\$ 101,451</b>	<b>\$ 9,069</b>
<b>NET INCOME (LOSS) PER SHARE:</b>				
Basic	\$ .30	\$ (.18)	\$ .80	\$ .09
Diluted	\$ .30	\$ (.18)	\$ .77	\$ .09
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic	131,761	102,064	127,288	102,064
Diluted	132,636	102,064	132,510	102,245

See Notes to Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2003	2002
<b>OPERATING ACTIVITIES:</b>		
Net Income	\$ 101,451	\$ 9,069
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,295	2,168
Purchased in-process research and development		13,334
Amortization of deferred financing costs	298	290
Accretion of promissory notes		4,627
Deferred income taxes	(16,315)	(14,304)
Compensation related to stock options	48,514	40,406
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(6,758)	(25,874)
Inventories	(10,488)	(5,493)
Other assets	(7,557)	925
Accounts payable	5,639	16,272
Accrued expenses	53,482	42,639
Income taxes payable	(4,552)	(845)
Other liabilities		
	<u>168,009</u>	<u>83,214</u>
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(4,182)	(2,221)
License fees	(25,000)	
Acquisition of BML Pharmaceuticals		(14,190)
	<u>(29,182)</u>	<u>(16,411)</u>
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(428)	
Exercise of pre-merger Endo warrants	2	4
Exercise of Endo Pharmaceuticals Holdings Inc. stock options	127	
Repayments of long-term debt		(118,889)
Repurchase of Class A Transferable and Class B Non-Transferable Warrants		(6,730)
	<u>(299)</u>	<u>(125,615)</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>138,528</b>	<b>(58,812)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>56,902</b>	<b>95,357</b>
	<u>\$ 195,430</u>	<u>\$ 36,545</u>
<b>SUPPLEMENTAL INFORMATION:</b>		
Interest Paid	\$ 287	\$ 430
Income Taxes Paid	\$ 82,891	\$ 27,479
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Promissory Note issued under Manufacturing & Supply Agreement		\$ 23,000



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**ENDO PHARMACEUTICALS HOLDINGS INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)  
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2003**

**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, 2003 and the results of operations and cash flows for the periods presented. The accompanying consolidated balance sheet as of December 31, 2002 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, 2002 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 2003.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In January 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We adopted the provisions of SFAS No. 144 on January 1, 2002, which had no material impact on our results of operations or financial position.

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 was 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 Note 3 to the Consolidated Financial Statements.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. SFAS No. 145 (1) rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, (2) rescinds SFAS No. 44 relating to the accounting for intangible assets of motor carriers, and (3) amends SFAS No. 13 relating to the accounting for leases. SFAS No. 145 also amends certain other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. Certain amounts were reclassified in accordance with SFAS No. 145 in the accompanying financial statements. The adoption of SFAS No. 145 did not have material impact on our results of operations or financial position.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 requires recognition of a liability for a cost associated with an exit or disposal activity when the liability is incurred, as opposed to when the entity commits to an exit plan under previous guidance. This statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS No. 146 did not have material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of certain guarantees, a guarantor must recognize a liability for the fair value of an obligation

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assumed under the guarantee. FIN 45 also requires significant new disclosures, in both interim and annual financial statements, by a guarantor, about obligations associated with guarantees issued. FIN 45 disclosure requirements were effective for our fiscal year ended December 31, 2002 and the initial recognition and measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. At September 30, 2003, we had no guarantees outstanding.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have not adopted the fair value based method of accounting for employee stock-based compensation.

**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):

	September 30, 2003	December 31, 2002
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 36,000	\$ 36,000
Patents	3,200	3,200
	39,200	39,200
Less accumulated amortization	(4,104)	(2,445)
Other Intangibles, net	\$ 35,096	\$ 36,755

Goodwill and other intangibles represents a significant portion of our assets and stockholders' equity. As of September 30, 2003, goodwill and other intangibles comprised approximately 31% of our total assets and 43% 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 the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos Pharmaceutical Corporation. 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 are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill was evaluated for impairment upon the adoption of SFAS No. 142 on January 1, 2002 and, based on the fair value of our reporting unit at such time, no impairment was identified. On January 1, 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit at such time, no impairment was identified.

Effective January 1, 2002, we reclassified the carrying amount of workforce-in-place as goodwill. The cost of



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license fees is capitalized and is being amortized using the straight-line method over the licenses' estimated useful lives of seventeen to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2002 is as follows (in thousands):

2003	\$2,212
2004	2,212
2005	2,212
2006	2,212
2007	2,212

**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 on July 17, 2000 (which took place in connection with the acquisition of Algos Pharmaceutical Corporation), the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC 1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserve an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. The effect of the recapitalization has been reflected in the accompanying financial statements. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC will be issued. As a result, exercise of these stock options will not result in the issuance of additional shares of Company common stock and will not dilute the ownership of our other public stockholders.

