

ENDO PHARMACEUTICALS HOLDINGS INC  
Form 10-Q  
November 09, 2005

Table of Contents

---

**UNITED STATES**  
**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, 2005.

OR

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_.

Commission file number: 001-15989

**ENDO PHARMACEUTICALS HOLDINGS INC.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware

13-4022871

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

(State or other jurisdiction of  
incorporation or organization)

(I.R.S. Employer  
Identification Number)

**100 Endo Boulevard**

**Chadds Ford, Pennsylvania 19317**

(Address of Principal Executive Offices)

**(610) 558-9800**

(Registrant's Telephone Number, Including Area Code)

**Not applicable**

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark 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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES  NO

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Common Stock, \$.01 par value: 132,716,065 shares as of November 3, 2005.

---

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

	<b>Page</b>
Forward-Looking Statements	
<b>PART I. FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets (Unaudited) September 30, 2005 and December 31, 2004</u>	6
<u>Condensed Consolidated Statements of Operations (Unaudited) Three and Nine Months Ended September 30, 2005 and 2004</u>	7
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Nine Months Ended September 30, 2005 and 2004</u>	8
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	
<u>Overview</u>	24
<u>Critical Accounting Policies and Estimates</u>	26
<u>Results of Operations</u>	29
<u>Three Months Ended September 30, 2005 Compared to the Three Months Ended September 30, 2004</u>	30
<u>Nine Months Ended September 30, 2005 Compared to the Nine Months Ended September 30, 2004</u>	31
<u>Liquidity and Capital Resources</u>	32
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
Item 4. <u>Controls and Procedures</u>	37
<b>PART II. OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	38
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	40
Item 3. <u>Defaults Upon Senior Securities</u>	40
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	40
Item 5. <u>Other Information</u>	40
Item 6. <u>Exhibits</u>	40
<b><u>SIGNATURES</u></b>	

## **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, future net income and future earnings per share, contained in the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations, are subject to risks and uncertainties. Forward-looking statements include the information concerning our possible or assumed results of operations. Also, statements including words such as believes, expects, anticipates, intends, estimates, or similar expressions are forward-looking statements. We have based these forward-looking statements on our current expectations and projections about the growth of our business, our financial performance and the development of our industry. Because these statements reflect our current views concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described in Management's Discussion and Analysis of Financial Condition and Results of Operations 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 growth and development will depend on our ability to successfully develop, commercialize and market new products, including both our own products and those developed with our collaboration partners. If we do not do so successfully, our growth and development will be impaired.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as the FDA's approval of products are uncertain. Before obtaining regulatory approvals for the sale of any of our products, other than generic products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large-scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals.

We face intense competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets. Competitive factors include: (i) the development of new products by our competitors that make our products or technologies uncompetitive or obsolete, (ii) competition with our branded products by generic versions that are generally significantly cheaper than the branded version, and, where available, may be required or encouraged in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies for branded versions by law, and (iii) competition to acquire intellectual property assets that we require to continue to develop and broaden our product range.

We are required to make significant cash payments to Endo Pharma LLC pursuant to a tax sharing agreement under which we have been and may be required to pay Endo Pharma LLC the amount of tax benefits usable by us as a result of the exercise of certain stock options into shares of our common stock held by Endo Pharma LLC.

Once approved by FDA, there is no guarantee that the market will accept our future products, and this may have an adverse effect on our profitability and cash flows.

The pharmaceutical industry is heavily regulated, which creates uncertainty about our ability to bring new products to market and imposes substantial compliance costs on our business. The federal, state and local governmental authorities in the United States, the principal one of which is the FDA, impose substantial requirements on the development, manufacture, labeling, sale, distribution, marketing, advertising, promotion and introduction of therapeutic pharmaceutical products through lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures. NDA approvals, if granted, may not include all uses for which we may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for non-indicated uses. Failure to comply with applicable regulatory requirements in this regard can result in, among other things, suspensions of approvals,

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

seizures or recalls of products, injunctions against a product's manufacture, distribution, sales and marketing, operating restrictions, civil penalties and criminal prosecutions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. The effect of government regulation may be to delay marketing of our new products for a considerable period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete with us. We cannot assure you that the FDA or other regulatory agencies will approve any products developed or in-licensed by us on a timely basis, if at all, or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

## **Table of Contents**

Most of our net sales come from a small number of products. Net sales of Lidoderm<sup>®</sup>, Endocet<sup>®</sup>, Percocet<sup>®</sup> and generic morphine sulfate accounted for 50%, 19%, 14% and 10% of our net sales for the year ended December 31, 2004, respectively. In addition, during the nine months ended September 30, 2005 we launched our generic extended-release oxycodone product which accounted for 14% of our net sales. If we were unable to continue to market any of these products, if any of them lost market share, for example, as the result of the entry of new competitors, or if the prices of any of these products declined significantly, our net sales, profitability and cash flows would be materially adversely affected.

We are dependent on outside manufacturers for the manufacture of our products. Third-party manufacturers currently manufacture all of our products pursuant to contractual arrangements. Accordingly, we have a limited ability to control the manufacturing process or costs related to this process. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain the facilities at which they manufacture our products in compliance with FDA, DEA, state and local regulations. If they fail to maintain compliance with FDA, DEA or other critical regulations, they could be ordered to cease manufacturing which would have a material adverse impact on our business, profitability and cash flows. In addition to FDA and DEA regulation, violation of standards enforced by the Environmental Protection Agency, or EPA, and the Occupational Safety and Health Administration, or OSHA, and their counterpart agencies at the state level, could slow down or curtail operations of third-party manufacturers. Certain of our manufacturers currently constitute the sole source of one or more of our products. Because of contractual restraints and the lead-time necessary to obtain FDA approval, and possibly DEA registration, of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of products to customers.

We are dependent on third parties to supply all raw materials used in our products and to provide many services for the core aspects of our business. Any interruption or failure by these suppliers, distributors and collaboration partners to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, profitability and cash flows.

Most of our core products contain narcotic ingredients. As a result of reports of misuse or abuse of prescription narcotics, the sale of such drugs may be subject to new regulation, including the development and implementation of risk management programs, which may prove difficult or expensive to comply with, and we and other pharmaceutical companies may face lawsuits.

We are exposed to product liability claims or product recalls and the possibility that we may not be able to obtain or maintain insurance adequate to cover these potential liabilities. Our business exposes us to potential liability risks that arise from the testing, manufacturing, marketing and sale of our products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Product liability is a significant commercial risk for us. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue.

Our ability to protect our proprietary technology, which is vital to our business, is uncertain. Our success, competitive position and amount of potential future income will depend in part on our ability to obtain patent protection relating to the technologies, processes and products we are currently developing and that we may develop in the future.

If the efforts of manufacturers of branded pharmaceuticals to use litigation and legislative and regulatory efforts to limit the use of generics and certain other products are successful, our sales may suffer. Pharmaceutical companies that produce patented brand products are increasingly employing a range of legal and regulatory strategies to delay the introduction of competing generics and certain other products to which we do not have a right of reference to all necessary preclinical and clinical data. Opposing such measures can be costly and time-consuming and result in delays in the introduction of our products.

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

The success of our acquisition and licensing strategy is subject to uncertainty and any completed acquisitions or licenses may reduce our earnings, be difficult to integrate, not perform as expected or require us to obtain additional financing. We regularly evaluate selective acquisitions and licenses and look to continue to enrich our product line by acquiring or licensing rights to additional products and compounds. Such acquisitions or licenses may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure you that we will be able to complete acquisitions or licenses that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify

## **Table of Contents**

suitable acquisition or licensing candidates, and we may have to compete for acquisition or license candidates. Our competitors may have greater resources than us and therefore be better able to complete acquisitions or licenses or may cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition or license goals, our growth may be limited.

The DEA limits the availability of the active ingredients used in many of our current products and products in development and, as a result, our procurement quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials. We must annually apply to the DEA for procurement quota in order to obtain these substances. Pursuant to recent legislation, the DEA may not establish procurement quota following FDA approval of an NDA or ANDA for a controlled substance until after DEA reviews and provides public comment on the labeling, promotion, risk management plan and other documents associated with such product. No assurance can be given that the DEA review of such materials may not result in delays in obtaining procurement quota for controlled substances, a reduction in the quota issued to us or an elimination of our quota entirely. Any delay by the DEA in establishing our procurement quota for controlled substances could delay our clinical trials, product launches or could cause trade inventory disruptions for those products that have already been launched.

The availability of third-party reimbursement for our products is uncertain, and thus we may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided. Our ability to commercialize our products depends in part on the extent to which reimbursement for the costs of these products is available from government health administration authorities, private health insurers and others. We cannot assure you that third-party insurance coverage will be adequate for us to maintain price levels sufficient for realization of an appropriate return on our investment. Government, private insurers and other third-party payers are increasingly attempting to contain health care costs by (1) limiting both coverage and the level of reimbursement for new products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, the substitution of generic alternatives to branded products.

The outcome of any litigation is uncertain, including claims asserting violations of the Federal False Claims Act, Anti-Kickback Statute or other violations in connection with Medicare and/or Medicaid. and

We are dependent on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales. We sell our products directly to a limited number of large pharmacy chains and through a limited number of wholesale drug distributors who, in turn, supply our products to pharmacies, hospitals, governmental agencies and physicians. Three distributors and one pharmacy chain individually accounted for 29%, 18%, 18% and 9% respectively, of net sales in 2004, 26%, 26%, 19% and 11% respectively, of net sales in 2003, and 24%, 24%, 23% and 11% respectively, of net sales in 2002. If we were to lose the business of any of these customers, or if any were to experience difficulty in paying us on a timely basis, our net sales, profitability and cash flows could be materially and adversely affected.

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. You are advised, however, to consult any further disclosures we make on related subjects in our 10-Q, 10-K and 8-K reports to the SEC. Also note that we provide the preceding cautionary discussion of risks, uncertainties and possibly inaccurate assumptions relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected and historical results. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the preceding to be a complete discussion of all potential risks or uncertainties.

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)****(In thousands, except share data)**

	<b>September 30,</b>	<b>December 31,</b>
	<b>2005</b>	<b>2004</b>
	<u>          </u>	<u>          </u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 410,487	\$ 278,034
Accounts receivable, net	258,547	139,039
Inventories	62,920	71,415
Prepaid expenses and other current assets	9,743	11,867
Deferred income taxes	92,677	67,222
	<u>          </u>	<u>          </u>
Total current assets	834,374	567,577
	<u>          </u>	<u>          </u>
PROPERTY AND EQUIPMENT, Net	34,322	28,875
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	100,874	117,258
NOTE RECEIVABLE	47,960	45,047
OTHER ASSETS	14,497	7,655
	<u>          </u>	<u>          </u>
TOTAL ASSETS	\$ 1,213,106	\$ 947,491
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 103,091	\$ 83,259
Accrued expenses	191,235	145,214
Accrued tax sharing payments to Endo Pharma LLC	23,599	42,939
Income taxes payable	73,574	1,836
	<u>          </u>	<u>          </u>
Total current liabilities	391,499	273,248
	<u>          </u>	<u>          </u>
DEFERRED INCOME TAXES	20,004	1,664
OTHER LIABILITIES	5,060	16,629
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS EQUITY</b>		
Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 175,000,000 shares authorized; 132,707,620 and 131,856,014 issued and outstanding at September 30, 2005 and December 31, 2004, respectively	1,327	1,319
Additional paid-in capital	643,705	635,915

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

Retained earnings	148,111	18,697
Accumulated other comprehensive income	3,400	19
	<u>          </u>	<u>          </u>
Total stockholders' equity	796,543	655,950
	<u>          </u>	<u>          </u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 1,213,106</b>	<b>\$ 947,491</b>
	<u>          </u>	<u>          </u>

See notes to condensed consolidated financial statements.

