

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

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

November 14, 2001

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, 2001

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 39040

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

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

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

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

The aggregate number of shares of the Registrant's common stock outstanding as of November 14, 2001 was 100,538,950.

ENDO PHARMACEUTICALS HOLDINGS INC.

REPORT ON FORM 10-Q  
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2001

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### Forward-Looking Statements

This Report contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on management's beliefs and assumptions, current expectations, estimates and projections. These statements are subject to risks and uncertainties and, therefore, actual results may differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are not historical facts and include information regarding the Company's possible or assumed results of operations. Also, statements or expressions that are preceded by, followed by, or that include, the words "believes," "anticipates," "plans," "expects," "intends," "estimates" or similar expressions are forward-looking statements. Endo's estimated or anticipated future results, product performance or other non-historical facts are forward-looking and reflect Endo's current perspective on existing trends and information. Many of the factors that will determine the Company's future results are beyond the ability of the Company to control or predict. The reader should not rely on any forward-looking statement. The Company undertakes no obligations to update any forward-looking statements whether as a result of new information, future events or otherwise. Several important factors, in addition to the specific factors discussed in connection with these forward-looking statements individually, could affect the future results of Endo and could cause those results to differ materially from those expressed in the forward-looking statements contained herein. Important factors that may affect future results include, but are not limited to:

- 
- |X| the Company's ability to successfully develop, commercialize and market new products;
  - |X| results of clinical trials on new products;
  - |X| competition for the business of the Company's branded and generic products, and in connection with the Company's acquisition of rights to intellectual property assets;
  - |X| market acceptance of the Company's future products;
  - |X| government regulation of the pharmaceutical industry;
  - |X| the Company's dependence on a small number of products;
  - |X| the Company's dependence on outside manufacturers for the manufacture of its products;
  - |X| the Company's dependence on third parties to supply raw materials and to provide services for the core aspects of its business;
  - |X| new regulatory action or lawsuits relating to the Company's use of narcotics in most of its core products;
  - |X| the Company's exposure to product liability claims and product recalls

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and the possibility that the Company may not be able to adequately insure itself;

- |X| the Company's ability to protect its proprietary technology;
- |X| the Company's ability to successfully implement its acquisition strategy;
- |X| the availability of controlled substances that constitute the active ingredients of some of the Company's products and products in development;
- |X| the availability of third-party reimbursement for the Company's products;
- |X| the Company's dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of its total net sales; and

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other risks and uncertainties detailed in Endo's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended, and in Endo's Registration Statement on Form S-3 dated October 17, 2001. Readers should evaluate any statement in light of these important factors.

### PART I

#### FINANCIAL INFORMATION

##### Item 1. Financial Statements

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

	September 30, 2001	December 31, 2000
	-----	-----
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents.....	\$ 89,309	\$ 59,196
Accounts receivable, net.....	79,419	78,312
Inventories.....	20,257	29,746
Prepaid expenses.....	2,731	3,496
Deferred income taxes.....	2,161	2,304
	-----	-----
Total current assets.....	193,877	173,054
	-----	-----
PROPERTY AND EQUIPMENT, Net.....	9,086	5,742
GOODWILL AND OTHER INTANGIBLES, Net.....	245,519	284,560
DEFERRED INCOME TAXES.....	1,979	736
RESTRICTED CASH.....	150	150
OTHER ASSETS .....	5,571	3,598
	-----	-----
TOTAL ASSETS .....	\$456,182	\$467,840
	=====	=====

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## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES:

Accounts payable.....	\$ 21,370	\$ 15,855
Accrued expenses.....	50,862	45,520
Income taxes payable.....	185	2,549
Current portion of long-term debt.....	16,140	36,371
	-----	-----

Total current liabilities.....	88,557	100,295
	-----	-----

LONG-TERM DEBT, Less current portion.....	174,516	162,154
OTHER LIABILITIES.....	2,183	7,218

### COMMITMENTS AND CONTINGENCIES

### STOCKHOLDERS' EQUITY

Preferred Stock, \$.01 par value; 40,000,000 shares authorized; none issued

Common Stock, \$.01 par value; 175,000,000 shares

authorized; and 89,138,950 issued and outstanding at

September 30, 2001 and December 31, 2000 ..... 891 891

Additional paid-in capital..... 423,208 385,955

Accumulated deficit..... (233,173) (188,673)

Total Stockholders' Equity..... 190,926 198,173

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY.....\$456,182 \$467,840

See Notes to Consolidated Financial Statements

## ENDO PHARMACEUTICALS HOLDINGS INC.

### CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED) (In thousands, except per share data)

	Three Months Ended September 30,	
	2001	2000
	-----	-----
NET SALES.....	\$ 66,268	\$ 50,902
COST OF SALES.....	20,622	15,254
	-----	-----
GROSS PROFIT.....	45,646	35,648
	-----	-----
COSTS AND EXPENSES:		
Selling, general and administrative.....	19,588	14,564
Research and development.....	7,886	8,315
Depreciation and amortization.....	12,394	10,715
Compensation related to stock options - primarily		

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selling, general and administrative	37,253	
Purchased in-process research and development		133,200
Merger and other related costs		1,583
Separation benefits.....	-----	-----
OPERATING INCOME (LOSS) .....	(31,475)	(132,729)
	-----	-----
INTEREST EXPENSE, Net of interest income of \$607, \$782, \$2,423 and \$1,809, respectively.....	2,686	3,672
	-----	-----
LOSS BEFORE INCOME TAX (BENEFIT)	(34,161)	(136,401)
	-----	-----
INCOME TAX (BENEFIT).....	(1,168)	147
	-----	-----
NET LOSS.....	\$ (32,993)	\$ (136,548)
	=====	=====
NET LOSS PER SHARE:		
Net Loss per Share:		
Basic.....	\$ (.37)	\$ (1.59)
Diluted.....	\$ (.37)	\$ (1.59)
Weighted Average Shares:		
Basic.....	89,139	85,848
Diluted.....	89,139	85,848

See Notes to Consolidated Financial Statements.