The Class C stock options under the Endo Pharma LLC 1997 Stock Option Plans vest in four discrete tranches contingent upon (i) the common stock of the Company exceeding an average 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:



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Option Class	Common Stock Closing Price Threshold
C1A and C1B	\$ 4.28
C2	\$ 6.62
C3	\$10.58
C4	\$17.29

As these share price targets are achieved, resulting in the vesting of each tranche of options, the Company has recorded non-cash compensation charges related to the vesting of the applicable options. Under performance-based options, the measurement of expense is calculated and recorded as a non-cash charge at the time performance is achieved as the difference between the market price of the stock and the exercise price of the options. The charges recorded by the Company in connection with the above options are significant. The above options will not, however, result in the issuance of additional shares of Company common stock.

During the fourth quarter of 2003, 4,810,936 Class C4 stock options vested upon achievement of the aforementioned conditions. Accordingly, we recorded a \$96.0 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price of the Company common stock on the date of vesting and the exercise price of the vested stock options.

During the year ended December 31, 2002, 6,924,363 Class C3 stock options vested upon achievement of the aforementioned conditions. Accordingly, we recorded a \$34.7 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price of the Company common stock on the date of vesting and the exercise price of the vested stock options.

During the year ended December 31, 2001, 4,594,535 Class C2 stock options vested upon achievement of the aforementioned conditions. We recorded a \$37.3 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price of the Company common stock on the date of vesting and the exercise price of the vested stock options.

During the year ended December 31, 2000, 5,880,713 Class C1A and C1B stock options vested upon achievement of the aforementioned conditions. We recorded a \$15.3 million compensation charge related to the vesting of these performance-based stock options. The amount represents the estimated difference in the market price of the Company common stock on the date of vesting and the exercise price of the vested stock options.

As stated above, these options are exercisable solely into shares of Company common stock that are held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of Company common stock and will not dilute the ownership of our other public stockholders.

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 Company common stock, after which neither Kelso & Company nor Endo Pharma LLC any longer own any shares of Company common stock or (ii) January 1, 2006.

In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these stock options. Finally, the shares of common stock that individuals receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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

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) and, together with the Endo Pharma LLC 1997 Stock Option Plans, the Endo Pharma LLC Stock Option Plans) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10.7 million shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were not effective until January 1, 2003. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of \$7.70 and the weighted average exercise price of these stock options of \$2.42. Upon exercise of these options, no additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options will not dilute the ownership of our other public stockholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these stock options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

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

All the stock 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 common stock on the date granted and, under accounting principles generally accepted in the United States of America, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan will dilute our public stockholders.

**Stock-Based Compensation**

We have adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, while following Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for all of our stock option plans. Under APB No. 25, no compensation expense is recognized when the exercise price of stock options equals at least the market price of the underlying stock at the date of grant or when a measurement date has not yet been reached. Accordingly, with respect to the stock options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan, no compensation expense has been recognized. If we were to have adopted the accounting provisions of SFAS No. 123, we would have been required to record compensation expense based on the fair value of all of these stock options on the date of their respective grants.

Pro-forma information regarding net income is required to be presented as if we had accounted for our stock options under the provisions of SFAS No. 123. The following assumptions were used for such estimates: no dividend yield; expected volatility of 70% in 2003 and 65% in 2002; risk-free interest rate of 3.0% for 2003 and 4.0% for 2002; and a weighted average expected life of the stock options of 5 years. Had the accounting provisions of SFAS No. 123 been adopted, net income would have been as follows (in thousands, except per share amounts):

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Net income (loss)	\$ 39,924	\$ (18,308)	\$ 101,451	\$ 9,069
APB 25 Compensation Expense		40,406	48,514	40,406
Tax effect of APB 25 compensation expense		(18,252)	(18,496)	(14,342)
SFAS 123 compensation expense	(11,310)	(5,411)	(79,855)	(5,638)
Tax effect of SFAS 123 compensation expense	4,287	2,444	30,445	2,001
Net income pro forma	\$ 32,901	\$ 879	\$ 82,059	\$ 31,496
Basic earnings (loss) per share as reported	\$ .30	\$ (.18)	\$ .80	\$ .09
Basic earnings per share pro forma	\$ .25	\$ .01	\$ .64	\$ .31
Diluted earnings (loss) per share as reported	\$ .30	\$ (.18)	\$ .77	\$ .09
Diluted earnings per share pro forma	\$ .25	\$ .01	\$ .62	\$ .31
Weighted average shares outstanding				
Basic	131,761	102,064	127,288	102,064
Diluted	132,636	102,064	132,510	102,245

**5. WARRANTS****Class A Transferable Warrants and Class B Non-Transferable Warrants**

Prior to March 31, 2003, our Class A Transferable Warrants and Class B Non-Transferable Warrants were exercisable at an exercise price of \$.01 per share into a specified number of shares of Company common stock depending on the timing of the FDA's approval of Morphidex® for one or more pain indications.

