ENDO PHARMACEUTICALS HOLDINGS INC Form 10-Q November 14, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

X	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
	For the quarterly period ended September 30, 2002 OR
o	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
	For the transition period from to Commission file number: 39040

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization)

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

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

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

Indicate by check ü whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES \flat NO o

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

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

CONSOLIDATED BALANCE SHEETS (UNAUDITED)

CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

Overview

Critical Accounting Policies

Results of Operations

Goodwill and Other Intangibles

Compensation Related to Stock Options

Other Events

Net Sales

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

<u> 2001</u>

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

2001

Liquidity and Capital Resources

Item 3. Quantitative and Qualitative Disclosures about Market Risk

<u>Item 4. Controls and Procedures</u>

PART II OTHER INFORMATION

Item 1. Legal Proceedings

Item 2. Changes in Securities and Use of Proceeds

Item 3. Defaults Upon Senior Securities

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

<u>Item 5. Other Information</u>

Item 6. Exhibits and Reports on Form 8-K

SIGNATURES

CERTIFICATIONS

EXHIBIT INDEX

EXHIBIT 11 STATEMENT REGARDING EARNINGS

EXHIBIT 99.1 CERTIFICATION OF CEO

EXHIBIT 99.2 CERTIFICATION OF CFO

Table of Contents

ENDO PHARMACEUTICALS HOLDINGS INC.

REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

TABLE OF CONTENTS

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

Table of Contents

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

Table of Contents

Forward Looking Statements

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales and consolidated EBITDA contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have ba 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.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements

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

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

Total Stockholders Equity	337,870	295,122
TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	\$ 458,035	\$ 470,995
See Notes to Consolidated Financial Statements		

1

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

	Three Months Ended September 30,			nths Ended nber 30,
	2002	2001	2002	2001
NET SALES	\$ 110,554	\$ 66,268	285,482	\$ 173,507
COST OF SALES	24,392	20,622	71,088	54,303
GROSS PROFIT	86,162	45,646	214,394	119,204
COSTS AND EXPENSES:				
Selling, general and administrative	28,753	19,588	79,898	54,931
Research and development	15,352	7,886	43,890	25,396
Depreciation and amortization	692	12,394	2,168	37,170
Compensation related to stock options - primarily selling, general and				
administrative	40,406	37,253	40,406	37,253
Purchased in-process research and development	13,334		13,334	
Manufacturing transfer fee	9,000		9,000	
OPERATING (LOSS) INCOME	(21,375)	(31,475)	25,698	(35,546)
·				<u> </u>
INTEREST EXPENSE, Net of interest income of \$376, \$607, \$1,024 and \$2,423				
respectively	1,031	2,686	4,302	9,129
(LOSS) INCOME BEFORE INCOME TAX (BENEFIT)	(22,406)	(34,161)	21,396	(44,675)
INCOME TAX (BENEFIT)	(4,098)	(1,168)	12,327	(175)
NET (LOSS) INCOME	\$ (18,308)	\$ (32,993)	\$ 9,069	\$ (44,500)
NET (LOSS) INCOME PER SHARE:				
Basic	\$ (.18)	\$ (.37)	\$.09	\$ (.50)
Diluted	\$ (.18)	\$ (.37)	\$.09	\$ (.50)
NET (LOSS) INCOME PRO FORMA TO EXCLUDE AMORTIZATION OF GOODWILL AND WORKFORCE-IN-PLACE:	\$ (18,308)	\$ (13,868)	\$ 9,069	\$ (5,886)
GOOD WILLIAM WORLD ONCE IN TERIOL.	ψ (10,500)	ψ (13,000)	Ψ 2,002	Ψ (3,000)
NET (LOSS) INCOME PER SHARE PRO FORMA TO EXCLUDE AMORTIZATION OF GOODWILL AND WORKFORCE-IN-PLACE: Basic	¢ (18)	\$ (.16)	\$.09	\$ (.07)
Diluted	\$ (.18) \$ (.18)	\$ (.16) \$ (.16)	\$.09 \$.09	\$ (.07) \$ (.07)
WEIGHTED AVERAGE SHARES:	φ (.10)	φ (.10)	φ .09	φ (.07)
Basic	102,064	89,139	102,064	89,139
Diluted	102,064	89,139	102,004	89,139
O N + + C 1'1 + 1E'	102,007	07,137	102,273	09,139