### ENDO PHARMACEUTICALS HOLDINGS INC.

#### CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED) (In thousands)

#### OPERATING ACTIVITIES:

Net Loss.....	\$ (4
Adjustments to reconcile net loss to net cash provided by operating activities:	
Depreciation and amortization.....	3
Purchased in-process research and development.....	
Amortization of deferred financing costs.....	
Accretion of promissory notes.....	
Deferred income taxes.....	(1
Compensation related to stock options.....	3
Changes in assets and liabilities which provided (used) cash:	
Accounts receivable.....	(1
Inventories.....	
Other assets.....	(2
Accounts payable.....	

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Accrued expenses.....	(2
Income taxes payable.....	16
Other liabilities.....	--
Net cash provided by operating activities.....	67
	--
INVESTING ACTIVITIES:	
Purchase of property and equipment.....	(4
Net cash acquired in the Merger	--
Net cash (used in) provided by investing activities.....	(4
	--
FINANCING ACTIVITIES:	
Repayments of long-term debt.....	(32
Issuance of Class A Common Stock on March 6, 2000.....	--
Net cash used in financing activities.....	(32
	--
NET INCREASE IN CASH AND CASH EQUIVALENTS.....	30
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD.....	59
	--
CASH AND CASH EQUIVALENTS, END OF PERIOD.....	\$89
	==
SUPPLEMENTAL INFORMATION:	
Interest Paid.....	\$ 6
Income Taxes Paid.....	\$ 2
SCHEDULE OF NON-CASH INVESTING AND FINANCIAL ACTIVITIES	
Promissory Note issued under Manufacturing & Supply Agreement	\$21
Fair value of net assets acquired in the Merger, net of cash	
Adjustment to fair value of net assets acquired in the Merger due to lease termination	\$3,

See Notes to Consolidated Financial Statements.

ENDO PHARMACEUTICALS HOLDINGS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001

## 1. CONSOLIDATED FINANCIAL STATEMENTS

In the opinion of management, the accompanying condensed consolidated financial statements of Endo Pharmaceuticals Holdings Inc. ("Endo" or the "Company") 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, 2001 and the results of operations and cash flows for the periods presented. The accompanying consolidated balance sheet as of December 31, 2000 is derived from the Company's audited financial statements. Certain information and footnote disclosure normally

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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 APB Opinion No. 28 and Rule 10-01 of Regulation S-X promulgated 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, 2000 contained in the Company's Annual Report on Form 10-K filed on March 29, 2001.

### 2. MERGER

On November 29, 1999, the Company and Algos Pharmaceutical Corporation ("Algos") announced that they had entered into a definitive merger agreement providing for the merger (the "Merger") of Algos into Endo Inc., a newly formed, wholly owned subsidiary of the Company. The Merger, which was completed on July 17, 2000, has been accounted for by the Company using the purchase method of accounting. The assets acquired and liabilities assumed of Algos were recorded at their fair values at the date of acquisition based on an independent appraisal. The assets acquired and liabilities assumed, results of operations and cash flows of Algos have been included in the Company's financial statements prospectively for reporting periods beginning July 17, 2000.

The total purchase price of \$248.6 million (including approximately \$7.0 million in transaction fees) was determined using an average closing price of the Algos common stock for a reasonable period of time before and after the April 17, 2000 measurement date of \$13.54 and the 17,832,106 common shares and common share equivalents of Algos outstanding at the date of the Merger (including 21,580 outstanding Algos Series A Warrants). The allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to workforce in place of \$11.9 million which is being amortized over its estimated useful life of two years, patents of \$3.2 million which is being amortized over their estimated useful lives of 17 years and goodwill of \$104.8 million which is being amortized over its estimated useful life of three years. In addition, the Company recorded estimated liabilities for exit costs of \$3.1 million related to non-cancelable lease payments and \$1.1 million for employee relocation costs. In the third quarter of 2001, the Company was released from its obligation under lease payments on the former Algos corporate offices. Accordingly, this estimated liability for exit costs of \$3.1 million was reversed and recorded as a reduction in goodwill. The balance of the estimated liabilities for exit costs is \$1.0 million as of September 30, 2001. Also, as a result of the Merger, it was determined that the utilization of the Company's federal deferred tax assets is uncertain. Accordingly, a valuation allowance has been recorded to fully reserve the Company's federal deferred tax assets.

The Merger included various on-going projects to research and develop innovative new products for pain management. As a result, the allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to purchased in-process research and development ("IPRD") of \$133.2 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology used by the Company on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that the Company will prioritize and continue; 2) project net future cash flows of the identified projects based on current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch the products (significant net cash inflows from MorphiDex(R) were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the



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estimated percentage of completion to the discounted cash flow for each individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the Merger, primarily the stage of project completion.

The Company allocated fair value to the three opioid analgesic projects of Algos: Morphidex(R), HydrocoDexTM and OxycoDexTM. The development program for a new pharmaceutical substance involves several different phases prior to submission of an application with the appropriate governmental agency for approval. Such application must be approved prior to marketing a new drug. Despite the Company's commitment to completion of the research and development projects, many factors may arise that could cause a project to be withdrawn or delayed, including the inability to prove the safety and efficacy of a drug during the development process. Upon withdrawal, it is unlikely that the development activities will have alternative use. If these projects are not successfully developed, the Company's results of operations and financial position in a future period could be negatively impacted.

### 3. RECAPITALIZATION

In connection with the Merger, the Company effected a recapitalization (the "Recapitalization") of its common stock, par value \$.01 per share ("Common Stock"), class A common stock, par value \$.01 per share ("Class A Common Stock") and preferred stock. The Recapitalization was effected on July 17, 2000 through a stock dividend of approximately 64.59 shares of Common Stock for each share of Common Stock and Class A Common Stock outstanding immediately prior to the Merger. Immediately prior to the Merger, the Company amended and restated its certificate of incorporation to effect the Recapitalization and to eliminate its Class A Common Stock. The effect of the Recapitalization has been reflected in the accompanying financial statements.