**Table of Contents****ENDO PHARMACEUTICALS HOLDINGS INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

(In thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
NET SALES	\$ 245,241	\$ 160,349	\$ 579,375	\$ 457,806
COST OF SALES	61,399	38,203	133,242	99,991
GROSS PROFIT	183,842	122,146	446,133	357,815
COSTS AND EXPENSES:				
Selling, general and administrative	47,309	43,512	156,984	125,271
Research and development	22,148	9,501	70,120	38,502
Depreciation and amortization	4,144	2,985	11,438	7,074
Loss on disposal of other intangible, including license termination fee of \$3,000				3,800
Impairment of other intangible asset	5,515		5,515	
OPERATING INCOME	104,726	66,148	202,076	183,168
INTEREST INCOME, Net of interest expense of \$453, \$290, \$1,412 and \$740, respectively	2,689	578	6,657	796
INCOME BEFORE INCOME TAX	107,415	66,726	208,733	183,964
INCOME TAX	40,862	25,349	79,319	69,865
NET INCOME	\$ 66,553	\$ 41,377	\$ 129,414	\$ 114,099
NET INCOME PER SHARE:				
Basic	\$ 0.50	\$ 0.31	\$ 0.98	\$ 0.87
Diluted	\$ 0.50	\$ 0.31	\$ 0.97	\$ 0.86
WEIGHTED AVERAGE SHARES:				
Basic	132,376	131,804	132,075	131,792
Diluted	133,532	132,460	133,122	132,688

See notes to condensed consolidated financial statements.

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2005</b>	<b>2004</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 129,414	\$ 114,099
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	11,438	7,074
Accretion of interest on note receivable	(930)	(103)
Deferred income taxes	(16,811)	7,473
Tax benefits of stock options exercised	7,602	23,443
Amortization of deferred financing costs	287	299
Loss on disposal of other intangible		3,800
Impairment of other intangible asset	5,515	
Loss on disposal of property and equipment	221	28
Selling, general and administrative expenses funded by Endo Pharma LLC	2,000	
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	(114,508)	(55,310)
Inventories	8,495	(41,476)
Note receivable	(1,983)	(208)
Other assets	2,170	(4,414)
Accounts payable	21,080	(7,235)
Accrued expenses	45,931	31,421
Income taxes payable	71,738	(8,295)
<b>Net cash provided by operating activities</b>	<b>171,659</b>	<b>70,596</b>
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(8,412)	(5,684)
Proceeds from the sale of property and equipment	1	246
Payment of license termination fee		(3,000)
Loan made to Vernalis		(50,000)
Other investments	(1,700)	(500)
License fees	(15,000)	(47,250)
<b>Net cash used in investing activities</b>	<b>(25,111)</b>	<b>(106,188)</b>
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(1,753)	(1,028)
Tax sharing payments to Endo Pharma LLC	(21,422)	(8,348)
Exercise of Endo Pharmaceutical Holdings Inc. Stock Options	9,080	375
<b>Net cash used in financing activities</b>	<b>(14,095)</b>	<b>(9,001)</b>

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

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	132,453	(44,593)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	278,034	229,573
	<u>          </u>	<u>          </u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 410,487	\$ 184,980
	<u>          </u>	<u>          </u>
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 305	\$ 321
Income taxes paid	\$ 16,900	\$ 47,006
SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment financed by capital leases	\$ 4,233	\$ 3,359
Change in accrual for purchases of property and equipment	\$ 1,248	\$ 985

See notes to condensed consolidated financial statements.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2005**

**1. BASIS OF PRESENTATION**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information. 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, 2005 and the results of our operations and our cash flows for the periods presented. The accompanying condensed consolidated balance sheet as of December 31, 2004 is derived from the Company's audited financial statements. Since certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted, we suggest that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto as of and for the year ended December 31, 2004 contained in the Company's Annual Report on Form 10-K. During the period ended September 30, 2005, the Company determined that acquisitions of property and equipment on account, which were previously reported as a component of changes in operating assets and liabilities and purchases of property and equipment, are now more appropriately shown as a non-cash investing activity, as opposed to cash used in investing activities, until paid by the Company. Accordingly, the Company's financial statements for the nine months ended September 30, 2004 have now been revised to reflect an increase in cash provided by operating activities with a corresponding increase in cash used in investing activities of approximately \$1.0 million. Purchases of property and equipment acquired on account have now been presented as a supplemental disclosure of non-cash items. This revision has no effect on net income or the amount of cash and cash equivalents reported. Certain prior period amounts on the statement of cash flows, within operating activities, have been reclassified to conform to the current period presentation.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In November 2004, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The adoption of SFAS No. 153 is not expected to have a material impact on the Company's results of operations or financial position.

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

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payments (revised 2004)*. This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award—the requisite service period (usually the vesting period). In March 2005, the SEC staff expressed their views with respect to SFAS No. 123R in Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107). SAB 107 provides guidance on valuing options. SFAS No. 123R will be effective for the Company's fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, (FIN 47). FIN 47 is an interpretation of SFAS No. 143, *Asset Retirement Obligations*, which was issued in June 2001. FIN 47 was issued to address diverse accounting practices that have developed with regard to the timing of liability recognition for legal obligations

**Table of Contents**

associated with the retirement of a tangible long-lived asset in which the timing and/or method of settlement are conditional on a future event that may or may not be within the control of the entity. According to FIN 47, uncertainty about the timing and/or method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective no later than December 31, 2005 for the Company. The Company is currently evaluating the impact of the adoption of FIN 47 on its financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's results of operations or financial position.

**3. INVENTORIES**

Inventories are comprised of the following at September 30, 2005 and December 31, 2004, respectively (in thousands):

	September 30,	December 31,
	2005	2004
	<u>          </u>	<u>          </u>
Raw Materials	\$ 12,959	\$ 14,936
Work-in-Process	10,954	16,294
Finished Goods	39,007	40,185
	<u>          </u>	<u>          </u>
Total	<u>\$ 62,920</u>	<u>\$ 71,415</u>

**4. LICENSE AND COLLABORATION AGREEMENTS***DURECT Corporation*

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the "DURECT Sufentanil Agreement"). The sufentanil patch, which is in early-stage clinical development, employs DURECT's proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee that has been expensed as research and development in the first quarter of 2005, with additional payments of approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of

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

arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

### *ProEthic Pharmaceuticals, Inc.*

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic's European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we paid a \$10 million upfront fee that has been expensed as research and development in the first quarter of 2005, and we could be required to make additional payments of approximately \$13.0 million upon the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th)

## **Table of Contents**

anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days' written notice.

### *SkyePharma, Inc.*

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma's patented development products, DepoDur<sup>®</sup>, previously referred to as DepoMorphine<sup>®</sup>, and Propofol IDD-D (collectively, the "Skye Products"). Under the terms of the agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other SkyePharma development products. In return, Endo made a \$25 million upfront payment to SkyePharma, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 17 years.

During the nine months ended September 30, 2005, we recorded a receivable from SkyePharma of \$5 million based upon the achievement of certain criteria as specified in the agreement. This receivable has been recorded as a reduction to our recorded intangible asset and the intangible asset is now being amortized over its remaining useful life of 15 years.

### *Vernalis Development Limited*

On July 1, 2005, we entered into a co-promotion Agreement with Vernalis. The co-promotion agreement is related to that certain license agreement that we entered into on July 14, 2004 with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement sets forth the detailed terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

### *Noven Pharmaceuticals, Inc.*

In February 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc. under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson's Duragesic<sup>®</sup> (fentanyl transdermal system). We made an upfront payment of \$8.0 million, \$1.5 million of which we expensed as research and development costs and \$6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic<sup>®</sup>. As a result, we incurred a charge of approximately \$5 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

## **5. GOODWILL AND OTHER INTANGIBLES**

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

	September 30,	December 31,
	2005	2004
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 112,100	\$ 123,600
Patents	3,200	3,200
	115,300	126,800
Less accumulated amortization	(14,426)	(9,542)
Other Intangibles, net	\$ 100,874	\$ 117,258

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2005, goodwill and other intangibles comprised approximately 23% of our total assets and 35% of our stockholders' equity. SFAS No. 142,

## **Table of Contents**

Goodwill and Other Intangible Assets, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2005 and 2004, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from twelve to twenty years. The determination to capitalize amounts related to licenses is based on management's judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the nine months ended September 30, 2005, the Company expensed \$20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations. As described in Note 4, we recorded an impairment loss of \$5.5 million during the three months ended September 30, 2005.

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2004 is as follows (in thousands):

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

2005	\$ 7,678
2006	7,235
2007	7,235
2008	7,235
2009	7,235

**Table of Contents****6. NOTE RECEIVABLE**

In July 2004, we entered into a license agreement and a loan agreement with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova<sup>®</sup> (frovatriptan) in North America. Under the loan agreement, we provided Vernalis with a loan of \$50 million in August 2004. The loan was primarily used to make a payment in full and final settlement of the amounts due to Elan Corporation from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova<sup>®</sup>. The loan is secured against the revenues receivable by Vernalis under the license agreement. At our election, we are able to offset \$20 million of the \$40 million menstrually related migraine indication ( MRM ) approval milestone and 50% of all royalties to be paid under the license agreement to Vernalis to repay the loan. To the extent not previously repaid, the loan is due in full after five years. Interest is at the rate of 5% per annum payable semi-annually. However, Vernalis has the option to defer payment of interest and increase the loan outstanding each time an interest payment becomes due. In January and July 2005, Vernalis elected to defer payment of the semi-annual interest amounts otherwise due January 31 and July 31, 2005 totaling approximately \$2.4 million.

We estimated that an approximate fair market rate of interest for this type of secured loan was 8% per annum and therefore recorded the note receivable at its present value at inception of \$43.8 million. The note receivable is being accreted up to its face amount at maturity using the effective interest method and thus the effective interest rate over the five year term will be 8% per annum. The difference of \$6.2 million between the face amount of the note and its present value at inception has been treated as additional consideration paid to acquire the license rights and has been included in Other Intangibles.

**7. COMPREHENSIVE INCOME**

Comprehensive income includes the following components for the three and nine months ended September 30, 2005 and 2004 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net income	\$ 66,553	\$ 41,377	\$ 129,414	\$ 114,099
Other comprehensive income:				
Unrealized gains (losses) on securities, net of tax	1,667	(1,951)	3,381	(1,042)
Total comprehensive income	\$ 68,220	\$ 39,426	\$ 132,795	\$ 113,057

**8. COMPENSATION RELATED TO STOCK OPTIONS**

Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Pharma LLC 2000 Supplemental 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 ). On July 17, 2000, the 1997 Stock Option Plans were amended and restated. The Endo Pharma LLC 1997 Stock Option Plans are these amended and restated 1997 Stock Options Plans and reserve an aggregate of 25,615,339 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 1997 Stock Option Plans expire on August 26, 2007. Upon exercise of these stock options, only currently outstanding shares of common stock of the Company held by Endo Pharma LLC will be issued. Exercise of these stock options will not result in the issuance of additional shares in the Company and will not dilute the public stockholders. The stock options granted pursuant to the 1997 Stock Option Plans are generally exercisable upon the earlier of (i) the occurrence of a sale, disposition or transfer of Company common stock, after which neither Endo Pharma LLC nor Kelso & Company hold any shares of Company common stock or (ii) January 1, 2006 and since neither of these conditions have been met, these options are not currently exercisable.

Pursuant to the Algos merger and related recapitalization of the Company on July 17, 2000, the Endo Pharma LLC 2000 Supplemental Stock Option Plans were established. The Endo Pharma LLC 2000 Supplemental Stock Option Plans reserve an aggregate of 10,672,314 shares of common stock of the Company held by Endo Pharma LLC for issuance. Stock options granted under the Endo Pharma LLC 2000 Supplemental Stock Option Plans expire on August 26, 2007. The Endo Pharma LLC 2000 Supplemental Stock Option Plans became effective on January 1, 2003, resulting in the issuance of 10,672,314 stock options to certain employees and members of management. No additional shares of Company common stock will be issued, however, because these stock options are exercisable only into shares of Company common stock that are held by Endo Pharma LLC. Accordingly, exercise of these stock options will not result in the issuance of additional shares in the Company and will not dilute the public stockholders.