See Notes to Consolidated Financial Statements

9

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

Nine Months Ended September 30,

		Septen	iber 30,		
		2002		2001	
OPERATING ACTIVITIES:					
Net Income (Loss)	\$	9,069	\$	(44,500)	
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		-,		(11,000)	
Depreciation and amortization		2,168		37,170	
Purchased in-process research and development		13,334		ĺ	
Amortization of deferred financing costs		290		1,165	
Accretion of promissory notes		4,627		3,771	
Deferred income taxes		(14,304)		(1,100)	
Compensation related to stock options		40,406		37,253	
Changes in assets and liabilities which provided (used) cash:					
Accounts receivable		(25,874)		(1,107)	
Inventories		(5,493)		9,489	
Other assets		925		(2,049)	
Accounts payable		16,272		5,515	
Accrued expenses		42,639		8,473	
Income taxes payable		(845)		(2,364)	
Other liabilities				16,266	
	-				
Net cash provided by operating activities		83,214		67,982	
INVESTING ACTIVITIES:					
Purchase of property and equipment		(2,221)		(4,928)	
Acquisition of BML Pharmaceuticals		(14,190)			
	_				
Net cash used in investing activities		(16,411)		(4,928)	
The basis about in in resumb area rates	_	(10,111)		(.,,,20)	
FINANCING ACTIVITIES:					
Repayments of long-term debt		(118,889)		(32,941)	
Exercise of Endo Pharmaceuticals Holdings Inc. stock options		4		(-)-)	
Repurchase of Class A Transferable and Class B Non-Transferable Warrants		(6,730)			
•	_				
Net cash used in financing activities		(125,615)		(32,941)	
Not easil used in imalicing activities		(123,013)		(32,771)	
NET (DEGRE AGE) INCREAGE IN CAGUANTE GAGIA FORMALI ENTEG		(50.010)		20.112	
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS		(58,812)		30,113	
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		95,357		59,196	
	-		•		
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	36,545	\$	89,309	
			1		
SUPPLEMENTAL INFORMATION:					
Interest Paid	\$	430	\$	6,622	
Income Taxes Paid	\$	27,479	\$		
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES	Ψ	21,717	ψ	2,107	
Promissory Note issued under Manufacturing & Supply Agreement	\$	23,000	\$	21,301	
Adjustment to fair value of net assets acquired in the Algos merger due to lease termination	Ψ	23,300	\$	3,131	
See Notes to Consolidated Financial Statements.			Ψ	5,151	

3

Table of Contents

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

1. CONSOLIDATED FINANCIAL STATEMENTS

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

2. RECENT ACCOUNTING PRONOUNCEMENTS

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

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

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

4

Table of Contents

3. GOODWILL AND OTHER INTANGIBLES

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

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

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

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

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

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

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

5

Table of Contents

	(Unaudited) Three Months Ended September 30,		(Unaudited) Nine Months Ende September 30,			nded		
	2	0002		2001	2	002	2	2001
		(in	thous	ands, excep	ot per s	hare dat	a)	
Add back: Amortization of workforce-in-place				.02				.05
Add back: Pro forma income tax benefit	_		_	.08	_		_	.04
Adjusted net (loss) income	\$	(.18)	\$	(.16)	\$.09	\$	(.07)
Diluted earnings (loss) per share:	_							
Reported net (loss) income	\$	(.18)	\$	(.37)	\$.09	\$	(.50)
Add back: Goodwill amortization				.11				.34
Add back: Amortization of workforce-in-place				.02				.05
Add back: Pro forma income tax benefit				.08				.04
	_		_		_		_	
Adjusted net (loss) income	\$	(.18)	\$	(.16)	\$.09	\$	(.07)

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

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

4. COMPENSATION RELATED TO STOCK OPTIONS

Endo Pharma LLC 1997 Executive and Employee Stock Option Plans

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

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

6

Table of Contents

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

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

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

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

Endo Pharma LLC 2000 Supplemental Executive and Employee Stock Option Plans

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

7

Table of Contents

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

Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan

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

5. WARRANTS

Class A Transferable Warrants and Class B Non-Transferable Warrants

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

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

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

Pre-Merger Endo Warrants

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

6. RELATED PARTY TRANSACTIONS

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

8

Table of Contents

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

7. COMMITMENTS AND CONTINGENCIES

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

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

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

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

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

8. OTHER EVENTS

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

9

Table of Contents

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

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

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

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

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

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

9. BML ACQUISITION

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

10

Table of Contents

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

10. CHRONOGESICTM LICENSE AGREEMENT

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

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

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

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

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

11

Table of Contents

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

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

Overview

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

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

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

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

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

Critical Accounting Policies

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

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

12

Table of Contents

Results of Operations

Goodwill and Other Intangibles

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

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

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

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

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

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

13

Table of Contents

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

	(Unaudited) Three Months Ended September 30,			(Unaudited) Nine Months Ended September 30,				
		2002		2001		2002		2001
			(in	thousands, except per share data)				
Reported net (loss) income	\$	(18,308)	\$	(32,993)	\$	9,069	\$	(44,500)
Add back: Goodwill amortization				10,225				30,675
Add back: Amortization of workforce-in-place				1,487				4,461