### 4. 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 is effective for all fiscal years beginning after June 15, 2000. SFAS 133, as amended by SFAS 137 and SFAS 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 133 defines new requirements for designation and documentation of hedging relationships as well as on-going effectiveness assessments in order to use hedge accounting. A derivative that does not qualify as a hedge will be marked to fair value through earnings.

At January 1, 2001, the Company recorded \$0.2 million as an accumulated transition adjustment as a reduction to earnings relating to cash flow hedges.

In December 1999, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin, SAB 101, entitled "Revenue Recognition in

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Financial Statements," as amended, effective as of October 1, 2000, which summarizes the SEC's views in applying generally accepted accounting principles to revenue recognition. The adoption of this guideline had no effect on the Company's financial statements.

In March 2000, the FASB issued Financial Accounting Series Interpretation No. 44 entitled "Accounting for Certain Transactions Involving Stock Compensation," which provides clarification to Accounting Principles Board Opinion No. 25 (APB No. 25), "Accounting for Stock Issued to Employees." The adoption of this interpretation had no effect on the Company's financial statements.

In June 2001, the FASB issued SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 is 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. Upon adoption, the Company will no longer amortize goodwill unless evidence of an impairment exists. Goodwill will be evaluated for impairment on at least an annual basis. Although the Company is currently evaluating all of the provisions of SFAS No. 141 and SFAS No. 142 and therefore is not presently able to quantify the impact of adoption, the Company does believe the adoption of SFAS No. 142 will have a material impact on its results of operations. The Company has \$228.1 million of goodwill as of September 30, 2001 and has recorded \$30.7 million of goodwill amortization for the nine months ended September 30, 2001. The Company will adopt the provisions of SFAS No. 142 effective January 1, 2002.

### 5. COMMITMENTS AND CONTINGENCIES

The Company has entered into employment agreements with certain members of management.

The Company is subject to various claims arising out of the normal course of business with respect to commercial matters, including product liabilities, patent infringement matters, governmental regulation and other actions. In the opinion of management, the amount of ultimate liability with respect to these actions will not materially affect the financial position, results of operations or liquidity of the Company.

Prior to July 17, 2000, Kelso & Company provided financial advisory services to the Company for an annual fee of \$347,000 plus the reimbursement of expenses. In connection with the Merger, which was completed on July 17, 2000, the Company terminated this agreement by making a one-time payment to Kelso of \$1.5 million, which was charged to expenses as of July 17, 2000.

### 6. COMPENSATION RELATED TO STOCK OPTIONS

During the period ended September 30, 2001, the Company recorded a non-cash charge of \$37.3 million for stock-based compensation relating to the vesting of options that were granted under the Endo Pharma LLC Amended and Restated 1997 Stock Option Plans. Under these plans, tranches of options vest when the Company attains certain 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

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

### 7. SEPARATION BENEFITS

During the period ended March 31, 2000 and immediately thereafter, the Company entered into separation and release agreements with two executives. The agreements were accounted for during the period ended March 31, 2000 as all material terms and conditions were known as of March 31, 2000. Severance and other termination benefits provided by the agreements amounting to \$1,252,000 were accrued as of March 31, 2000.

The separation and release agreements provided that certain options granted to the two executives under then existing option plans became fully vested on the effective dates of the agreements. The agreements also provided that other options previously granted to the executives would terminate. The agreements further provided terms and conditions for the exercise of the vested options. Cost related to stock options resulting from the agreements resulted in a charge to the Company of \$20,782,000 during the period ended March 31, 2000.

### 8. SUBSEQUENT EVENTS

On October 23, 2001, the Company completed a public offering of 11.4 million primary shares of Common Stock. On October 29, 2001, the Company used the net proceeds of this public offering totaling \$84.9 million together with \$16.1 million of cash and cash equivalents to repay in full the term loans under its existing credit facility. In connection with the extinguishment of the term loans, the Company expensed approximately \$2.4 million in deferred financing fees. This charge will be reflected as an extraordinary item, net of tax, in the Company's statement of operations in the fourth quarter of 2001.

The Company is currently negotiating the terms of a new senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters of the recent public offering, to replace the Company's existing credit agreement. The Company currently expects the new credit facility to be in the amount of approximately \$100 million and to have a final maturity of five years. Any outstanding loans under the new credit facility may be secured by a first priority security interest in substantially all of the Company's assets. The new credit facility is expected to contain representations and warranties, covenants, events of default and other provisions customarily found in similar agreements. The Company cannot assure you that it will be able to enter into the new credit facility on the terms described above or at all.

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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

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statements that involve risks and uncertainties.

### Overview

The Company, through its wholly owned subsidiaries, Endo Pharmaceuticals Inc. and Endo Inc., is 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 68%, 76% and 67% of net sales for the year ended December 31, 1999, the year ended December 31, 2000 and the nine months ended September 30, 2001, respectively. On August 26, 1997, an affiliate of Kelso & Company and 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. On November 19, 1999, the Company formed Endo Inc. as a wholly owned subsidiary to effect the acquisition of Algos Pharmaceutical Corporation ("Algos"). The stock of Endo Pharmaceuticals Inc. and the stock of Endo Inc. are the only assets of the Company, and the Company has no other operations or business. The Company was formed as a holding company and incorporated on November 18, 1997 under the laws of the state of Delaware and has its principal executive offices at 100 Painters Drive, Chadds Ford, Pennsylvania 19317 (telephone number: (610) 558-9800).

On July 17, 2000, the Company completed its merger with Algos (the "Merger"). In the Merger, the Company issued to the former Algos stockholders, in the aggregate, 17,810,526 shares of Company Common Stock and 17,810,526 warrants to purchase in the aggregate up to 20,575,507 additional shares of Company Common Stock in certain circumstances as more fully described in the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended. In the Merger, the Company also issued to the pre-Merger Endo 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 in the Company's Registration Statement on Form S-4 filed with the Securities and Exchange Commission on June 9, 2000, as amended.