## **Table of Contents**

The shares of Company common stock that individuals receive upon exercise of stock options pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders' agreements.

The Class C Endo Pharma LLC stock options (all of which are vested) become exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options are not exercised by January 1, 2006, they would terminate. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC have decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of \$26.04, with a weighted average exercise price of \$2.72, and an assumed tax rate of 38.4%. Assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$175 million, which will be accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 to 75 days of our fiscal year-end of December 31, 2005) and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, we anticipate that up to 3 million additional stock options granted under the Endo Pharma LLC stock option plans will be exercised prior to January 1, 2006 and therefore, assuming exercise at a market price of \$26.04, with a weighted average exercise price of \$2.52, an assumed tax rate of 38.4% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$27 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.5 million stock options discussed above, we expect to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders' equity in our consolidated financial statements. Following the exercise of the 19.5 million Class C stock options discussed above and the 3 million additional stock options that are anticipated to be exercised prior to January 1, 2006, there will be approximately 3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.52 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$26.04 per share, we would generally be able to deduct, for income tax purposes, compensation of approximately \$71 million, which could result in a tax benefit amount of approximately \$27 million payable to Endo Pharma LLC.

## **Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans**

On August 11, 2000, we established the 2000 Stock Incentive Plan. The 2000 Stock Incentive Plan reserves an aggregate of 4,000,000 shares of common stock of the Company for issuance to employees, officers, directors and consultants. The 2000 Stock Incentive Plan provides for the issuance of stock options, restricted stock, stock bonus awards, stock appreciation rights or performance awards. In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of Company stock reserved for issuance under the 2004 Plan is 4,000,000 shares. The 2004 Plan provides for the grant of stock options, stock appreciation rights, shares of restricted stock, performance shares, performance units or other share-based awards that may be granted to executive officers and other employees of the Company, including officers and directors who are employees, to non-employee directors and to consultants to the Company. As of September 30, 2005, only stock options have been awarded under both plans. Stock options granted under the 2000 and 2004 Stock

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

Incentive Plans generally vest over four years, except in the case of certain change of control events as defined in the Plans, and expire ten years from the date of grant. Unlike the stock options granted under the Endo Pharma LLC Stock Option Plans, the exercise of the stock options granted pursuant

**Table of Contents**

to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans will dilute our public stockholders. During the three and nine months ended September 30, 2005, 7,169 and 332,964 stock options were granted pursuant to these plans, respectively.

**Stock-Based Compensation**

The Company accounts for its stock-based employee compensation plan under the intrinsic value method in accordance with Accounting Principles Board Opinion ( APB ) No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. The Company has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*.

Pro-forma information regarding net income and earnings per share, as presented below, is required by SFAS No. 123, as amended by SFAS No. 148, and has been determined as if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123 as of its effective date. We estimated the fair value of our stock options, as of the respective date of grant, using a Black-Scholes option-pricing model. The following weighted average assumptions were used for such estimates: no dividend yield; expected volatility of 58% in 2005 and 63% in 2004; risk-free interest rate of 3.7% and 3.2% for 2005 and 2004, respectively; and a weighted average expected life of the options of 5 years. Had the Company elected to adopt the fair value recognition provisions of SFAS No. 123, pro forma net income and net income per share would be as follows (in thousands, except per share data):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Net income, as reported	\$ 66,553	\$ 41,377	\$ 129,414	\$ 114,099
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(1,865)	(1,619)	(5,437)	(4,132)
Add: Tax effect of stock-based employee compensation expense under fair value based methods	710	615	2,066	1,572
Pro forma net income	\$ 65,398	\$ 40,373	\$ 126,043	\$ 111,539
Basic earnings per share, as reported	\$ 0.50	\$ 0.31	\$ 0.98	\$ 0.87
Basic earnings per share, pro forma	\$ 0.49	\$ 0.31	\$ 0.95	\$ 0.85
Diluted earnings per share, as reported	\$ 0.50	\$ 0.31	\$ 0.97	\$ 0.86
Diluted earnings per share, pro forma	\$ 0.49	\$ 0.30	\$ 0.95	\$ 0.84
Weighted average shares outstanding				
Basic	132,376	131,804	132,075	131,792
Diluted	133,532	132,460	133,122	132,688

**9. RELATED PARTY TRANSACTIONS**

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

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that currently holds approximately 17% of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2005, approximately 10.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2005, approximately \$152 million), which is estimated to result in a tax benefit amount of approximately \$59 million. Under the tax sharing agreement, we are required to pay this \$59 million, \$35 million of which has already been paid as of September 30, 2005 as well as approximately \$21.4 million paid in October 2005, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

On April 30, 2004, the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made. The amended tax sharing agreement provides that the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be

## **Table of Contents**

paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

In 2004, we paid \$13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of \$17.46 and 20.02, respectively, with a weighted average exercise price of \$2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately \$41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating \$21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004 financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately \$21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004. As of September 30, 2005, approximately \$23.6 million is payable to Endo Pharma LLC related to estimated tax sharing payments that we are obligated to pay which are attributable to 2004 and 2005. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders' equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remained eligible for sale by Endo Pharma LLC under this shelf registration statement. On September 2, 2005, we filed another registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on September 26, 2005. This shelf registration statement, as amended, effectively increased the shares available for sale by Endo Pharma LLC from 11 million shares to up to 33.35 million currently issued and outstanding shares of our common stock. All of the shares available under this registration statement were sold pursuant to an offering on October 12, 2005, as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

The Class C Endo Pharma LLC stock options (all of which are vested) become exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options are not exercised by January 1, 2006, they would terminate. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC have decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of \$26.04, with a weighted average exercise price of \$2.72, and an assumed tax rate of 38.4%. Assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$175 million, which will be accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 to 75 days of our fiscal year-end of December 31, 2005).

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

and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, we anticipate that up to 3 million additional stock options granted under the Endo Pharma LLC stock option plans will be exercised prior to January 1, 2006 and therefore, assuming exercise at a market price of \$26.04, with a weighted average exercise price of \$2.52, an assumed tax rate of 38.4% and assuming the attributable compensation charge deductions are usable to reduce our

## **Table of Contents**

taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$27 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.5 million stock options discussed above, we expect to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders' equity in our consolidated financial statements. Following the exercise of the 19.5 million Class C stock options discussed above and the 3 million additional stock options that are anticipated to be exercised prior to January 1, 2006, there will be approximately 3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.52 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$26.04 per share, we would generally be able to deduct, for income tax purposes, compensation of approximately \$71 million, which could result in a tax benefit amount of approximately \$27 million payable to Endo Pharma LLC.

**Settlement of Contingent Obligation.** During the nine months ended September 30, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized on May 10, 2005, and the \$2 million has been recorded in selling, general and administrative expenses during the nine months ended September 30, 2005. It is anticipated that Endo Pharma LLC will make these payments totaling \$2 million on behalf of the Company, and they will be treated as a capital contribution by Endo Pharma LLC once payments are made. Endo Pharma LLC made a payment of \$800,000, pursuant to the settlement agreement, on behalf of the Company in May 2005 and this payment has been treated as a capital contribution in the accompanying financial statements. The remaining obligation pursuant to this agreement is \$1.2 million as of September 30, 2005. Endo Pharma LLC paid the remaining \$1.2 million in November 2005 and this will be treated as a capital contribution in the fourth quarter of 2005.

## **10. COMMITMENTS AND CONTINGENCIES**

**Manufacturing, Supply and Other Service Agreements** We contract with various third party manufacturers and suppliers to provide us with our raw materials used in our products and finished goods. Our most significant agreements are with Novartis Consumer Health, Teikoku Seiyaku Pharmaceuticals and Mallinckrodt. If for any reason we are unable to obtain sufficient quantities of any of the finished goods or raw materials or components required for our products, this may have a material adverse effect on our business, financial condition and results of operations.

*Novartis Consumer Health, Inc.*

On May 3, 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 are required to purchase, on an annual basis, a minimum amount of product from Novartis. The purchase price per product is equal to a predetermined amount per unit, subject to periodic adjustments. This agreement had a five-year term, with automatic five-year renewals thereafter. In August 2005, we extended this agreement until 2011. Either party may terminate this agreement on three-years' notice, effective at any time after the initial five-year term. In addition, we may terminate this agreement effective prior to the fifth anniversary of the agreement upon three-years' notice and the payment of certain early termination fees. Either party may also terminate this agreement on account of a material breach by the other.

*Teikoku Seiyaku Co., Ltd.*

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

Under the terms of this agreement, Teikoku, a Japanese manufacturer, manufactures Lidoderm® at its Japanese facility for commercial sale by us in the United States. We also have an option to extend the supply area to other territories within a defined period of time. The purchase price for the product is equal to a predetermined amount per unit of product. We are required to purchase a minimum of approximately \$18 million of product from Teikoku in 2006. The term of this agreement is from November 23, 1998 until the shorter of (1) the expiration of the last to expire patent that is licensed to us from Hind Healthcare Inc. or (2) November 20, 2011. This agreement may be terminated for material breach by either party and by us if the Hind Healthcare license agreement is terminated.

### *Mallinckrodt Inc.*

Under the terms of this agreement, Mallinckrodt manufactures and supplies to us narcotic active drug substances, in bulk form, and raw materials for inclusion in our controlled substance pharmaceutical products. We are required to purchase a fixed percentage of our

## **Table of Contents**

annual requirements of each narcotic active drug substance from Mallinckrodt. The purchase price for these substances is equal to a fixed amount, adjusted on an annual basis. The initial term of this agreement is July 1, 1998 until June 30, 2013, with an automatic renewal provision for unlimited successive one-year periods. Either party may terminate this agreement for a material breach.

In addition, under a separate agreement, Mallinckrodt exclusively manufactures and supplies to us a narcotic active drug substance that is not covered under the previously discussed Mallinckrodt agreement. We are required to purchase a fixed percentage of our annual requirements of this narcotic active drug substance from Mallinckrodt. The purchase price of the substance is a fixed amount that may be adjusted annually in the event of Mallinckrodt product cost increases. The current term of this agreement is April 1, 1998 until June 30, 2004, as extended pursuant to an amendment, dated as of May 8, 2000, with an automatic renewal provision for unlimited successive one-year periods, unless terminated by either party. The current renewal term expires on June 30, 2006. This agreement may also be terminated for material breach by either party.

### *General*

In addition to the manufacturing and supply agreements described above, we have agreements with (1) UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services, Inc.) for customer service support, warehouse and distribution services and certain financial functions that expires in 2010 and (2) Kunitz and Associates Inc. for medical affairs. We also have agreements and arrangements with various contract research organizations for our pre-clinical and clinical studies. These other agreements continue into 2008, and contain options to renew. Although we have no reason to believe that these agreements will not be honored, failure by any of these third parties to honor their contractual obligations may have a materially adverse effect on our business, financial condition and/or results of operations.

## **License Agreements, Milestones and Royalties**

### *Hind Healthcare Inc.*

Under the terms of the Hind License Agreement, royalties are recorded as a reduction to net sales due to the nature of the license agreement and the characteristics of the license involvement by Hind in Lidoderm<sup>®</sup>. The royalty rate is 10% of net sales through the shorter of (1) the expiration of the last licensed patent or (2) November 20, 2011, including a minimum royalty of at least \$500,000 per year. During the three months ended September 30, 2005 and 2004, we accrued \$13.7 million and \$9.4 million for these royalties to Hind, respectively, which were recorded as a reduction to net sales. During the nine months ended September 30, 2005 and 2004, we accrued \$31.9 million and \$23.2 million for these royalties to Hind, respectively.