Because Morphidex® was not approved prior to March 31, 2003, the Class A Transferable Warrants and Class B Non-Transferable Warrants expired on such date and have no economic value. Accordingly, the Company de-listed the Class A Transferable Warrants (Nasdaq: ENDPW) upon their expiration.

On December 5, 2001, we commenced a tender offer to purchase up to 13.5 million 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. We accepted an aggregate of 8.6 million 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 were outstanding 9.2 million of these warrants.

**Pre-Merger Endo Warrants**

The holders of Company common stock prior to the Algos merger received warrants (known as the Pre-Merger Endo Warrants), which were exercisable at an exercise price of \$.01 per share into a specified number of shares of Company common stock if the FDA did not approve Morphidex® for any pain indication prior to December 31, 2002. As of December 31, 2002, there were outstanding 71.3 million of these warrants. As the FDA did not approve Morphidex® before December 31, 2002, these warrants then became exercisable. Each of these outstanding 71.3 million warrants were exercisable into 0.416667 shares of Company common stock. These warrants were exercisable at an exercise price of \$0.01 per share into a maximum of 29.7 million shares of Company common stock. As of July 8, 2003, all of the 71.3 million warrants had been exercised into 29,687,602 shares of Company common stock.

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**6. RELATED PARTY TRANSACTIONS**

On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2003, approximately 3.4 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2003, approximately \$35 million), which is estimated to result in a tax benefit amount of approximately \$13 million. Under the tax sharing agreement, we are required to pay this \$13 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of \$2.61 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.4 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$10.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$268 million, which could result in a tax benefit amount of approximately \$103 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$15.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$450 million, which could result in a tax benefit amount of approximately \$172 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$631 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. This recent offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

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**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 pharmaceutical products. These agreements may require us to share in the development costs of such products, make payments to these third parties upon the achievement of certain defined milestones, make payments to such third parties based on a percentage of the net sales of such products and generally grant marketing rights to us for such products. If any of our third party partners are unable or unwilling 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. On March 18, 2003, we received notice from Penwest Pharmaceuticals Co. (a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing its pipeline project, oxymorphone ER) that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of oxymorphone ER on account of Penwest's concern about its ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until such time as the FDA approves oxymorphone ER, at which time we will recoup from the royalties due to Penwest the full amount of what Penwest should have contributed had it not exercised such right. We believe that our cash and cash equivalents and cash flow from operating activities will be more than sufficient to meet our normal operating, investing and financing activities in the foreseeable future, including the funding of 100% of the costs to bring our pipeline products, including oxymorphone ER, to market.

**8. OTHER EVENTS**

On October 20, 2003, we announced that the U.S. Food and Drug Administration had issued approvable letters for both oxymorphone extended-release tablets (oxymorphone ER) and immediate-release tablets (oxymorphone IR). In the letters, the FDA requested that we address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of these products. We intend to communicate with the FDA throughout the final approval process in order to discuss the issues raised in the approvable letters and determine the appropriate course of action, including the launch date of these products, which we no longer believe will be the first quarter of 2004.

On October 24, 2003, we announced results from our pivotal Phase III clinical trial of the investigational oral rinse EN3247 (0.1% triclosan) being evaluated for use in preventing oral mucositis (OM), which are painful mouth sores that often occur in patients undergoing cancer treatment. Specifically, the study assessed the safety and efficacy of EN3247 oral rinse for prevention of ulcerative oral mucositis resulting from cytotoxic conditioning regimens administered prior to autologous bone marrow or peripheral stem cell transplant therapy. These results indicated that EN3247 did not meet its primary endpoint of preventing oral mucositis. We are continuing to analyze the data from the program to determine the future of this product.

During the fourth quarter of 2003, we made the decision to manufacture additional launch quantities of our extended-release oxycodone tablets to provide us the opportunity to launch our generic product should we win our litigation with Purdue Frederick and make the determination to launch. Due to the uncertainty surrounding the ultimate timing of the product's final approval and launch, however, we will fully reserve for this inventory and, accordingly, estimates recording a charge of approximately \$25.0 million, or \$0.12 per share, net of tax, during the fourth quarter of 2003.

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### **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 67%, 63% and 70% of net sales for the years ended December 31, 2001, 2002 and the nine months ended September 30, 2003, respectively.

On August 26, 1997, certain members of the management of the then DuPont Merck Pharmaceutical Company and an affiliate of Kelso & Company entered into an asset purchase agreement with DuPont Merck 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 November 19, 1999, we formed Endo Inc. as a wholly owned subsidiary to effect the acquisition of Algos Pharmaceutical Corporation. On December 31, 2001, Endo Inc. was merged with and into Endo Pharmaceuticals Inc. 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. During the nine months ending September 30, 2003 and 2002, we incurred approximately \$4.7 million and \$2.9 million of these costs, respectively, which are reflected in research and development expense.