The Merger has been accounted for by the Company using the purchase method of accounting. The assets acquired and liabilities assumed of Algos have been recorded at their fair values based on an independent appraisal. The assets acquired and liabilities assumed, results of operations and cash flows of Algos have been 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 17, 2000.

The Merger included various on-going projects to research and develop innovative new products for pain management. As a result, the allocation of the fair value of the assets acquired and liabilities assumed includes an allocation to purchased in-process research and development ("IPRD") of \$133.2 million which was immediately expensed in the consolidated statement of operations on the acquisition date. The methodology used by the Company on the acquisition date in determining the value of IPRD was to: 1) identify the various on-going projects that the Company will prioritize and continue; 2) project net future cash flows of the identified projects based on current demand and pricing assumptions, less the anticipated expenses to complete the development program, drug application, and launch the products (significant net cash inflows from MorphiDex(R) were projected in 2003); 3) discount these cash flows based on a risk-adjusted discount rates ranging from 25% to 33% (weighted average discount rate of 27%); and 4) apply the estimated percentage of completion to the discounted cash flow for each

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individual project ranging from 4% to 81%. The discount rate was determined after considering various uncertainties at the time of the merger, primarily the stage of project completion.

The Company allocated fair value to the three opioid analgesic projects of Algos: Morphidex(R), HydrocoDexTM and OxycoDexTM. The development program for a new pharmaceutical substance involves several different phases prior to submission of an application with the appropriate governmental agency for approval. Such application must be approved prior to marketing a new drug. Despite the Company's commitment to completion of the research and development projects, many factors may arise that could cause a project to be withdrawn or delayed, including the inability to prove the safety and efficacy of a drug during the development process. Upon withdrawal, it is unlikely that the development activities will have alternative use. If these projects are not successfully developed, the Company's results of operations and financial position in a future period could be negatively impacted.

The Company's 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 the Company's customers, market acceptance of the Company's products and the impact of competitive products and pricing.

### Results of Operations

#### Net Sales

Net sales consist of revenues from sales of pharmaceutical products, less estimates for certain chargebacks, sales allowances, the cost of returns and losses. Net sales are recognized when products are shipped.

The following table presents unaudited net sales for select products for the three months and the nine months ended September 30, 2001 and 2000:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001 ----	2000 ----	2001 ----	2000 ----
	(in thousands, unaudited)			
Percocet (R)	\$ 16,430	\$ 23,379	\$ 72,831	\$54,251
Lidoderm(R)	16,268	7,343	26,933	12,833
Other Brands	8,087 -----	8,330 -----	16,678 -----	21,311 -----
Total Brands	\$ 40,785 =====	\$39,052 =====	\$ 116,442 =====	\$88,395 =====
Total Generics	25,483	11,850	57,065	31,441

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	-----	-----	-----	-----
Total Net Sales	\$66,268	\$50,902	\$173,507	\$119,836
	=====	=====	=====	=====

The following table presents unaudited net sales as a percentage of total net sales for select products for the three months and nine months ended September 30, 2001 and 2000:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
	----	----	----	----
	(unaudited)			
Percocet (R)	25%	46%	42%	45%
Lidoderm(R)	25%	15%	15%	11%
Other Brands	12%	16%	10%	18%
	---	---	---	---
Total Brands	62%	77%	67%	74%
	===	===	===	===
Total Generics	38%	23%	33%	26%
	----	---	----	---
Total Net Sales	100%	100%	100%	100%
	====	====	====	====

## Goodwill and Other Intangibles

Goodwill and other intangibles represent a significant portion of the assets and stockholders' equity of the Company. As of September 30, 2001, goodwill and other intangibles comprised approximately 54% of total assets and 129% of stockholders' equity. The Company assesses the recoverability and the amortization period of goodwill by determining whether the amount can be recovered through undiscounted net cash flows of the businesses acquired over the remaining amortization period. The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, such as in the event of a significant adverse change in business conditions or a significant change in the intended use of an asset. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset are less than its carrying amount. Assets are grouped at the lowest level for which there are identifiable cash flows that are largely independent from other asset groups. The Company uses the discounted future expected net cash flows, as its estimate of fair value, to determine the amount of impairment

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loss. As a result of the significance of goodwill and other intangibles, amortization of goodwill and other intangibles will significantly impact the results of operations of the Company. In addition, the Company's results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill and other intangible assets occur. See "Recent Accounting Pronouncements."

### Compensation Related to Stock Options

In the third quarter of 2001 and the fourth quarter of 2000, the Company incurred non-cash charges of \$37.3 million and a non-cash charge of \$15.3 million, in each case for stock-based compensation relating to the vesting of options that were granted under the Endo Pharma LLC stock option plans. Under these plans, tranches of options vest when the Company attains certain stock price targets. As each tranche vests, the Company incurs a non-cash charge representing the difference between the market price of the shares of Common Stock underlying the options and the exercise price of such options. The Company may in the future incur up to two additional charges in relation to the Endo Pharma LLC options. These charges may be substantial. These options are exercisable into shares of Common Stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of Common Stock and will not dilute the public stockholders of Endo.

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

### Three Months Ended September 30, 2001 Compared to the Three Months Ended September 30, 2000

**Net Sales.** Net sales for the three months ended September 30, 2001 increased by 30% to \$66.3 million from \$50.9 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales from Lidoderm(R) and certain generic products. Specifically, in September 1999, the Company launched Lidoderm(R), the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In November 1998, the Company launched the 15mg, 30mg and 60mg strengths, in May 2001, the Company launched the 100mg strength and in September 2001, the Company launched the 200mg strength of its generic morphine sulfate extended release tablets. In the second quarter of 2001, the Company launched two new strengths of its generic product Endocet(R). The increase in net sales resulting from the foregoing launches were primarily offset by a decrease in net sales of Percocet(R). In April 2001, generic equivalents to Percocet(R) 7.5/500 and Percocet(R) 10.0/650 became available. These generics may have a material impact on the results of operations and cash flows of the Company in the future.