### *Penwest Pharmaceuticals*

Under the terms of the amended and restated strategic alliance agreement with Penwest Pharmaceuticals Co. (Penwest), Penwest is entitled to receive royalties equal to a percentage beginning at 50%, which could decline to 40% based upon the achievement of certain criteria, of the net realization (as defined in the agreement) of oxymorphone ER. On March 18, 2003, we received notice from Penwest that it was exercising its right under the agreement to cease funding its share of the development and pre-launch marketing costs of this product on account of its concern about its ability to access external capital funding opportunities in the future. Accordingly, we are now responsible for funding 100% of these remaining costs until oxymorphone ER is approved by the FDA, at which time we will recoup from the royalties due to Penwest the full amount

of what Penwest should have contributed had it not exercised such right.

*Lavipharm*

In November 1999, Endo entered into a collaboration agreement with Lavipharm Laboratories, Inc. pursuant to which Endo obtained exclusive worldwide rights to Lavipharm's existing drug delivery technology platforms. Under the terms of this collaboration agreement, Endo paid an upfront license fee of \$1 million. In September 2001, we amended this agreement to limit its scope to one of Lavipharm's existing drug delivery technologies in combination with two specific active drug substances. In January 2004, we terminated this agreement and made a termination payment to Lavipharm of \$3 million plus the potential for up to an additional \$5 million upon the occurrence of future events. We wrote-off the unamortized portion of the upfront license fee and expensed the termination payment of \$3 million during the nine months ended September 30, 2004.

**Table of Contents***DURECT Corporation*

Once a specified clinical trial of CHRONOGESIC is started or beginning on January 1, 2006 (whichever is earlier), unless the agreement is earlier terminated, Endo will be obligated to fund 50% of the ongoing development costs of CHRONOGESIC. 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. Endo and DURECT will share profits equally, based on projected financial performance of CHRONOGESIC. In addition, the DURECT CHRONOGESIC agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. With respect to termination rights, this 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.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the DURECT Sufentanil Agreement). The sufentanil patch, which is in early-stage clinical development, employs DURECT's proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, which was expensed as research and development in the first quarter of 2005, with additional payments of approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

*SkyePharma, Inc.*

Under the terms of our agreement with SkyePharma, we are required to pay to SkyePharma a share of each product's sales revenue, which share may increase from 20% initially, to a maximum of 60%, of net sales as the products' combined sales achieve certain thresholds. In addition, future milestone payments may be due SkyePharma as follows (in thousands):

<u>Milestone Event</u>	<u>Milestone Payment</u>
The first time net sales of DepoDur® in a calendar year exceed \$125,000	\$ 15,000
The first time net sales of DepoDur® in a calendar year exceed \$175,000	20,000
<b>Total contingent sales milestones for DepoDur®</b>	<b>\$ 35,000</b>
FDA acceptance of the NDA for Propofol IDD-D in the United States	5,000
FDA final approval of the NDA for Propofol IDD-D in the United States	40,000
<b>Total contingent regulatory milestones for Propofol IDD-D</b>	<b>\$ 45,000</b>



## **Table of Contents**

In addition, this agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. This agreement generally lasts until the underlying patents on the product expire. With respect to termination rights, this agreement permits Endo to terminate its continued participation under a number of circumstances, one of which could require us to pay SkyePharma \$5.0 million.

### *Noven Pharmaceuticals, Inc.*

Under the terms of our license agreement with Noven, upon our first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from \$5.0 million to \$10.0 million, depending on the timing of launch and the number of generic competitors on the market. The profit on the product will be shared. This license agreement also establishes an ongoing collaboration between the two companies to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven's transdermal patch technology. Endo is expected to fund and manage clinical development of those compounds proceeding into clinical trials.

On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately \$5 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

### *EpiCept Corp.*

Our license agreement with EpiCept provides for Endo to pay EpiCept milestones as well as royalties on the net sales of EpiCept's LidoPAIN® BP product. EpiCept has also retained an option to co-promote the LidoPAIN® BP product. Under this agreement, Endo also received an exclusive, worldwide license to certain patents of EpiCept Corp. Milestone payments made by Endo under this agreement, including regulatory milestones and sales thresholds, could total up to \$82.5 million.

### *Vernalis Development Limited*

Under the terms of our license agreement with Vernalis, we will make anniversary payments for the first two years of \$15 million in 2005 and 2006 (the first \$15 million anniversary payment was made in September 2005), and a \$40 million milestone payment upon FDA approval for the menstrually related migraine indication. In addition, Vernalis will receive one-time milestone payments for achieving defined annual net sales targets. These sales milestone payments increase based on increasing net sales targets ranging from a milestone of \$10 million on \$200 million in net sales to a milestone of \$75 million on \$1.2 billion in net sales. These sales milestones could total up to \$255 million if all of the defined net sales targets are achieved. We will also pay royalties to Vernalis based on the net sales of Frova®. On July 1, 2005, we entered into a co-promotion Agreement with Vernalis. The co-promotion agreement is related to that certain license agreement that we entered into on July 14, 2004 with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova® (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova® in the United States. Vernalis has exercised its co-promotion option, and the co-promotion agreement sets forth the detailed terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

*Orexo AB*

Our agreement with Orexo provides for us to make additional license fees and payments based on development and regulatory milestones, which may total up to \$22.1 million through FDA approval of Rapinyl's New Drug Application, \$6.5 million of which became payable in the three months ended September 30, 2005 and has been included in research and development expense. The agreement also provides for royalties upon commercial sales and may include sales milestones, up to \$39.2 million, if defined sales thresholds are achieved. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the expiration of any market exclusivity right. We can terminate the license agreement under certain circumstances, including upon six months' written notice, and we may be required to pay a termination fee of up to \$1.5 million.

## **Table of Contents**

### *ProEthic Pharmaceuticals, Inc.*

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic's European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we made a \$10 million upfront payment, which was expensed as research and development in the first quarter of 2005, and we could be required to make additional payments of approximately \$13.0 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of this license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days' written notice.

### *Life Sciences Opportunities Fund (Institutional) II, L.P.*

On December 12, 2003, we entered into a subscription agreement to invest up to \$10 million into Life Sciences Opportunities Fund (Institutional) II, L.P., a Delaware limited partnership formed to carry out investments in life science companies. As part of this investment, we are able to capitalize on the knowledge of LOF Partners, LLC, the general partner, and its access to, life sciences entities with promising pharmaceutical assets, technologies and management talent and on the general partner's wide range of industry contacts and resources. As of September 30, 2005, we have invested \$2.7 million in this partnership and are accounting for this investment utilizing the equity method.

## **Employment Agreements**

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

## **Research Contracts**

We routinely contract with universities, medical centers, contract research organizations and other institutions for the conduct of research and clinical studies on our behalf. These agreements are generally for the duration of the contracted study and contain provisions that allow us to terminate prior to completion.

## **Collaboration Agreements**

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

We have also entered into certain other collaboration agreements with third parties for the development of pain management products. Potential milestone payments pursuant to these contracts could total up to \$61 million. These agreements require us to share in the development costs of such products and grant marketing rights to us for such products. If our third party partners are unable or unwilling to fund their portion of the collaboration project with us, this may adversely affect our results of operations and cash flows in the foreseeable future.

### **Legal Proceedings**

While we cannot predict the outcome of the following legal proceedings, we believe that the claims against us are without merit, and we intend to vigorously defend our position. An adverse outcome in any of these proceedings could have a material adverse effect on our current and future financial position and results of operations. No amounts have been accrued with respect to any of these unsettled legal proceedings at September 30, 2005.

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

On October 20, 2000, The Purdue Frederick Company and related companies (Purdue Frederick) filed suit against us and our subsidiary, Endo Pharmaceuticals Inc. (EPI), in the U.S. District Court for the Southern District of New York alleging that EPI s

## **Table of Contents**

bioequivalent version of Purdue Frederick's OxyContin<sup>®</sup> (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<sup>®</sup>, 40mg strength, challenged the listed patents for OxyContin<sup>®</sup> 40mg tablets. On March 13, 2001, Purdue Frederick filed a second suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent versions of Purdue Frederick's OxyContin<sup>®</sup>, 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<sup>®</sup>. On August 30, 2001, Purdue Frederick filed a third suit against us and EPI in the U.S. District Court for the Southern District of New York alleging that EPI's bioequivalent version of Purdue Frederick's OxyContin<sup>®</sup>, 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<sup>®</sup>.

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<sup>®</sup>. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI 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 trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court's infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo's favor by the U.S. District Court for the Southern District of New York on January 5, 2004. This affirmance by the Federal Circuit Court dismisses the claims that Endo's oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick's OxyContin<sup>®</sup>, infringe Purdue's U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoins Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue's petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. The Company remains confident that the prior decision of the Federal Circuit Court will remain in effect and intends to continue to pursue its antitrust claims against Purdue.

On June 8, 2005, EPI filed a complaint against Purdue Pharma L.P., the Purdue Frederick Company, the Purdue Pharma Company, Ivax Corporation and Ivax Pharmaceuticals, Inc. (collectively, Defendants) in the Superior Court of the Judicial District of Norwalk-Stamford Connecticut, alleging a violation of the Connecticut Unfair Trade Practices Act. Specifically, EPI claimed that the Defendants have engaged in unfair trade practices by launching an authorized generic version of Purdue's OxyContin<sup>®</sup> on the heels of the Federal Circuit's ruling that Purdue obtained its patents on OxyContin<sup>®</sup> through inequitable conduct. EPI sought temporary and permanent injunctions enjoining Defendants from marketing or selling their authorized generic OxyContin<sup>®</sup> during Endo's 180-day market exclusivity period, as well as compensatory damages, punitive damages, and attorneys' fees incurred in connection with the action. Defendants removed the case to the U.S. District Court for the District of Connecticut on July 1, 2005. In addition, Purdue filed a Motion to Dismiss, on July 1, 2005, and Ivax filed a Motion to Dismiss on July 8, 2005. EPI filed a Motion for Remand on August 5, 2005. On September 19, 2005, the District of Connecticut denied EPI's motion for remand. On the same date, EPI voluntarily dismissed the complaint without prejudice to refile.

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

*Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)*

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone and OxyContin®. The complaint alleges that EPI and another defendant manufactured oxycodone, OxyContin® and/or Percocet®. The complaint alleges that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. EPI intends to defend itself vigorously in this case.

Litigation similar to that described above may also be brought by other plaintiffs in other jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

## **Table of Contents**

### *Pricing Litigation*

A number of cases, brought by local and state government entities, are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees. The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re:*

*Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases have been consolidated into one consolidated complaint in *MDL 1456*: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v. Abbott Laboratories, Inc., et al.*; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories, Inc., et al.*; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott Laboratories, Inc., et al.*; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al.*; and *County of Yates v. Abbott Laboratories, Inc., et al.* One previously reported case filed in state court and removed to federal court has been transferred to *MDL 1456: County of Erie v. Abbott Laboratories, Inc., et al.*

There is a previously reported case pending in state court in Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.*, filed in January 2005 in the Circuit Court of Montgomery County.

The State of Mississippi filed a complaint similar to the complaint filed by the State of Alabama against EPI and numerous other pharmaceutical companies: *State of Mississippi v. Abbott Laboratories, Inc., et al.*, filed in October, 2005 in the Chancery Court of Hinds County, Mississippi.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

### *Other Legal Proceedings*

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



**Table of Contents****11. Earnings Per Share**

The following is a reconciliation of the numerator and denominator of basic and diluted earnings per share (in thousands, except per share data):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
<b>Numerator:</b>				
Net income available to common stockholders	\$ 66,553	\$ 41,377	\$ 129,414	\$ 114,099
<b>Denominator:</b>				
For basic per share data weighted average shares	132,376	131,804	132,075	131,792
Effect of dilutive stock options	1,156	656	1,047	896
For diluted per share data weighted average shares	133,532	132,460	133,122	132,688
Basic earnings per share	\$ 0.50	\$ 0.31	\$ 0.98	\$ 0.87
Diluted earnings per share	\$ 0.50	\$ 0.31	\$ 0.97	\$ 0.86

During the three and nine months ended September 30, 2005, employees exercised stock options to acquire 559,498 and 851,606 shares of common stock, respectively, at exercise prices ranging from \$6.88 to \$22.31.