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, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and purchase accounting.

#### **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 of America 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. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of amortization periods for identifiable intangible assets and the potential impairment of goodwill and other intangible assets. 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 section. Our most critical accounting policies are described below:

**Table of Contents*****Sales Deductions***

When we recognize revenue from the sale of our products, we simultaneously record an adjustment to revenue for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. These provisions are estimated based on historical experience, estimated future trends, estimated customer inventory levels, current contract sales terms with our wholesale and indirect customers and other competitive factors. If the assumptions we used to calculate these adjustments do not appropriately reflect future activity, our financial position, results of operations and cash flows could be impacted. The provision for chargebacks is the most significant and complex estimate used in the recognition of our revenue. We establish contract prices for indirect customers who are supplied by our wholesale customers. A chargeback represents the difference between our invoice price to the wholesaler and the indirect customer's contract price. Provisions for estimating chargebacks are calculated primarily using historical chargeback experience, estimated wholesaler inventory levels and estimated future trends. We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives and other allowances. Some customers receive rebates upon attaining established sales volumes. We estimate rebates, sales incentives and other allowances based upon the terms of the contracts with our customers, historical experience, estimated inventory levels of our customers and estimated future trends. We estimate an accrual for Medicaid rebates as a reduction of revenue at the time product sales are recorded. The Medicaid rebate reserve is estimated based upon the historical payment experience, historical relationship to revenues and estimated future trends. Royalties represent amounts accrued pursuant to the license agreement with Hind Healthcare Inc. (Hind). Royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm®. Royalties are paid to Hind at a rate of 10% of net sales of Lidoderm®. Our return policy allows customers to receive credit for expired products within three months prior to expiration and within one year after expiration. We estimate the provision for product returns based upon the historical experience of returns for each product, historical relationship to revenues, estimated future trends, estimated customer inventory levels and other competitive factors. We continually monitor the factors that influence each type of sales deduction and make adjustments as necessary.

***Amortizable Intangibles: Licenses***

Licenses are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives ranging from seventeen to twenty years. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The remaining useful life of licenses is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining period of amortization. Licenses are assessed periodically for impairment in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of*. This impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs.

***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 and other intangibles represents a significant portion of our assets and stockholders' equity. As of September 30, 2003, goodwill and other intangibles comprised approximately 31% of our total assets and 43% 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 of goodwill is less than its carrying amount. As a result of the

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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 the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) 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 are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. Goodwill was 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 was identified. On January 1, 2003, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

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

	September 30, 2003	December 31, 2002
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 36,000	\$ 36,000
Patents	3,200	3,200
	39,200	39,200
Less accumulated amortization	(4,104)	(2,445)
Other Intangibles, net	\$ 35,096	\$ 36,755

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 using the straight-line method over the licenses' estimated useful lives of seventeen to twenty years. The cost of acquired patents is capitalized and is being amortized using the straight-line method over their estimated useful lives of seventeen years.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2002 is as follows (in thousands):

2003	\$2,212
2004	2,212
2005	2,212
2006	2,212
2007	2,212

**Compensation Related to Stock Options - Endo Pharma LLC Stock Option Plans**

In our 2000 fiscal year we incurred a non-cash charge of \$15.3 million, in our 2001 fiscal year we recorded a non-cash charge of \$37.3 million, in our 2002 fiscal year we recorded a non-cash charge of \$34.7 million and during the fourth quarter of 2003 we recorded a non-cash charge of \$96.0 million (representing the vesting of 4.8 million Class C4 stock options and the difference between the market price of the common stock on the date of vesting of \$22.59 and the weighted average exercise price of these stock options of \$2.63). Each of these non-cash charges were for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated





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Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans ). Under the Endo Pharma LLC 1997 Stock Option 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.

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 ) and, together with the Endo Pharma LLC 1997 Stock Option Plans, the Endo Pharma LLC Stock Option Plans ) were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10.7 million shares of our common stock that is held by Endo Pharma LLC for issuance. The Endo Pharma LLC 2000 Supplemental Stock Option Plans were not effective until January 1, 2003. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock on the date vesting occurs of \$7.70 and the weighted average exercise price of these stock options of \$2.42. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options will not dilute the public shareholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

### ***Compensation Related to Stock Options Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan***

All the stock 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 of America, a measurement date occurs on the date of each grant. Consequently, we do not expect to incur a charge upon the vesting or exercise of those options.

## **Results of Operations**

### ***Net Sales***

Our net sales consist of revenues from sales of our pharmaceutical products, less estimates for certain chargebacks, sales allowances, the cost of returns and losses. We recognize revenue when products are shipped and title and risk of loss has passed to the customer, which is typically upon delivery to the customer. Our shipping terms are free on board customer's destination.