**Gross Profit.** Gross profit for the three months ended September 30, 2001 increased by 28% to \$45.6 million from \$35.6 million in the comparable 2000 period. Gross profit margins decreased to 69% from 70% in the comparable 2000 period due to an increase in the percentage of net sales attributable to generic products. Net sales of generic products for the three months ended September 30, 2001 increased to 38% of net sales from 17% of net sales in the comparable 2000 period. Although net sales of brand products increased 4% for the three months ended September 30, 2001 over the comparable 2000 period, generic products increased 115% in the three months ended September 30, 2001 over the comparable 2000 period due to the factors discussed above. If the Company achieves its forecast for revenue

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and product mix, the Company's management expects an increase in gross profit and gross profit margin for fiscal year 2001 over fiscal year 2000.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended September 30, 2001 increased by 34% to \$19.6 million from \$14.6 million in the comparable 2000 period. This increase was due to a \$2.1 million increase in sales and promotional efforts in 2001 over the comparable 2000 period to support Lidoderm(R) and Percocet(R). The increase in sales and promotional efforts was primarily due to the first quarter 2001 deployment of a dedicated contract sales force of 230 full-time representatives comprised of 70 full-time specialty representatives and 160 full-time primary care representatives compared to 300 part-time representatives in the comparable 2000 period. In addition, the Company experienced an increase in personnel-related costs in the general and administrative functions in order to support its growth.

**Research and Development Expenses.** Research and development expenses for the three months ended September 30, 2001 decreased by 6% to \$7.8 million from \$8.3 million in the comparable 2000 period. Research and development expenses in the three months ended September 30, 2000 included a significant portion of the cost to manufacture clinical supplies for ongoing trials.

**Depreciation and Amortization.** Depreciation and amortization for the three months ended September 30, 2001 increased to \$12.4 million from \$10.7 million in the comparable 2000 period. This increase was substantially due to the increase in amortization of goodwill and other intangibles resulting from the intangible assets acquired as a result of the Merger. The results of operations of Algos have been included in the Company's financial statements prospectively for reporting periods beginning July 17, 2000.

**Compensation Related to Stock Options.** Compensation related to stock options of \$37.3 million reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC stock option plans. Under these plans, tranches of options vest when the Company attains certain Common Stock price targets. As each tranche vests, the Company incurs a non-cash charge representing the difference between the market price of the shares of Common Stock underlying the options and the exercise price of such options. The Company may in the future incur up to two additional charges in relation to the Endo Pharma LLC options. These charges may be substantial. These options are exercisable into shares of Common Stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of Common Stock and will not dilute the public stockholders of Endo.

**Purchased In-Process Research and Development.** Purchased in-process research and development for the three months ended September 30, 2000 of \$133.2 million resulted from the estimated fair value of the products under development that the Company acquired in the Merger with Algos.

**Merger and Other Related Costs.** Merger and other related costs for the three months ended September 30, 2000 of \$1.6 million resulted from fees incurred as a result of the Merger with Algos that were not considered direct costs of the acquisition.

**Consolidated EBITDA.** Consolidated EBITDA for the three months ended September 30, 2001 increased 58% to \$24.7 million from \$15.6 million in the comparable 2000 period.

**Interest Expense, Net.** Interest expense, net for the three months ended September 30, 2001 decreased by 27% to \$2.7 million from \$3.7 million



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in the comparable 2000 period. The decrease was primarily due to a decrease in interest expense of \$1.0 million due to a decrease in interest rates.

**Income Tax (Benefit).** Income tax (benefit) for the three months ended September 30, 2001 increased as a result of an increase in the taxable loss and, for the three months ended September 30, 2001, reflects only state income tax benefit. The Company has recorded a valuation allowance on its existing federal deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future. The Company continually evaluates whether conditions exist that indicate that the utilization of deferred tax assets will be more likely than not.

Nine Months Ended September 30, 2001 Compared to the Nine Months Ended September 30, 2000

**Net Sales.** Net sales for the nine months ended September 30, 2001 increased by 45% to \$173.5 million from \$119.8 million in the comparable 2000 period. This increase in net sales was primarily due to the increase in net sales from several new products. Specifically, in November 1999, the Company launched Percocet(R) 2.5/325, Percocet(R) 7.5/500 and Percocet(R) 10.0/650 to complement the existing Percocet(R) 5.0/325 for the relief of moderate-to-severe pain. In September 1999, the Company launched Lidoderm(R), the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia. In November 1998, the Company launched the 15mg, 30mg and 60mg strengths, in May 2001, the Company launched the 100mg strength and in September 2001, the Company launched the 200mg strength of its generic morphine sulfate extended release tablets. In the second quarter of 2001, the Company launched two new strengths of its generic product Endocet(R). In April 2001, generic equivalents to Percocet(R) 7.5/500 and Percocet(R) 10.0/650 became available. These generics may have a material impact on the results of operations and cash flows of the Company in the future.

**Gross Profit.** Gross profit for the nine months ended September 30, 2001 increased by 56% to \$119.2 million from \$76.2 million in the comparable 2000 period. Gross profit margins increased to 69% from 64% due to a more favorable mix of higher margin products resulting from the product launches discussed above, and the discontinuation of some lower margin non-core products. In addition, the increase in gross profit margins was also due to the existing fixed cost nature of the Company's manufacturing relationship with Bristol-Myers Squibb Company (formerly DuPont Pharmaceuticals), currently the Company's most significant contract manufacturing relationship. If the Company achieves its forecast for revenue and product mix, the Company's management expects the increase in gross profits to continue.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the nine months ended September 30, 2001 increased by 35% to \$54.9 million from \$40.7 million in the comparable 2000 period. This increase was due to a \$7.1 million increase in sales and promotional efforts in 2001 over the comparable 2000 period to support Lidoderm(R) and Percocet(R). The increase in sales and promotional efforts was primarily due to the first quarter 2001 deployment of a dedicated contract sales force of 230 full-time representatives comprised of 70 full-time specialty representatives and 160 full-time primary care representatives compared to 300 part-time representatives in the comparable 2000 period. In addition, the Company experienced an increase in personnel-related costs in the general and administrative functions in order to support its growth.