**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. See "Forward-Looking Statements" beginning on page 3 of this Report.

**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 70%, 69% and 70% of net sales for the years ended December 31, 2003 and 2004 and the nine months ended September 30, 2005, 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. The stock of Endo Pharmaceuticals Inc. is our only asset, and we have no other operations or business.

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

On March 9, 2005, we announced that Peter A. Lankau, the then current president and chief operating officer of Endo, had been appointed president and chief executive officer by our Board of Directors, effective May 20, 2005, the day following the Annual Meeting of Endo Stockholders. Carol A. Ammon, Endo's former chief executive officer, will continue to serve Endo as Chairman of the Board of Directors. In addition, Endo's Board of Directors had appointed Lankau to the Endo Board of Directors, effective March 9, 2005. This appointment expanded the number of directors to 11.

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the "DURECT Sufentanil Agreement"). The sufentanil patch, which is in early-stage clinical development, employs DURECT's proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee, with additional payments of approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch.

Also on March 14, 2005, we announced that we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in

## **Table of Contents**

soft-tissue injury and ankle sprains have been completed in Europe by ProEthic's European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we made a \$10 million upfront payment and could be required to make additional payments of approximately \$13.0 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch.

On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo's favor by the U.S. District Court for the Southern District of New York on January 5, 2004. This affirmation by the Federal Circuit Court dismissed the claims that Endo's oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick's OxyContin®, infringe Purdue's U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoins Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue's petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. The Company remains confident that the prior decision of the Federal Circuit Court will remain in effect and intends to continue to pursue its antitrust claims against Purdue. The U.S. Food and Drug Administration had previously granted final approval of our abbreviated new drug application (ANDA) for all four strengths of the product in 2004. Our oxycodone extended-release tablets are AB-rated bioequivalent versions of OxyContin®, a product of The Purdue Frederick Company that is indicated for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. All OxyContin® strengths, as well as generics of the 80 mg strength, had combined 2004 U.S. sales of approximately \$2 billion. We launched all four strengths of the product on June 7, 2005 and had net sales of \$78.5 million for the nine months ended September 30, 2005. The launch of this product will materially impact our future results.

On October 20, 2003, we announced that the Food and Drug Administration, or the FDA, had issued an approvable letter for oxymorphone extended-release (ER) tablets. In the letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of an additional clinical trial to further confirm the safety and efficacy of this product. We have undertaken two additional Phase III clinical trials of oxymorphone ER to provide the FDA with additional safety and efficacy data. On August 22, 2005, we reported the results from one of the oxymorphone ER Phase III clinical trials that was conducted under the special protocol assessment (SPA) process of the FDA. In this multi-center, randomized, double-blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 205 opioid-naïve patients with moderate-to-severe chronic low back pain. This study demonstrated a statistically significant ( $p < 0.0001$ ) difference in pain scores between oxymorphone ER and placebo during a 12-week treatment period. On October 3, 2005, we reported positive results from the second of the Phase III clinical trials of our oxymorphone ER tablets. In this multi-center, randomized, double-blind, parallel group trial, the safety and efficacy of oxymorphone ER were compared with placebo in 142 opioid-experienced patients with moderate-to-severe chronic low back pain. The study demonstrated a statistically significant ( $p < 0.0001$ ) difference in pain scores between oxymorphone ER and placebo during a 12-week treatment period. These two studies supplement the previously submitted Phase III trial that the company believes the FDA already has accepted as demonstrating efficacy in the intended patient population. We believe we will be in a position to submit the complete response to the approvable letter to the FDA in early 2006 and expect an action letter from the FDA approximately six months following our complete response submission. There is no certainty that the FDA will accept these studies or what, if any, additional information the FDA will require for final approval of oxymorphone ER.

On October 20, 2003, we announced that the FDA had issued an approvable letter for oxymorphone immediate release (IR) tablets. In the letter, the FDA requested that we address certain questions and provide additional clarification and information, including some form of an additional clinical trial to further confirm the safety and efficacy of this product. We have undertaken an additional Phase III clinical trial of oxymorphone IR to provide the FDA with additional safety and efficacy data. In September 2005, we completed the oxymorphone IR Phase III clinical trial that was conducted under the SPA process of the FDA. In this randomized, double-blind, single and multiple dose trial of the analgesic efficacy and safety of oxymorphone IR tablets in patients with moderate-to-severe pain following abdominal surgery, the result demonstrated a statistically significant difference in pain scores between oxymorphone IR and placebo both following a single-dose and repeat doses. We believe we will be in a position to submit the complete response to the approvable letter to the FDA in early 2006 and expect an action letter from the FDA approximately six months following our complete response submission. There is no certainty that the FDA will accept this study or what, if any, additional information the FDA will require for final approval of oxymorphone IR.

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

On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately \$5 million related to the write-off of our portion of the transdermal

## **Table of Contents**

fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options, impairment of intangible assets, and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements.

## **Critical Accounting Policies and Estimates**

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of sales deductions for estimated chargebacks, rebates, sales incentives and allowances, royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories and related inventory reserves and the potential impairment of goodwill and other intangible assets. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made. Actual results may differ significantly from our estimates. Our most critical accounting policies and estimates are described below:

### ***Sales Deductions***

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

***Inventories***

Inventories consist of finished goods held for distribution, raw materials and work in process. Our inventories are stated at the lower of cost or market. Cost is determined by the first-in, first-out method. We write down inventories to net realizable value based on forecasted demand and market conditions, which may differ from actual results. Inventories may also include costs associated with certain products prior to regulatory approval based on management's judgment of probable future commercial use and net realizable value.

---

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

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of September 30, 2005, goodwill and other intangibles comprised approximately 23% of our total assets and 35% of our stockholders' equity. SFAS No. 142, *Goodwill and Other Intangible Assets*, prescribes a two-step method for determining goodwill impairment. In the first step, we determine the fair value of our one reporting unit. If the net book value of our reporting unit exceeds the fair value, we would then perform the second step of the impairment test which requires allocation of our reporting unit's fair value to all of its assets and liabilities in a manner similar to a purchase price allocation, with any residual fair value being allocated to goodwill. An impairment charge will be recognized only when the implied fair value of our reporting unit's goodwill is less than its carrying amount. As a result of the significance of goodwill, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill occur.

We have one reportable segment, pharmaceutical products. Goodwill arose as a result of the August 26, 1997 acquisition of certain branded and generic pharmaceutical products, related rights and certain assets of the then DuPont Merck Pharmaceutical Company (n/k/a Bristol-Myers Squibb Pharma Company) and the July 17, 2000 acquisition of Algos. Although goodwill arose in two separate transactions, the components of our operating segment have been integrated and are managed as one reporting unit. Our components extensively share assets and other resources with the other components of our business and have similar economic characteristics. In addition, our components do not maintain discrete financial information. Accordingly, the components of our business have been aggregated into one reporting unit and are evaluated as such for goodwill impairment. Goodwill is evaluated for impairment on an annual basis on January 1st of each year unless events or circumstances indicate that an impairment may have occurred between annual dates. On January 1, 2005 and 2004, our goodwill was evaluated for impairment and, based on the fair value of our reporting unit, no impairment was identified.

The cost of licenses are either expensed immediately or, if capitalized, are stated at cost, less accumulated amortization and are amortized using the straight-line method over their estimated useful lives ranging from twelve to twenty years. The determination to capitalize amounts related to licenses is based on management's judgments with respect to stage of development, the nature of the rights acquired, alternative future uses, developmental and regulatory issues and challenges, the net realizable value of such amounts based on projected sales of the underlying products, the commercial status of the underlying products and/or various other competitive factors. We determine amortization periods for licenses based on our assessment of various factors impacting estimated useful lives and cash flows of the acquired rights. Such factors include the expected launch date of the product, the strength of the intellectual property protection of the product and various other competitive, developmental and regulatory issues, and contractual terms. Significant changes to any of these factors may result in a reduction in the useful life of the license and an acceleration of related amortization expense, which could cause our operating income, net income and earnings per share to decrease. The value of these licenses is subject to continuing scientific, medical and marketplace uncertainty. During the nine months ended September 30, 2005, the Company expensed \$20 million with respect to the acquisitions of marketing and development license rights for two products that are currently in development. We expensed the cost of these license rights based on the fact that we acquired both marketing and development rights for products that do not have regulatory approval and that do not have currently identifiable alternative future uses. As such, it was determined that the cost of the right to develop the products and the cost of the right to market the products were inextricably linked and therefore expensed in the accompanying financial statements. Patents acquired in the Algos merger are stated at cost, less accumulated amortization, and are amortized using the straight-line method over their estimated useful lives of seventeen years.

Licenses and patents are assessed for impairment, in accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows of the product. In the event the carrying value of the asset exceeds the undiscounted future cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income in the period that the impairment occurs. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. As a result of the significance of our amortizable intangibles, any recognized impairment loss could have a material adverse impact on our financial position and/or results of operations. As described above, we recorded an impairment loss of \$5.5 million during the three months ended September 30, 2005.



**Table of Contents**

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

	September 30,	December 31,
	2005	2004
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 112,100	\$ 123,600
Patents	3,200	3,200
	115,300	126,800
Less accumulated amortization	(14,426)	(9,542)
Other Intangibles, net	\$ 100,874	\$ 117,258

Estimated amortization of intangibles for the five fiscal years subsequent to December 31, 2004 is as follows (in thousands):

2005	\$ 7,678
2006	7,235
2007	7,235
2008	7,235
2009	7,235

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

In our 2001 fiscal year we incurred a non-cash charge of \$37.3 million, in our 2002 fiscal year we recorded a non-cash charge of \$34.7 million and in our 2003 fiscal year we recorded non-cash charges of \$144.5 million, in each case for stock-based compensation relating to the vesting of options that were issued under the Endo Pharma LLC 1997 Amended and Restated Executive Stock Option Plan and the Endo Pharma LLC 1997 Amended and Restated Employee Stock Option Plan (together, the Endo Pharma LLC 1997 Stock Option Plans ) and 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 ). Under the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans, tranches of options vested if we attained certain stock price targets. As each tranche vested, we incurred a non-cash charge representing the difference between the market price of the shares underlying the options and the exercise price of such options. Upon exercise, no additional shares of our common stock will be issued, however, because these stock options are exercisable only into shares of our common stock that are held by Endo Pharma LLC. Accordingly, these stock options do not dilute the public stockholders. In addition, Endo Pharma LLC, and not us, will receive the exercise price payable in connection with these options. Further, the shares of common stock that individuals receive upon exercise of stock options granted pursuant to the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans are currently subject to significant restrictions that are set forth in stockholders agreements.

The Class C Endo Pharma LLC stock options (all of which are vested) become exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options are not exercised by January 1, 2006, they would terminate. Although the Company had considered

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

extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC have decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of \$26.04, with a weighted average exercise price of \$2.72, and an assumed tax rate of 38.4%. Assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$175 million, which will be accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we

## **Table of Contents**

receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 to 75 days of our fiscal year-end of December 31, 2005) and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, we anticipate that up to 3 million additional stock options granted under the Endo Pharma LLC stock option plans will be exercised prior to January 1, 2006 and therefore, assuming exercise at a market price of \$26.04, with a weighted average exercise price of \$2.52, an assumed tax rate of 38.4% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$27 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.5 million stock options discussed above, we expect to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders' equity in our consolidated financial statements. Following the exercise of the 19.5 million Class C stock options discussed above and the 3 million additional stock options that are anticipated to be exercised prior to January 1, 2006, there will be approximately 3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.52 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$26.04 per share, we would generally be able to deduct, for income tax purposes, compensation of approximately \$71 million, which could result in a tax benefit amount of approximately \$27 million payable to Endo Pharma LLC.

For a discussion of the tax sharing agreement between the Company and Endo Pharma LLC relating to the Endo Pharma LLC Stock Options, see [Liquidity and Capital Resources; Tax Sharing Agreement](#).