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The following table presents our unaudited net sales by product category for the three months and nine months ended September 30, 2003 and 2002.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(in thousands, unaudited)			
Percocet®	\$ 58,972	\$ 36,585	\$ 166,865	\$ 100,663
Lidoderm®	37,451	24,080	129,558	59,916
Other brands	3,739	6,048	19,216	15,669
Total brands	\$ 100,162	\$ 66,713	\$ 315,639	\$ 176,248
Total generics	\$ 49,193	\$ 43,841	\$ 138,017	\$ 109,234
Total net sales	\$ 149,355	\$ 110,554	\$ 453,656	\$ 285,482

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, 2003 and 2002.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	(unaudited)			
Percocet®	39%	33%	37%	35%
Lidoderm®	25	22	29	21
Other brands	3	5	4	6
Total brands	67	60	70	62
Total generics	33	40	30	38
Total net sales	100%	100%	100%	100%

**Three Months Ended September 30, 2003 Compared to the Three Months Ended September 30, 2002**

**Net Sales.** Net sales for the three months ended September 30, 2003 increased by 35% to \$149.4 million from \$110.6 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in Percocet®, the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. Net sales of Percocet® increased to \$59.0 million from \$36.6 million in the comparable 2002 period due to the increase in net sales of Percocet® 7.5/325 and Percocet® 10.0/325. In September 2003, a competitor announced that they had received approval of generic versions of these two strengths. On October 20, 2003, Watson Pharmaceuticals announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. Net sales of Lidoderm® increased to \$37.5 million from \$24.1 million in the comparable 2002 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Net sales of our generic products increased to \$49.2 million from \$43.8 million in the comparable 2002 period primarily due to the growth of Endocet® and our generic morphine sulfate extended-release tablets. During the third quarter of 2003, the FDA approved all five strengths of Mallinckrodt Inc.'s generic extended-release morphine sulfate. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

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

**Gross Profit.** Gross profit for the three months ended September 30, 2003 increased by 42% to \$122.3 million from \$86.2 million in the comparable 2002 period. Gross profit margins increased to 82% from 78% due to a more

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favorable mix of higher margin brand and generic products resulting from the products discussed above. 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 (f/k/a The DuPont Merck Pharmaceutical Company), currently one of our more significant contract manufacturing relationships.

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses for the three months ended September 30, 2003 increased by 24% to \$35.8 million from \$28.8 million in the comparable 2002 period. This increase was due to a \$4.6 million increase in sales and promotional efforts in 2003 over the comparable 2002 period to support Lidoderm® and Percocet® and in preparation of new product launches. 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.*** Research and development expenses for the three months ended September 30, 2003 increased by 34% to \$20.7 million from \$15.4 million in the comparable 2002 period. This increase is primarily attributable to a \$5.0 million milestone charge we incurred pursuant to our Development and Marketing Strategic Alliance with SkyePharma Inc. Under the terms of this agreement, a \$5.0 million milestone becomes due upon acceptance for substantive review by the FDA of DepoMorphine . DepoMorphine was accepted for substantive review by the FDA during the third quarter of 2003.

***Depreciation and Amortization.*** Depreciation and amortization for the three months ended September 30, 2003 increased to \$1.6 million from \$0.7 million in the comparable 2002 period due to an increase in depreciation of \$.5 million due to an increase in depreciation related to an increase in capital expenditures and an increase in amortization of license fees of \$.4 million arising from the SkyePharma license entered into on December 31, 2002 and an increase in depreciation from capital expenditures.

***Compensation Related to Stock Options.*** Compensation related to stock options of \$40.4 million during the three months ended September 30, 2002, relates to a non-cash compensation charge of \$40.4 million for the estimated probable vesting of the outstanding Class C3 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. 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.*** Purchased in-process research and development during the three months ended September 30, 2002 of \$13.3 million resulted from the preliminary estimate of fair value of the oral mucositis development product that the Company acquired in its acquisition of BML Pharmaceuticals, Inc.

***Manufacturing Transfer Fee.*** Manufacturing transfer fee during the three months ended September 30, 2002 was 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.*** Interest expense, net for the three months ended September 30, 2003 decreased to twelve thousand dollars from \$1.0 million in the comparable 2002 period. This decrease is substantially due to the repayment on August 26, 2002 of the promissory notes issued to Bristol-Myers Squibb in connection with our 1997 acquisition from Bristol-Myers Squibb Pharma Company (f/k/a The Dupont Merck Pharmaceutical Company).

***Income Tax (Benefit).*** Income tax for the three months ended September 30, 2003 increased to \$24.4 million from a benefit of (\$4.1) million in the comparable 2002 period. This increase is due to the increase in income before income tax for the three months ended September 30, 2003 from a net loss before income taxes in the three months ended September 30, 2002.