**Research and Development Expenses.** Research and development expenses for the nine months ended September 30, 2001 increased by 59% to \$25.4

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million from \$16.0 million in the comparable 2000 period. This increase was due to the Company's increased spending on products under development that are focused in pain management including the products under development that had been part of the former Algos pipeline. The results of operations of Algos have been included in the Company's financial statements prospectively for reporting periods beginning July 17, 2000.

**Depreciation and Amortization.** Depreciation and amortization for the nine months ended September 30, 2001 increased to \$37.2 million from \$15.0 million in the comparable 2000 period. This increase was substantially due to the increase in amortization of goodwill and other intangibles resulting from the intangible assets acquired as a result of the Merger. The results of operations of Algos have been included in the Company's financial statements prospectively for reporting periods beginning July 17, 2000.

**Compensation Related to Stock Options.** Compensation related to stock options of \$37.3 million in the nine months ended September 30, 2001 reflects the charge arising from the vesting of performance-based stock options granted pursuant to the Endo Pharma LLC stock option plans. Under these plans, tranches of options vest when the Company attains certain Common Stock price targets. As each tranche vests, the Company incurs a non-cash charge representing the difference between the market price of the shares of Common Stock underlying the options and the exercise price of such options. The Company may in the future incur up to two additional charges in relation to the Endo Pharma LLC options. These charges may be substantial. These options are exercisable into shares of Common Stock that are presently held by Endo Pharma LLC. As a result, the exercise of these options will not result in the issuance of additional shares of Common Stock and will not dilute the public stockholders of Endo.

**Purchased In-Process Research and Development.** Purchased in-process research and development for the nine months ended September 30, 2000 of \$133.2 million resulted from the estimated fair value of the products under development that the Company acquired in the Merger with Algos.

**Merger and Other Related Costs.** Merger and other related costs for the nine months ended September 30, 2000 of \$1.6 million resulted from fees incurred as a result of the Merger with Algos that were not considered direct costs of the acquisition.

**Separation Benefits.** Separation benefits of \$22.0 million for the nine months ended September 30, 2000 resulted from a \$20.8 million charge related to the acceleration of vesting of stock options held by two former executives and a \$1.2 million charge from compensation and other benefits pursuant to two separation and release agreements the Company entered into. The stock compensation charge reflects the estimated difference in the fair value and the exercise price of such stock options on the effective date of the separation and release agreements.

**Consolidated EBITDA.** Consolidated EBITDA for the nine months ended September 30, 2001 increased by 83% to \$55.9 million from \$30.6 million in the comparable 2000 period.

**Interest Expense, Net.** Interest expense, net for the nine months ended September 30, 2001 decreased by 20% to \$9.1 million from \$11.4 million in the comparable 2000 period. The decrease was primarily due to a decrease in interest expense of \$1.8 million due to a decrease in interest rates. In addition, the decrease was due to an increase in interest income of \$.6 million due to an increase in the average cash balance for the nine months ended September 30, 2001 compared to the comparable 2000 period. The increase in the average cash balance was in part due to the acquisition of \$19.6 million in net cash and cash equivalents in the Merger with Algos.

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Income Tax (Benefit). Income tax (benefit) for the nine months ended September 30, 2001 decreased as a result of an decrease in the taxable loss and, for the nine months ended September 30, 2001, reflects only state income tax benefit. The Company has recorded a valuation allowance on its existing federal deferred tax assets due to the uncertainty of the utilization of such amounts in the foreseeable future. The Company continually evaluates whether conditions exist that indicate that the utilization of deferred tax assets will be more likely than not.

### Liquidity and Capital Resources

Net cash provided by operating activities increased by \$47.0 million to \$68.0 million for the nine months ended September 30, 2001 from \$21.0 million for the nine months ended September 30, 2000. This increase was substantially due to a reduction in cash flow utilized in inventory and other working capital improvements. Specifically, during the nine months ended September 30, 2000, the Company was building up inventories to support the launches of several new products, which utilized a significant amount of cash flow.

Net cash used in investing activities was \$4.9 million for the nine months ended September 30, 2001 compared to net cash provided by investing activities of \$18.7 million for the nine months ended September 30, 2000. The \$19.6 million in net cash acquired from the merger with Algos was offset by an increase in capital expenditures of \$4.0 million. This increase in capital expenditures was due to the implementation of an electronic document management system during 2001 and the purchase of leasehold improvements and other furniture and fixtures related to the Company's new principal executive offices, the lease of which commenced in the third quarter of 2001.

Net cash utilized in financing activities increased by \$20.1 million to \$32.9 million for the nine months ended September 30, 2001 from \$12.8 million for the nine months ended September 30, 2000 due to repayments made on the Company's existing credit facility. On October 29, 2001, the Company repaid in full the term loans under its existing credit facility.

On March 15, 2001, Penwest Pharmaceuticals Co., a collaboration partner of Endo with which Endo has an alliance agreement and with which Endo is developing one of its pipeline projects, received a "going concern" opinion from Ernst & Young LLP, its independent auditors, in connection with Penwest's Annual Report on Form 10-K for the year ended December 31, 2000. Specifically, Ernst & Young stated that they had substantial doubt about Penwest's ability to continue as a going concern in light of its recurring operating losses and negative cash flows from operations in each of the three years in the period ended December 31, 2000. In addition, Penwest's Annual Report indicated that, based on anticipated levels of operations and currently available capital resources, Penwest's management expects continued operating losses and negative cash flows during 2001. On July 10, 2001, Penwest announced that it had entered into definitive agreements for the sale of 2.4 million shares of newly issued common stock to selected institutional and other accredited investors for an aggregate of \$30.0 million. On July 25, 2001, Penwest filed a Report on Form 8-K with the SEC that contained an opinion of Ernst & Young LLP that, on account of this issuance of \$30.0 million of common stock, the conditions that raised substantial doubt about whether Penwest will continue as a going concern no longer exist. In Penwest's quarterly report for the quarter ended June 30, 2001, Penwest stated that its existing capital resources, including, among other things, the proceeds of the private placement of \$30.0 million of common stock, will enable Penwest to "maintain currently-planned operations into at least the fourth quarter of 2002." If Penwest is unable to fund

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their portion of the collaboration project with Endo, this may adversely affect the Company's results of operations and cash flows in the foreseeable future.