### ***Compensation Related to Stock Options – Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans***

All the stock options we have granted pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans 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 occurs on the date of each grant. Consequently, we have not incurred charges upon the vesting or exercise of these options. In December 2004, the FASB issued SFAS No. 123, *Share-Based Payments (revised 2004)*, (SFAS No. 123(R)). This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award – the requisite service period (usually the vesting period). SFAS No. 123(R) will be effective for the Company's fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

## **Results of Operations**

### *Net Sales*

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



**Table of Contents**

The following table presents our net sales by product category for the three months and nine months ended September 30, 2005 and 2004.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
	(in thousands)		(in thousands)	
Lidoderm®	\$ 124,337	\$ 83,758	\$ 288,901	\$ 207,349
Percocet®	28,771	26,044	80,955	70,412
Frova®	10,278	5,019	25,086	5,019
DepoDur®	740		2,996	
Other brands	2,673	2,834	8,142	10,290
Total brands	166,799	117,655	406,080	293,070
Oxycodone extended release	49,266		78,485	
Other generics	29,176	42,694	94,810	164,736
Total generics	78,442	42,694	173,295	164,736
Total net sales	\$ 245,241	\$ 160,349	\$ 579,375	\$ 457,806

The following table presents our net sales of select products as a percentage of total net sales for the three months and nine months ended September 30, 2005 and 2004.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2005	2004	2005	2004
Lidoderm®	51%	52%	50%	45%
Percocet®	12%	16%	14%	16%
Frova®	4%	3%	4%	1%
DepoDur®			1%	
Other brands	1%	2%	1%	2%
Total brands	68%	73%	70%	64%
Oxycodone extended release	20%		14%	
Other generics	12%	27%	16%	36%
Total generics	32%	27%	30%	36%
Total net sales	100%	100%	100%	100%

*Three Months Ended September 30, 2005 Compared to the Three Months Ended September 30, 2004*

**Net Sales.** Net sales for the three months ended September 30, 2005 increased by 53% to \$245.2 million from \$160.3 million in the comparable 2004 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm<sup>®</sup>, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, Percocet<sup>®</sup>, our generic oxycodone extended release product, sales of which were not present in the comparable 2004 period, and Frova<sup>®</sup>. These increases were partially offset by the reduction in the sales of certain of our generic products. Net sales of Lidoderm<sup>®</sup> increased by 48% to \$124.3 million from \$83.8 million in the comparable 2004 period. The increase primarily reflects the continued growth of the product. In September 1999, we launched Lidoderm<sup>®</sup>, which continues to gain market share due to our ongoing promotional and educational efforts. Percocet<sup>®</sup> net sales increased to \$28.8 million from \$26.0 million in the comparable 2004 period. Net sales of Frova<sup>®</sup> increased to \$10.3 million from \$5.0 million in the comparable 2004 period. We began shipping Frova<sup>®</sup> upon the closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased by 84% to \$78.4 million from \$42.7 million in the comparable 2004 period primarily due to the net sales of \$49.3 million from our generic oxycodone extended release product, which we launched in June 2005, offset by the reduction in the net sales of our morphine sulfate extended release tablets and Endocet<sup>®</sup>, both of which experienced additional generic competition which has decreased both our market share as well as the price of these generic products. Generic competition with our products may have a material impact on our results of operations and cash flows in the future. We believe net sales for 2005 will be approximately \$800 million to \$825 million. Further, we expect net sales of Lidoderm<sup>®</sup> to be approximately \$390 to \$400 million in 2005. Of course, there can be no assurance of Endo achieving these results.

**Gross Profit.** Gross profit for the three months ended September 30, 2005 increased by 51% to \$183.8 million from \$122.1 million in the comparable 2004 period. Gross profit margins decreased to 75% from 76% primarily due to the write-off of approximately \$5 million in inventory costs related to the transdermal fentanyl patch.

## **Table of Contents**

***Selling, General and Administrative Expenses.*** Selling, general and administrative expenses for the three months ended September 30, 2005 increased by 9% to \$47.3 million from \$43.5 million in the comparable 2004 period. This increase was primarily due to an increase in sales and promotional efforts in 2005 over the comparable 2004 period to support Lidoderm<sup>®</sup>, Frova<sup>®</sup> and DepoDur<sup>®</sup>. The increase is also due to the support provided to our products and new product pipeline in anticipation of product launches.

***Research and Development Expenses.*** Research and development expenses for the three months ended September 30, 2005 increased by \$12.6 million to \$22.1 million from \$9.5 million in the comparable 2004 period. This increase is primarily attributable to \$6.5 million in milestone payments, incurred in the third quarter of 2005, to Orexo related to Rapinyl<sup>™</sup> and our increased developmental efforts with respect to oxymorphone extended-release tablets and immediate-release tablets and the advancement of other recently acquired pipeline products in the third quarter of 2005.

***Depreciation and Amortization.*** Depreciation and amortization for the three months ended September 30, 2005 increased to \$4.1 million from \$3.0 million in the comparable 2004 period primarily due to an increase in amortization expense as a result of new license rights acquired during 2004 and an increase in depreciation expense as a result of an increase in capital expenditures.

***Impairment of Other Intangible Asset.*** For the three months ended September 30, 2005, the impairment of other intangible asset is due to the FDA's decision not to approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

***Interest Income, Net.*** Interest income, net for the three months ended September 30, 2005 was \$2.7 million compared to \$0.6 million in the comparable 2004 period. This increase is substantially due to a full quarter of interest income earned on our note receivable from Vernalis in 2005 compared to a partial period of interest income earned on the note receivable from Vernalis during the three months ended September 30, 2004 since the funds were loaned to Vernalis in late August 2004.

***Income Tax.*** Income tax for the three months ended September 30, 2005 increased to \$40.9 million from \$25.3 million in the comparable 2004 period. This increase is due to the increase in income before income tax for the three months ended September 30, 2005.

### *Nine Months Ended September 30, 2005 Compared to the Nine Months Ended September 30, 2004*

***Net Sales.*** Net sales for the nine months ended September 30, 2005 increased by 27% to \$579.4 million from \$457.8 million in the comparable 2004 period. This increase in net sales was primarily due to the increase in the net sales of Lidoderm<sup>®</sup>, Percocet<sup>®</sup>, our generic oxycodone extended release product, sales of which were not present in the comparable 2004 period, and Frova<sup>®</sup>. These increases were offset by the reduction in the sales of certain of our generic products. Net sales of Lidoderm<sup>®</sup> increased by 39% to \$288.9 million from \$207.3 million in the comparable 2004 period due to the continued prescription growth of the product. Percocet<sup>®</sup> net sales increased to \$81.0 million from \$70.4 million in the comparable 2004 period. Net sales of Frova<sup>®</sup> increased to \$25.1 million from \$5.0 million in the comparable 2004 period. We began shipping Frova<sup>®</sup> upon the closing of the license agreement in mid-August 2004 and initiated our promotional efforts in September 2004. Net sales of our generic products increased by 5% to \$173.3 million from \$164.7 million in the comparable 2004 period primarily due to the net sales of \$78.5 million from our generic oxycodone extended release product, which we launched in June 2005, offset by the reduction in the net sales of our morphine sulfate extended release tablets and Endocet<sup>®</sup>, both of which experienced additional generic competition which has decreased both our market share as well as the price of these generic products. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

**Gross Profit.** Gross profit for the nine months ended September 30, 2005 increased by 25% to \$446.1 million from \$357.8 million in the comparable 2004 period. Gross profit margins decreased to 77% from 78% due to the write-off of approximately \$5 million in inventory costs related to the transdermal fentanyl patch and the introduction of more costly single-pouch child-resistant packaging for Lidoderm® during the second quarter of 2004.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the nine months ended September 30, 2005 increased by 25% to \$157.0 million from \$125.3 million in the comparable 2004 period. This increase was primarily due to an increase in sales and promotional efforts in 2005 over the comparable 2004 period to support Lidoderm®, Frova® and DepoDur®. The increase is also due to the support provided to our products and new product pipeline in anticipation of product launches.

## **Table of Contents**

**Research and Development Expenses.** Research and development expenses for the nine months ended September 30, 2005 increased by 82% to \$70.1 million from \$38.5 million in the comparable 2004 period. This increase is primarily related to \$20 million expensed during the nine months ended September 30, 2005 related to the upfront payments to license the topical ketoprofen patch and the transdermal sufentanil patch, \$6.5 million in milestone payments, incurred in the third quarter of 2005, to Orexo related to Rapinyl™, our increased developmental efforts with respect to oxymorphone extended-release tablets and immediate-release tablets and the advancement of other recently acquired products partially offset by \$10 million in milestone payments, incurred in the second quarter of 2004, to SkyePharma related to the FDA approval of DepoDur® and the advancement of Propofol IDD-D™ into Phase III clinical development.

**Depreciation and Amortization.** Depreciation and amortization for the nine months ended September 30, 2005 increased to \$11.4 million from \$7.1 million in the comparable 2004 period primarily due to an increase in amortization expense as a result of new license rights acquired during 2004 and an increase in depreciation expense as a result of an increase in capital expenditures.

**Loss on Disposal of Other Intangible.** For the nine months ended September 30, 2004, the loss on disposal of other intangible is due to the termination of our collaboration agreement with Lavipharm and the resulting write-off of the unamortized portion of the upfront license fee of \$0.8 million. The loss also includes a \$3 million termination payment made by us to Lavipharm.

**Impairment of Other Intangible Asset.** For the nine months ended September 30, 2005, the impairment of other intangible assets is due to the FDA's decision not to approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch and represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

**Interest Income, Net.** Interest income, net for the nine months ended September 30, 2005 was \$6.7 million compared to \$0.8 million in the comparable 2004 period. This increase is substantially due to a full nine months of interest income earned on our note receivable from Vernalis in 2005 compared to a partial period of interest income earned on the note receivable from Vernalis during the nine months ended September 30, 2004 since the funds were loaned to Vernalis in late August 2004.

**Income Tax.** Income tax for the nine months ended September 30, 2005 increased to \$79.3 million from \$69.9 million in the comparable 2004 period. This increase is due to the increase in income before income tax for the nine months ended September 30, 2005.

## *Liquidity and Capital Resources*

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

**Net Cash Provided by Operating Activities.** Net cash provided by operating activities increased to \$171.7 million for the nine months ended September 30, 2005 from \$70.6 million for the nine months ended September 30, 2004. Significant components of the \$171.7 million of operating cash flows for the nine months ended September 30, 2005 included net income of \$129.4 million, an increase in income taxes payable of \$71.7 million due to a higher tax provision resulting from increased earnings as well as the timing of estimated tax payments, increases in accounts payable and accrued expenses of \$67.0 million, a decrease in inventory of \$8.5 million and depreciation and amortization expense of

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

\$11.4 million partially offset by an \$114.5 million increase in accounts receivable primarily due to the timing and volume of net sales during the three months ended September 30, 2005.

**Net Cash Used in Investing Activities.** Net cash used in investing activities decreased to \$25.1 million for the nine months ended September 30, 2005 from \$106.2 million for the nine months ended September 30, 2004. During the nine months ended September 30, 2005, the Company made a \$15.0 million installment payment to Vernalis for the acquisition of the product rights to Frova<sup>®</sup>, paid \$8.4 million for capital expenditures and invested \$1.7 million in a limited partnership. During the nine months ended September 30, 2004, the Company loaned \$50 million to Vernalis, paid \$47.3 million in license fees, paid a termination penalty of \$3 million to Lavipharm, invested \$0.5 million in a limited partnership and had capital expenditures of \$5.7 million primarily related to our new research and development facility in Long Island, New York.

**Net Cash Used in Financing Activities.** Net cash used in financing activities increased to \$14.1 million for the nine months ended September 30, 2005 from \$9.0 million for the nine months ended September 30, 2004. The increase is primarily due to a \$21.4 million payment to Endo Pharma LLC pursuant to the tax sharing agreement and an increase in capital lease obligation repayments partially offset by an increase in the proceeds received from the exercise of employee stock options.