***Nine Months Ended September 30, 2003 Compared to the Nine Months Ended September 30, 2002***

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**Net Sales.** Net sales for the nine months ended September 30, 2003 increased by 59% to \$453.7 million from \$285.5 million in the comparable 2002 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, Percocet®, and certain generic products. Net sales of Lidoderm® increased to \$129.6 million from \$59.9 million in the comparable 2002 period. In September 1999, we launched Lidoderm®, which continues to gain market share due to our ongoing promotional and educational efforts. Percocet® net sales increased to \$166.9 million from \$100.7 million in the comparable 2002 period due to the increase in net sales of Percocet® 7.5/325 and Percocet® 10.0/325. In September 2003, a competitor announced that they had received approval of generic versions of these two strengths. On October 20, 2003, Watson Pharmaceuticals announced that it was launching its generic versions of Percocet® 7.5/325 and Percocet® 10.0/325. In addition for the nine months ended September 30, 2003, each of Percocet® and Lidoderm® were favorably impacted from our customers' increasing their inventories back to normalized levels from the relatively low levels that were maintained at the end of 2002. Net sales of our generic products increased 26% to \$138.0 million from \$109.2 million in the comparable 2002 period primarily due to the growth of our generic morphine sulfate extended-release tablets and Endocet®. In April 2001, we launched two new strengths of our generic product Endocet®. During the third quarter of 2003, the FDA approved all five strengths of Mallinckrodt Inc.'s generic extended-release morphine sulfate. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

**Gross Profit.** Gross profit for the nine months ended September 30, 2003 increased by 74% to \$372.8 million from \$214.4 million in the comparable 2002 period. Gross profit margins increased to 82% from 75% due to a more favorable mix of higher margin brand and generic products resulting from the products discussed above. 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 (f/k/a The DuPont Merck Pharmaceutical Company), currently one of our more significant contract manufacturing relationships.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the nine months ended September 30, 2003 increased by 42% to \$113.7 million from \$79.9 million in the comparable 2002 period. This increase was due to a \$19.6 million increase in sales and promotional efforts in 2003 over the comparable 2002 period to support Lidoderm® and Percocet® and in preparation of new product launches. 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.** Research and development expenses for the nine months ended September 30, 2003 decreased by 4% to \$42.2 million from \$43.9 million in the comparable 2002 period. This decrease reflects the overall stage of development of our development portfolio. During 2002, we were performing clinical trials on our extended-release and immediate-release oxymorphone products and MorphoDex®. During 2003, our development efforts are focused on our oral mucositis product which is currently in Phase III clinical trials as well as other earlier stage projects focused in the area of pain management and other complementary therapeutic areas. This decrease is partially offset by a \$5.0 million milestone charge we incurred pursuant to our Development and Marketing Strategic Alliance with SkyePharma Inc. Under the terms of this agreement, a \$5.0 million milestone becomes due upon acceptance for substantive review by the FDA of DepoMorphine™. DepoMorphine™ was accepted for substantive review by the FDA during the third quarter of 2003.

**Depreciation and Amortization.** Depreciation and amortization for the nine months ended September 30, 2003 increased to \$4.3 million from \$2.2 million in the comparable 2002 period primarily due to an increase in amortization of license fees arising from the SkyePharma license entered into on December 31, 2002.

**Compensation Related to Stock Options.** Compensation related to stock options was \$48.5 million during the nine months ended September 30, 2003. Effective January 1, 2003, the Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective resulting in the issuance of approximately 10.7 million stock options to certain employees and members of management. Because approximately 9.2 million of these stock options were immediately vested upon their issuance, we recorded a non-cash compensation charge of approximately \$48.5 million in the first quarter of 2003 representing the difference between the market price of the common stock of \$7.70 and the exercise price of these stock options of \$2.42. No additional shares of our common stock will be

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issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, the exercise of these stock options will not dilute the ownership of our other public stockholders.

Compensation related to stock options of \$40.4 million during the nine months ended September 30, 2002, relates to a non-cash compensation charge of \$40.4 million for the estimated probable vesting of the outstanding Class C3 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. 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.*** Purchased in-process research and development during 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, Inc.

***Manufacturing Transfer Fee.*** Manufacturing transfer fee during the nine months ended September 30, 2002 was 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.*** Interest expense, net for the nine months ended September 30, 2003 decreased to \$.2 million from \$4.3 million in the comparable 2002 period. This decrease is substantially due to the repayment on August 26, 2002 of the promissory notes issued to Bristol-Myers Squibb in connection with our 1997 acquisition from Bristol-Myers Squibb Pharma Company (f/k/a The Dupont Merck Pharmaceutical Company).

***Income Tax.*** Income tax for the nine months ended September 30, 2003 increased to \$62.5 million from \$12.3 million in the comparable 2002 period. This increase is due to the increase in income before income tax for the nine months ended September 30, 2003.