The Company's cash and cash equivalents totaled \$89.3 million at September 30, 2001. On October 23, 2001, the Company completed a public offering of 11.4 million primary shares of Common Stock. On October 29, 2001, the Company used the net proceeds of this public offering totaling \$84.9 million together with \$16.1 million of cash and cash equivalents to repay in full the term loans under its existing credit facility. The Company believes that its (a) cash and cash equivalents and (b) cash flow from operations, will be sufficient to meet its normal operating, investing and financing requirements in the foreseeable future, including the funding of the Company's pipeline projects in the event that Endo's collaboration partners are unable to fund their portion of any particular project. The Company may use a portion of its cash and cash equivalents to repay all or a portion of the notes that it has issued to Bristol-Myers Squibb Company (formerly DuPont Pharmaceuticals), for possible acquisitions and/or for possible repurchase of warrants originally issued to the former stockholders of Algos in connection with the Company's acquisition of Algos. The Company may repurchase these warrants in privately negotiated transactions, open market purchases, tender offers or otherwise. Repurchase of these warrants would be subject to market conditions and receipt of any required third party consents and waivers. In the event that the Company makes any significant acquisitions or other strategic investments, it may be required to raise additional funds, through the issuance of additional debt or equity securities.

The Company is currently negotiating the terms of a new senior secured credit facility with a number of lenders, including affiliates of certain of the underwriters of the recent public offering, to replace the Company's existing credit agreement. The Company currently expects the new credit facility to be in the amount of approximately \$100 million and to have a final maturity of five years. Any outstanding loans under the new credit facility may be secured by a first priority security interest in substantially all of the Company's assets. The new credit facility is expected to contain representations and warranties, covenants, events of default and other provisions customarily found in similar agreements. The Company cannot assure you that it will be able to enter into the new credit facility on the terms described above or at all.

### 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 is effective for all fiscal years beginning after June 15, 2000. SFAS 133, as amended by SFAS 137 and SFAS 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 133 defines new requirements for designation and documentation of hedging relationships as well as on-going effectiveness assessments in order to use hedge accounting. A derivative that does not qualify as a hedge will be marked to fair value through earnings.

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At January 1, 2001, the Company recorded \$0.2 million as an accumulated transition adjustment as a reduction to earnings relating to cash flow hedges.

In December 1999, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin, SAB 101, entitled "Revenue Recognition in Financial Statements," as amended, effective as of October 1, 2000, which summarizes the SEC's views in applying generally accepted accounting principles to revenue recognition. The adoption of this guideline had no effect on the Company's financial statements.

In March 2000, the FASB issued Financial Accounting Series Interpretation No. 44 entitled "Accounting for Certain Transactions Involving Stock Compensation," which provides clarification to Accounting Principles Board Opinion No. 25 (APB No. 25), "Accounting for Stock Issued to Employees." The adoption of this interpretation had no effect on the Company's financial statements.

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 is 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. Upon adoption, the Company will no longer amortize goodwill unless evidence of an impairment exists. Goodwill will be evaluated for impairment on at least an annual basis. Although the Company is currently evaluating all of the provisions of SFAS No. 141 and SFAS No. 142 and therefore is not presently able to quantify the impact of adoption, the Company does believe the adoption of SFAS No. 142 will have a material impact on the results of operations of the Company. The Company has \$228.1 million of goodwill as of September 30, 2001 and has recorded \$30.7 million of goodwill amortization for the nine months ended September 30, 2001. The Company will adopt the provisions of SFAS No. 142 effective January 1, 2002.

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

The Company's primary market risk exposure is to changes in interest rates (LIBOR) on its variable rate borrowings. The Company does not utilize financial instruments for trading purposes and holds no derivative financial instruments that could expose it to significant market risk. The Company monitors interest rates and enters into interest rate agreements as considered appropriate. To manage a portion of its exposure to fluctuations in interest rates, the Company had entered into an interest rate cap agreement with a notional amount of \$82.5 million that sets a maximum LIBOR rate of 8% that it will pay on the related notional amount. This interest rate cap agreement expired on August 27, 2000. Effective August 27, 2000, the Company has entered into a new interest rate cap agreement with a notional amount of \$70.0 million that sets a maximum LIBOR rate of 8% that the Company will pay on the related notional amount through August 27, 2003. On October 29, 2001, the Company repaid its existing variable rate borrowings, thereby terminating its interest rate cap agreement.

## PART II

### OTHER INFORMATION

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### Item 1. Legal Proceedings.

On October 20, 2000, The Purdue Frederick Company and related companies ("Purdue Frederick") filed suit against the Company and its 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(R) (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(R), 40mg strength, challenged the listed patents for OxyContin(R) 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against the Company 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(R), 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(R). On August 30, 2001, Purdue Frederick filed a third suit against the Company 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(R), 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(R).

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(R). 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 and 40mg 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. The Company intends to pursue a similar litigation strategy with respect to the 80mg strength of this product. However, the Company cannot make assurances as to the outcome of this patent challenge. Purdue Frederick was granted a preliminary injunction (Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 98 F. Supp. 2d 362 (SDNY 2000)), which decision was affirmed on appeal (Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359 (Fed. Cir. 2001)), against a different manufacturer based on the same patents that are being asserted against the Company and EPI, and in the same Court in which Purdue Frederick sued. The Company believes the defenses rejected in the preliminary injunction decision and in the appellate decision do not substantially impact the principal defenses raised by the Company and EPI.

We expect to be sued again as early as the fourth quarter of 2001 with respect to another ANDA we have filed with the FDA. Similar litigation may also result from products we currently have in development, as well as those which 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.