## **Table of Contents**

**Credit Facility.** In December 2001, we amended and restated our senior secured credit facility with a number of lenders. This amended and restated credit facility provides us with a line of credit of \$75.0 million. The line of credit matures on December 21, 2006. Any loans outstanding under the amended and restated credit facility are secured by a first priority security interest in substantially all of our assets. The credit facility contains representations and warranties, covenants, including a covenant requiring us to maintain minimum EBITDA of \$50 million over the prior four-quarter period, events of default and other provisions customarily found in similar agreements. Our ability to borrow under the credit facility is dependent, among other things, on our compliance with those provisions. As of September 30, 2005, we have not borrowed any amounts under our credit facility.

**Tax Sharing Agreement.** On July 14, 2000, Endo Pharma LLC was formed in connection with the Algos merger to ensure that the stock options granted pursuant to the Endo Pharma LLC Stock Option Plans diluted only the Endo common stock held by persons and entities that held such shares prior to our merger with Algos. Endo Pharma LLC is a limited liability company that currently holds approximately 17% of our common stock, in which affiliates of Kelso & Company and certain members of management have an interest. Upon the exercise of these stock options, only currently outstanding shares of our common stock held by Endo Pharma LLC will be delivered. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we have entered into a tax sharing agreement with Endo Pharma LLC under which we are required to pay to Endo Pharma LLC the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of September 30, 2005, approximately 10.7 million of these stock options had been exercised into shares of our common stock held by Endo Pharma LLC. Upon exercise of any of these Endo Pharma LLC stock options, we generally will be permitted to deduct as a compensation charge, for federal income tax purposes, an amount equal to the difference between the market price of our common stock and the exercise price paid upon exercise of these options (as of September 30, 2005, approximately \$152 million), which is estimated to result in a tax benefit amount of approximately \$59 million. Under the tax sharing agreement, we are required to pay this \$59 million, \$35 million of which has already been paid as of September 30, 2005 as well as approximately \$21.4 million paid in October 2005, to Endo Pharma LLC to the extent that a compensation charge deduction is usable by us to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

On April 30, 2004, the tax sharing agreement was amended to provide for a specific schedule upon which payments currently contemplated by the tax sharing agreement would be made. The amended tax sharing agreement provides that the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i) 50% of the estimated amount shall be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return.

In 2004, we paid \$13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 6.6 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offerings on August 9, 2004 and November 29, 2004, at prices of \$17.46 and 20.02, respectively, with a weighted average exercise price of \$2.44, and an assumed tax rate of 38.7%, we were obligated to pay Endo Pharma LLC a tax benefit of approximately \$41 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and other Endo Pharma LLC stock option exercises in 2004, aggregating \$21.4 million, was due and was paid within 15 business days of the date we received an opinion on our audited 2004 financial statements from our independent registered public accounting firm and the remaining fifty percent of the tax benefit amount attributable to 2004 was due within 30 business days of the date on which we filed our 2004 tax return with the Internal Revenue Service (which occurred in September 2005) and approximately \$21.4 million was paid in October 2005 to satisfy the tax sharing obligations attributable to 2004. As of September 30, 2005, approximately \$23.6 million is payable to Endo Pharma LLC related to estimated tax sharing payments that we are obligated to pay which are attributable to 2004 and 2005. All payments made and accrued pursuant to the tax sharing agreement have been reflected as a reduction of stockholders' equity in the accompanying financial statements. The estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised may increase if certain holders of Endo Pharma LLC stock options exercise additional stock options in the future.

On April 30, 2004, we filed a shelf registration statement on Form S-3, as amended on June 10, June 14 and June 25, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders named therein, including certain of our directors and officers, from time to time, of up to 30 million currently issued and outstanding shares of our common stock. The shelf registration statement was declared effective by

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

the Securities and Exchange Commission on June 28, 2004. After the closing of the August 9, 2004 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remained eligible for sale by Endo Pharma LLC under this shelf registration statement. On September 2, 2005, we filed another registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on September 26, 2005. This shelf registration statement, as amended, effectively increased the shares available for sale by Endo Pharma LLC from 11 million shares to up to 33.35

**Table of Contents**

million currently issued and outstanding shares of our common stock. All of the shares available under this registration statement were sold pursuant to an offering on October 12, 2005, as discussed below. Endo Pharma LLC has informed us that, subject to a variety of factors, including market conditions and stock price levels, it may initiate additional secondary offerings of our common stock in the future.

The Class C Endo Pharma LLC stock options (all of which are vested) become exercisable at the earlier of an exit event, as defined, or January 1, 2006. If the Class C stock options are not exercised by January 1, 2006, they would terminate. Although the Company had considered extending the term of the Class C stock options, following enactment of the 2004 American Jobs Creation Act, an extension of the term of the stock options would result in adverse tax consequences for the option holders. As a result, the Company and Endo Pharma LLC have decided to accelerate the exercisability of the Class C stock options to allow approximately 22 million Class C stock options to be exercised before their expiration on January 1, 2006. The exercise of the Class C stock options is expected to generate a significant tax deduction for the Company and create a significant tax sharing payment obligation to Endo Pharma LLC pursuant to the tax sharing agreement. Upon exercise, option holders will receive shares of Company common stock currently owned by Endo Pharma LLC. Accordingly, no shares of Company common stock will be issued upon exercise of the Class C stock options.

On October 12, 2005, as part of the sale of 33,350,000 shares of our common stock, approximately 19.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised at a market price of \$26.04, with a weighted average exercise price of \$2.72, and an assumed tax rate of 38.4%. Assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we are obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$175 million, which will be accrued in the fourth quarter of 2005. Fifty percent of the estimated tax benefit amount attributable to the October 12, 2005 offering and any additional tax benefits attributable to the exercise of stock options granted under the Endo Pharma LLC stock option plans in 2005 will be due within 15 business days of the date we receive an opinion on our final audited 2005 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 to 75 days of our fiscal year-end of December 31, 2005) and the remaining tax benefit amount attributable to 2005 is due within 30 business days of the date on which we file our 2005 tax return with the Internal Revenue Service. Additionally, we anticipate that up to 3 million additional stock options granted under the Endo Pharma LLC stock option plans will be exercised prior to January 1, 2006 and therefore, assuming exercise at a market price of \$26.04, with a weighted average exercise price of \$2.52, an assumed tax rate of 38.4% and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2005, we will be obligated, under our amended tax sharing agreement, to pay to Endo Pharma LLC an additional tax benefit amount of approximately \$27 million in 2006. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of the 22.5 million stock options discussed above, we expect to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006. All payments that have been, or will be, made or accrued pursuant to the tax sharing agreement have been, or will be, reflected as a reduction of stockholders' equity in our consolidated financial statements. Following the exercise of the 19.5 million Class C stock options discussed above and the 3 million additional stock options that are anticipated to be exercised prior to January 1, 2006, there will be approximately 3 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.52 per share and an assumed tax rate of 38.4%, if all of these remaining stock options under the Endo Pharma LLC stock option plans were vested and exercised, and assuming the price of our common stock was \$26.04 per share, we would generally be able to deduct, for income tax purposes, compensation of approximately \$71 million, which could result in a tax benefit amount of approximately \$27 million payable to Endo Pharma LLC.

**Settlement of Contingent Obligation.** During the nine months ended September 30, 2005, the Company reached an agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was finalized on May 10, 2005, and the \$2 million has been recorded in selling, general and administrative expenses during the nine months ended September 30, 2005. It is anticipated that Endo Pharma LLC will make these payments totaling \$2 million on behalf of the Company, and they will be treated as a capital contribution by Endo Pharma LLC once payments are made. Endo Pharma LLC made a payment of \$800,000, pursuant to the settlement agreement, on behalf of the Company in May 2005 and this payment has been treated as a capital contribution in the accompanying financial statements. The remaining obligation pursuant to this agreement is \$1.2 million as of September 30, 2005. Endo Pharma LLC paid the remaining \$1.2 million in November 2005 and this will be treated as a capital contribution in the fourth quarter of 2005.

## Table of Contents

***Licenses and Collaboration Agreements.*** We enter into licenses and collaboration agreements to develop, use, market and promote certain of our products from or with other pharmaceutical companies and universities. A description of the material developments with respect to our significant third party license and collaboration agreements that took place during the nine months ended September 30, 2005 follows:

### *DURECT Corporation*

On March 14, 2005, we announced that we signed an agreement that gives us the exclusive license to develop and commercialize DURECT's sufentanil-containing transdermal patch in the U.S. and Canada (the "DURECT Sufentanil Agreement"). The sufentanil patch, which is in early-stage clinical development, employs DURECT's proprietary TRANSDUR drug-adhesive matrix formulation and is intended to provide relief of moderate-to-severe chronic pain for up to seven days. We have assumed all remaining development and regulatory filing responsibility for this product, including the funding thereof. Under the terms of the DURECT Sufentanil Agreement, in April 2005, we paid DURECT a \$10 million upfront fee that has been expensed in the first quarter of 2005 as research and development, with additional payments of approximately \$35 million upon achievement of predetermined regulatory and commercial milestones. We will also pay royalties to DURECT on net sales of the sufentanil transdermal patch. In addition, the DURECT Sufentanil Agreement also contains terms and conditions customary for this type of arrangement, including representations, warranties, indemnities and termination rights. The DURECT Sufentanil Agreement will continue in effect until terminated. The DURECT Sufentanil Agreement provides each party with specified termination rights, including the right of each party to terminate the DURECT Sufentanil Agreement upon material breach of the DURECT Sufentanil Agreement by the other party and the right of Endo to terminate the DURECT Sufentanil Agreement at any time without cause subject to a specified notice period.

### *ProEthic Pharmaceuticals, Inc.*

On March 14, 2005, we entered into an agreement with ProEthic Pharmaceuticals, Inc. for the U.S. and Canadian rights to develop and commercialize a once-daily ketoprofen-containing topical patch. Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) generally used for the treatment of inflammation and pain and currently available in the U.S. only in oral form. Currently in Phase II clinical trials in the U.S., the ketoprofen patch is being developed for the localized treatment of acute pain associated with soft-tissue injuries such as tendonitis or joint sprains and strains. Two Phase III placebo-controlled studies in soft-tissue injury and ankle sprains have been completed in Europe by ProEthic's European partner APR Applied Pharma Research AG, with statistically significant results. Under the terms of the agreement, in March 2005, we made a \$10 million upfront payment that has expensed in the first quarter of 2005 as research and development, and could be required to make additional payments of approximately \$13.0 million for the achievement of certain regulatory and other milestones. We will also pay royalties on net sales of the ketoprofen patch. In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement shall be until the later of (i) the expiration of the patents or (ii) the tenth (10th) anniversary of the date of the first commercial sale of the product. We can terminate the agreement at any time upon no more than ninety (90) days' written notice.

### *SkyePharma, Inc.*

In December 2002, we entered into a Development and Marketing Strategic Alliance Agreement with SkyePharma, Inc. and SkyePharma Canada, Inc. relating to two of SkyePharma's patented development products, DepoDur<sup>®</sup>, previously referred to as DepoMorphine<sup>®</sup>, and Propofol IDD-D (collectively, the "Skye Products"). Under the terms of the agreement, Endo received an exclusive license to the U.S. and Canadian marketing and distribution rights for the Skye Products, with options for certain other SkyePharma development products. In return, Endo made a \$25 million upfront payment to SkyePharma, which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 17 years.

During the nine months ended September 30, 2005, we recorded a receivable from SkyePharma of \$5 million based upon the achievement of certain criteria as specified in the agreement. This receivable has been recorded as a reduction to our recorded intangible asset and the intangible asset is now being amortized over its remaining useful life of 15 years.