## **Liquidity and Capital Resources**

Our principal source of liquidity is cash generated from operations. Under our credit facility, we may borrow up to \$75.0 million on a revolving basis for certain purposes as described below. Our principal liquidity requirements are for working capital for operations, acquisitions, licenses and capital expenditures.

***Net Cash Provided by Operating Activities.*** Net cash provided by operating activities increased by \$84.8 million to \$168.0 million for the nine months ended September 30, 2003 from \$83.2 million for the nine months ended September 30, 2002. This increase was due to the cash provided by the increase in net sales and gross profit for the nine months ended September 30, 2003 compared to the nine months ended September 30, 2002, offset by an increase in selling, general and administrative expenses for the nine months ended September 30, 2003 as compared to the nine months ended September 30, 2002.

***Net Cash Used in Investing Activities.*** Net cash utilized in investing activities increased by \$12.8 million to \$29.2 million for the nine months ended September 30, 2003. In January 2003, the Company paid a \$25.0 million license fee to SkyePharma, Inc. for the marketing rights to DepoMorphine™ and Propofol IDD-D™. In addition, capital expenditures increased in 2003 to \$4.2 million from \$2.2 million. This increase in capital expenditures was due to the implementation of a sales automation system during 2003. This increase is partially offset by cash utilized of \$14.2 million to purchase BML Pharmaceuticals in 2002.

***Net Cash Utilized in Financing Activities.*** Net cash utilized in financing activities decreased by \$125.3 million to \$.3 million for the nine months ended September 30, 2003 from \$125.6 million for the nine months ended September 30, 2002. During the nine months ended September 30, 2002, we repaid all of the promissory notes

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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.

**Credit Facility.** In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of \$50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. As of September 30, 2003, we have not borrowed any amounts under our credit facility.

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2003, approximately 3.4 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2003, approximately \$35 million), which is estimated to result in a tax benefit amount of approximately \$13 million. Under the tax sharing agreement, we are required to pay this \$13 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Using a weighted average exercise price of \$2.61 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 3.4 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$10.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$268 million, which could result in a tax benefit amount of approximately \$103 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$15.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$450 million, which could result in a tax benefit amount of approximately \$172 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$631 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments have been made or accrued to date. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by



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itself, trigger a payment under the tax sharing agreement, and no liquidity event. This offering may, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings in the future

### **Recent Accounting Pronouncements**

In January 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. We adopted the provisions of SFAS No. 144 on January 1, 2002, which had no material impact on our results of operations or financial position.

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 was 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 Note 3 to the Consolidated Financial Statements.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections*. SFAS No. 145 (1) rescinds SFAS No. 4 and SFAS No. 64, which relate to the extinguishment of debt, (2) rescinds SFAS No. 44 relating to the accounting for intangible assets of motor carriers, and (3) amends SFAS No. 13 relating to the accounting for leases. SFAS No. 145 also amends certain other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. Certain amounts were reclassified in accordance with SFAS No. 145 in the accompanying financial statements. The adoption of SFAS No. 145 did not have material impact on our results of operations or financial position.

In July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. SFAS No. 146 requires recognition of a liability for a cost associated with an exit or disposal activity when the liability is incurred, as opposed to when the entity commits to an exit plan under previous guidance. This statement is effective for exit or disposal activities initiated after December 31, 2002. The adoption of SFAS No. 146 did not have material impact on our results of operations or financial position.

In November 2002, the FASB issued FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 requires that upon issuance of certain guarantees, a guarantor must recognize a liability for the fair value of an obligation assumed under the guarantee. FIN 45 also requires significant new disclosures, in both interim and annual financial statements, by a guarantor, about obligations associated with guarantees issued. FIN 45 disclosure requirements were effective for our fiscal year ended December 31, 2002 and the initial recognition and measurement provisions are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. At September 30, 2003, we had no guarantees outstanding.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*. SFAS No. 148 amends SFAS No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We have not adopted the fair value based method of accounting for employee stock-based compensation.

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

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On December 21, 2001, we amended and restated our senior credit facility to provide 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.**

Our management, including our Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective for timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed under the Securities Exchange Act of 1934, as amended.

In addition, there have been no changes in our internal control over financial reporting that occurred during the quarter covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **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*

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*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.

The district court began the trial of the patent claims in all three of the suits against EPI on June 2, 2003. Post-trial briefing was completed on August 8, 2003, and a decision on the patent claims is expected in due course. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial.