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

None.

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

(a) Exhibits.

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

(b) Reports on Form 8-K.

The Company filed three reports on Form 8-K during the quarter ended September 30, 2001. The dates of these reports (and the items reported) are as follows: August 31, 2001 (Item 5); September 5, 2001 (Item 5); and September 10, 2001 (Items 5 and 9). Item 9 of the September 10, 2001 Form 8-K incorporated the Company's Form S-3 (File No. 333-69136), which was filed with the SEC on September 7, 2001 and included financial statements.

### SIGNATURES

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/s/ CAROL A. AMMON

-----  
Name: Carol A. Ammon  
Title: President and Chief Executive  
Officer

/s/ JEFFREY R. BLACK

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

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Date: November 14, 2001

## Exhibit Index

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



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- Employee Stockholders (as defined therein)  
(incorporated herein by reference to Exhibit 4.2  
of the Form 10-Q for the Quarter ended June 30,  
2000 filed with the Commission on August 15,  
2000)
- 4.3 Form of Stock Certificate of Endo Common Stock  
(incorporated herein by reference to Exhibit 4.3  
of the Form 10-Q for the Quarter ended June 30,  
2000 filed with the Commission on August 15,  
2000)
- 4.4 Registration Rights Agreement, dated as of July  
17, 2000, by and between Endo and Endo LLC  
(incorporated herein by reference to Exhibit 4.4  
of the Form 10-Q for the Quarter ended June 30,  
2000 filed with the Commission on August 15,  
2000)
- 10.1 Endo Warrant Agreement, dated as of July 17,  
2000, by and between Endo and United States  
Trust Company of New York (incorporated herein  
by reference to Exhibit 10.1 of the Form 10-Q  
for the Quarter ended June 30, 2000 filed with  
the Commission on August 15, 2000)
- 10.2 Algos Warrant Agreement, dated as of July 17,  
2000, by and between Endo and United States  
Trust Company of New York (incorporated herein  
by reference to Exhibit 10.2 of the Form 10-Q  
for the Quarter ended June 30, 2000 filed with  
the Commission on August 15, 2000)
- 10.3 Form of Series A Warrant to Purchase Shares of  
Common Stock and Warrants of Endo (incorporated  
herein by reference to Exhibit 10.3 of the  
Registration Statement filed with the Commission on  
June 9, 2000)
- 10.4 Letter Agreement, dated as of November 26, 1999,  
by and among Algos, Endo, KIA V and KEP V  
(incorporated herein by reference to Exhibit  
10.4 of the Registration Statement filed with  
the Commission on June 9, 2000)
- 10.5 Tax Sharing Agreement, dated as of July 17,  
2000, by and among Endo, Endo Inc. and Endo LLC  
(incorporated herein 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 Agreement, dated as of July 17, 2000, by and  
between Endo and Endo LLC (incorporated herein  
by reference to Exhibit 10.6 of the Form 10-Q  
for the Quarter ended June 30, 2000 filed with  
the Commission on August 15, 2000)
- 10.7 Credit Agreement, dated as of August 26, 1997,  
by and between Endo Pharmaceuticals and The  
Chase Manhattan Bank (incorporated herein by  
reference to Exhibit 10.7 of the Registration

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Statement filed with the Commission on June 9, 2000)

- 10.8 [Intentionally Omitted.]
- 10.9 [Intentionally Omitted.]
- 10.10 Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Hind Health Care, Inc. (incorporated herein by reference to Exhibit 10.10 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.11 Analgesic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.11 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.12 Anti-Epileptic License Agreement, dated as of October 27, 1997, by and among Endo Pharmaceuticals, Endo Laboratories, LLC and DuPont Merck Pharmaceutical (incorporated herein by reference to Exhibit 10.12 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.13 [Intentionally Omitted.]
- 10.14 Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.15 Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ("Mallinckrodt") (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.16 Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and 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 (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.18 Strategic Alliance Agreement, dated as of September 17, 1997, by and between Endo Pharmaceuticals and

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- Penwest Pharmaceuticals Group (incorporated herein by reference to Exhibit 10.18 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.19 Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and Livingston Healthcare Services Inc. (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.20 Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.21 Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000)
- 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)
- 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)
- 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)
- 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)
- 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)
- 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

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- as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
- 10.29 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29 of the Current Report on Form 8-K dated August 31, 2001)
- 10.30 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
- 10.31 Separation and Release Agreement, dated as of March 22, 2000, by and between Endo Pharmaceuticals, Endo and Osagie O. Imasogie (incorporated herein by reference to Exhibit 10.31 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.32 Separation and Release Agreement, dated as of April 20, 2000, by and between Endo Pharmaceuticals, Endo and Louis J. Vollmer (incorporated herein by reference to Exhibit 10.32 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.33 Office Lease, dated as of August 26, 1997, by and between Endo Pharmaceuticals and Northstar Development Company (incorporated herein by reference to Exhibit 10.33 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.34 Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters' Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
- 10.35 Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (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 Inc. (f/k/a Algos

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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 Inc. (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001)

10.40 [Intentionally Omitted.]

10.41 Service Agreement, dated as of February 1, 2001, by and between Endo Pharmaceuticals Inc. 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)

11 Statement Regarding Computation of per Share Earnings

Endo Pharmaceuticals Holdings Inc.  
Statement Regarding Computation of Per Share Earnings  
(in thousands, except per share data)

	Three Months Ended September 30,		Ni
	2001	2001	200
	----	----	----
Numerator:			
Net loss available to common stockholders	\$ (32,993)	\$ (136,548)	\$ (44,
	=====	=====	=====
Denominator:			
For basic per share data - weighted average shares	89,139	85,848	89,
Effect of dilutive stock options	-	-	-
	-----	-----	-----
For diluted per share data	89,139	85,848	89,
	=====	=====	=====

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Basic loss per share

\$ (.37)

\$ (1.59)

\$ (.50)

=====

=====

=====

Diluted loss per share

\$ (.37)

\$ (1.59)

\$ (.50)

=====

=====

=====