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

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*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.); In Re: PPA Products Liability Litigation, MDL No. 1407 (W.D. Wash.)*

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. Each of these six cases was transferred to the United States District Court for the Western District of Washington by order of the United States Judicial Panel on Multidistrict Litigation. Each plaintiff in the above-referenced cases was directed by the presiding judge to file, not later than June 29, 2003, a separate, single-plaintiff action identifying particular defendant manufacturers whose products allegedly harmed each plaintiff. EPI neither has been named, nor served with process in any single-plaintiff case filed by any of the foregoing plaintiffs pursuant to the court's prior order. On August 25, 2003, Judge Rothstein of the United States District Court for the Western District of Washington signed an order whereby each of the six above-referenced multiple plaintiff cases was dismissed with prejudice. Consequently, EPI is no longer a party defendant in any multidistrict litigation proceedings concerning alleged harm from PPA.

*John Fontenot et al. v. Able Laboratories, Inc. et al., No. 98-845 (34th Judicial District Court for the Parish of St. Bernard, State of Louisiana)*

On May 7, 2003, EPI was named, along with thirteen other pharmaceutical companies and four pharmacies, as a defendant in a lawsuit filed by John Fontenot, Helen Fontenot Serpas and Andre Paul Fontenot in the 34th Judicial District Court for the Parish of St. Bernard, State of Louisiana. Defendants removed the matter to the U.S. District Court, Eastern District of Louisiana, and a motion to remand, filed by plaintiffs, was set for hearing in September; however, on plaintiffs' motion, the hearing is now re-set for November 19, 2003. Federal court is the preferred jurisdiction so defendants will vigorously oppose the remand. Discovery has not yet begun as several defendants have not made appearances. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone, hydrocodone and/or OxyContin. The complaint alleges that the defendants failed to adequately warn physicians and their patients of the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs suffered injury. EPI intends to defend itself vigorously in this case. On or about November 7, 2003, plaintiffs filed a motion to dismiss without prejudice and order, moving to dismiss all named defendants from this suit, including EPI, but reserving rights to proceed against all other entities not named in the dismissal. Since EPI was named, we believe this order, once signed, will conclude the litigation, although the dismissal is without prejudice. Defendants are researching whether there exist grounds to argue for a dismissal with prejudice so suit may not be re-filed.

*General*

In addition to the above, we are involved in, or have been involved in, arbitrations or legal proceedings that arise from the normal course of our business. We cannot predict the timing or outcome of these claims and proceedings. Currently, we are not involved in any arbitration and/or legal proceeding that we expect to have a material effect on our business, financial condition or results of operations and cash flows.

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**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.***

On October 20, 2003, Endo Pharmaceuticals Inc., a wholly owned subsidiary of the Registrant announced that the U.S. Food and Drug Administration had issued approvable letters for both oxymorphone extended-release tablets (oxymorphone ER) and immediate-release tablets (oxymorphone IR). In the letters, the FDA requested that Endo address certain questions and provide additional clarification and information, including some form of additional clinical trials to further confirm the safety and efficacy of these products. Endo intends to communicate with the FDA throughout the final approval process in order to discuss the issues raised in the approvable letters and determine the appropriate course of action, including the launch date of these products, which we no longer believe will be the first quarter of 2004.

On October 24, 2003, Endo Pharmaceuticals Inc. announced results from its pivotal Phase III clinical trial of the investigational oral rinse EN3247 (0.1% triclosan) being evaluated for use in preventing oral mucositis (OM), which are painful mouth sores that often occur in patients undergoing cancer treatment. Specifically, the study assessed the safety and efficacy of EN3247 oral rinse for prevention of ulcerative oral mucositis resulting from cytotoxic conditioning regimens administered prior to autologous bone marrow or peripheral stem cell transplant therapy. These results indicated that EN3247 did not meet its primary endpoint of preventing oral mucositis. Endo is continuing to analyze the data from the program to determine the future of this product.

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**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, 2003:

<b>Dates</b>	<b>Item(s)</b>
July 24, 2003	7 and 12

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

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**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

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

/s/ JEFFREY R. BLACK

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

Date: November 14, 2003

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Exhibit No.	Title
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 March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, 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, 2003 filed with the Commission on August 14, 2003)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.3	[Intentionally Omitted.]
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)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	[Intentionally Omitted.]
10.2	[Intentionally Omitted.]
10.3	[Intentionally Omitted.]
10.4	[Intentionally Omitted.]
10.5	Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference 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





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Exhibit No.	Title
	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 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)
10.17.2	Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company (incorporated herein by reference to Exhibit 10.17.2 of the Current Report on Form 8-K dated August 27, 2002)
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/d/b/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

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Exhibit No.	Title
	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)
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)
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 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	[Intentionally Omitted.]
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

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Exhibit No.	Title
	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 Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.40	[Intentionally Omitted.]
10.41	Service Agreement, dated as of February 1, 2001, by and between Endo Pharmaceuticals and Ventiv Health U.S. Sales Inc. (incorporated herein by reference to Exhibit 10.41 of the Current Report on Form 8-K dated August 31, 2001)
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
10.43	Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals Inc., SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
10.44	Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
11	Statement Regarding Computation of Per Share Earnings
31.1	Certification of the Chairman and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the Chairman and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002