*Vernalis Development Limited*

On July 1, 2005, we entered into a co-promotion Agreement with Vernalis. The co-promotion agreement is related to that certain license agreement that we entered into on July 14, 2004 with Vernalis, under which Vernalis agreed to exclusively license to us rights to market the product Frova<sup>®</sup> (frovatriptan) in North America. Pursuant to the license agreement, Vernalis had retained rights to co-promote Frova<sup>®</sup> in the United States. Vernalis has exercised its co-promotion option and the co-promotion agreement sets forth the detailed terms and conditions governing such co-promotion and amends, restates and supersedes certain sections of the license agreement. Under the terms of both the license and co-promotion agreements, we will reimburse Vernalis for certain defined costs of their sales personnel beginning in January 2006.

## **Table of Contents**

*Noven Pharmaceuticals, Inc.*

In February 2004, we entered into a License Agreement and a Supply Agreement with Noven Pharmaceuticals, Inc. under which Noven exclusively licensed to us the U.S. and Canadian rights to its developmental transdermal fentanyl patch, which is intended to be the generic equivalent of Johnson & Johnson's Duragesic® (fentanyl transdermal system). We made an upfront payment of \$8.0 million, \$1.5 million of which we expensed as research and development costs and \$6.5 million of which we capitalized as an intangible asset representing the fair value of the exclusive license of these distribution and marketing rights. We were amortizing this intangible asset over its useful life of 11 years. On September 27, 2005, the U.S. Food & Drug Administration informed our partner, Noven, that it will not approve Noven's currently pending Abbreviated New Drug Application for its developmental transdermal fentanyl patch based on the FDA's assessment of potential safety concerns related to the higher drug content in the Noven product versus the reference-listed product, Duragesic®. As a result, we incurred a charge of approximately \$5 million related to the write-off of our portion of the transdermal fentanyl patch inventory and an impairment charge of approximately \$5.5 million, which represents the unamortized portion of the upfront license fee that we paid Noven in February 2004.

**Fluctuations.** Our quarterly results have fluctuated in the past, and may continue to fluctuate. These fluctuations are primarily due to the timing of new product launches, purchasing patterns of our customers, market acceptance of our products, the impact of competitive products and pricing as well as charges incurred for compensation related to stock options and upfront, milestone and certain other payments made or accrued pursuant to licensing agreements. Further, a substantial portion of our net sales are through three wholesale drug distributors who in turn supply our products to pharmacies, hospitals and physicians. Accordingly, we are potentially subject to a concentration of credit risk with respect to our trade receivables.

**Growth Opportunities.** We continue to evaluate growth opportunities including strategic investments, licensing arrangements and acquisitions of product rights or technologies, which could require significant capital resources.

**Non-U.S. Operations.** We currently have no operations outside of the United States. As a result, fluctuations in foreign currency exchange rates do not have a material effect on our financial statements.

**Inflation.** We do not believe that inflation had a material adverse effect on our financial statements for the periods presented.

**Expected Cash Requirements for Contractual Obligations.** Our expected cash requirements for contractual obligations outstanding have increased as of September 30, 2005 by approximately \$1 million for 2005 and \$21 million for 2006 as a result of minimum purchase commitments when compared to the amounts contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2004. In the fourth quarter of 2005 as a result of the exercise of 19.5 million Endo Pharma LLC stock options in connection with the offering on October 12, 2005, our minimum our expected cash requirements for contractual obligations increased by approximately \$175 million, for anticipated tax sharing payments due to Endo Pharma LLC in 2006 when compared to the amounts contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2004. As a result of the significant tax deductions expected to be generated in 2005 from the exercise of stock options discussed above, we expect to incur a net operating loss in 2005 for tax purposes which will permit us to obtain a tax refund of prior years' payments during 2006.

**Cash and Cash Equivalents.** Our cash and cash equivalents totaled \$410.5 million at September 30, 2005. We believe that our (a) cash and cash equivalents, (b) cash flow from operations and (c) our credit facility (which has an available unused line of credit of \$75 million) will be sufficient to meet our normal operating, investing and financing requirements in the foreseeable future, including the funding of our pipeline

projects in the event that our collaboration partners are unable or unwilling to fund their portion of any particular project. We may use a portion of our cash and cash equivalents for possible acquisitions and licensing opportunities.

#### **Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. The purpose of this statement is to clarify the accounting of abnormal amounts of idle facility expense, freight, handling costs and waste material. ARB No. 43 stated that under some circumstances these costs may be so abnormal that they are required to be treated as current period costs. SFAS No. 151 requires that these costs be treated, as current period costs regardless if they meet the criteria of so abnormal. In addition, the statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provision of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS No. 151 is not expected to have a material impact on the Company's results of operations or financial position.

## **Table of Contents**

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29*. SFAS No. 153 is effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005, with earlier application permitted. The adoption of SFAS No. 153 is not expected to have a material impact on the Company's results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payments (revised 2004)*. This statement eliminates the option to apply the intrinsic value measurement provisions of APB Board Opinion No. 25, *Accounting for Stock Issued to Employees*, to stock compensation awards issued to employees. Rather, the Statement requires companies to measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. That cost will be recognized over the period during which an employee is required to provide services in exchange for the award—the requisite service period (usually the vesting period). In March 2005, the SEC staff expressed their views with respect to SFAS No. 123(R) in Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107). SAB 107 provides guidance on valuing options. SFAS No. 123(R) will be effective for the Company's fiscal year beginning January 1, 2006. The Company is currently evaluating the impact of the adoption of this statement on its financial statements.

In March 2005, the FASB issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, (FIN 47). FIN 47 is an interpretation of SFAS No. 143, *Asset Retirement Obligations*, which was issued in June 2001. FIN 47 was issued to address diverse accounting practices that have developed with regard to the timing of liability recognition for legal obligations associated with the retirement of a tangible long-lived asset in which the timing and/or method of settlement are conditional on a future event that may or may not be within the control of the entity. According to FIN 47, uncertainty about the timing and/or method of settlement of a conditional asset retirement obligation should be factored into the measurement of the liability when sufficient information exists. FIN 47 also clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective no later than December 31, 2005 for the Company. The Company is currently evaluating the impact of the adoption of FIN 47 on its financial statements.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, a replacement of APB Opinion No. 20 and Statement No. 3. SFAS No. 154 changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The adoption of SFAS No. 154 is not expected to have a material impact on the Company's results of operations or financial position.

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

On December 21, 2001, we entered into a new credit facility that provides for a line of credit of \$75.0 million. Borrowings under the new credit facility are variable rate borrowings. There are no amounts outstanding under the new credit facility. We do not utilize financial instruments for trading purposes and hold no derivative financial instruments that could expose us to significant market risk. We monitor interest rates and enter into interest rate agreements as considered appropriate.

As of September 30, 2005 and December 31, 2004, we had no assets or liabilities that have significant interest rate sensitivity.

At September 30, 2005, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$10.5 million in Other assets. The fair value of this investment is subject to significant fluctuations due to volatility of the stock market and changes in general economic conditions. Based on the fair value of the publicly traded equity securities we held at September 30, 2005, an assumed 25%, 40% and 50% adverse change in the market prices of this security would result in a corresponding decline in total fair value of approximately

\$2.6 million, \$4.2 million and \$5.3 million, respectively.

**Item 4. Controls and Procedures.**

***Disclosure Controls and Procedures***

Our management, including our Chief Executive Officer and Chief Financial Officer, has conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective for

## **Table of Contents**

timely gathering, analyzing and disclosing the information we are required to disclose in our reports filed with the SEC under the Securities Exchange Act of 1934, as amended.

### ***Internal Control Over Financial Reporting***

In addition, we evaluated our internal control over financial reporting, and there have been no changes in our internal control over financial reporting that occurred during the third quarter of 2005 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II**

### **OTHER INFORMATION**

#### **Item 1. *Legal Proceedings.***

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

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

For each of the 10mg, 20mg, 40mg and 80mg strengths of this product, EPI made the required Paragraph IV certification against the patents listed in the FDA's Orange Book as covering these strengths of OxyContin®. EPI pleaded counterclaims that the patents asserted by Purdue Frederick are invalid, unenforceable and/or not infringed by EPI's formulation of oxycodone hydrochloride extended-release tablets, 10mg, 20mg, 40mg and 80mg strengths. EPI 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.

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

The trial of the patent claims in all three of the suits against us and EPI concluded on June 23, 2003. On January 5, 2004, the district court issued an opinion and order holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to inequitable conduct. The district court, therefore, dismissed the patent claims against us and EPI, declared the patents invalid, and enjoined Purdue from further enforcement of the patents. Purdue filed an appeal, as well as motions to expedite the appeal and to stay the injunction against enforcement of the patents until the appeal is resolved. Both motions were denied on March 18, 2004. In turn, we have cross-appealed the district court's infringement ruling. Briefing on the appeal and cross-appeal concluded in July 2004. By an earlier order, the judge bifurcated the antitrust counterclaims for a separate and subsequent trial. On November 3, 2004, the oral arguments relating to the appeal of this case were heard by the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., at which hearing both sides presented their arguments before a three-judge panel. On June 7, 2005, we announced that the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., had affirmed the Opinion and Order issued in Endo's favor by the U.S. District Court for the Southern District of New York on January 5, 2004. This affirmance by the Federal Circuit Court dismisses the claims that Endo's oxycodone extended-release tablets, 10mg, 20mg, 40mg, and 80mg, a bioequivalent version of Purdue Frederick's OxyContin, infringe Purdue's U.S. Patent Nos. 5,549,912, 5,508,042 and 5,656,295, and permanently enjoins Purdue from enforcing these patents. On June 21, 2005, Purdue filed a petition with the Federal Circuit seeking rehearing of the case by the panel that issued the June 7, 2005 decision, or alternatively by the entire court. On July 22, 2005, the Federal Circuit Court of Appeals requested that Endo submit a response brief as part of its review process of Purdue's petition for rehearing and rehearing en banc. Endo submitted this response on August 1, 2005. The Company remains confident that the prior decision of the Federal Circuit Court will remain in effect and intends to continue to pursue its antitrust claims against Purdue.

On June 8, 2005, EPI filed a complaint against Purdue Pharma L.P., the Purdue Frederick Company, the Purdue Pharma Company, Ivax Corporation and Ivax Pharmaceuticals, Inc. (collectively, Defendants) in the Superior Court of the Judicial District of Norwalk-Stamford Connecticut, alleging a violation of the Connecticut Unfair Trade Practices Act. Specifically, EPI claimed that the Defendants have engaged in unfair trade practices by launching an authorized generic version of Purdue's OxyContin® on the heels of the Federal Circuit's ruling that Purdue obtained its patents on OxyContin® through inequitable conduct. EPI sought temporary and permanent injunctions enjoining Defendants from marketing or selling their authorized generic OxyContin® during Endo's 180-day market exclusivity period, as well as compensatory damages, punitive damages, and attorneys' fees incurred in connection with the action. Defendants removed the case to the U.S. District Court for the District of Connecticut on July 1, 2005. In addition, Purdue filed a Motion to Dismiss, on July 1, 2005, and Ivax filed a Motion to Dismiss on July 8, 2005. EPI filed a Motion for Remand on August 5, 2005. On September 19, 2005, the District of Connecticut denied EPI's motion for remand. On the same date, EPI voluntarily dismissed the complaint without prejudice to refile.

## **Table of Contents**

Litigation similar to that described above may also result from products we currently have in development, as well as those that we may develop in the future. We, however, cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

*Linda Serafin, et al. v. Purdue Pharma L.P., et al., No. 103031/04 (Supreme Court of the State of New York, County of New York)*

On February 27, 2004, EPI was named, along with three other pharmaceutical companies, a hospital, and a doctor, as a defendant in a lawsuit filed by Linda Serafin and Michael Serafin in the Supreme Court of the State of New York, County of New York. According to the complaint, each of the pharmaceutical companies manufactured or distributed the drugs oxycodone and OxyContin®. The complaint alleges that EPI and another defendant manufactured oxycodone, OxyContin® and/or Percocet®. The complaint alleges that the defendants failed to adequately warn about the dangers involved with these drugs and that as a result of this failure to warn, plaintiffs sustained injury. EPI intends to defend itself vigorously in this case.

Litigation similar to that described above may also be brought by other plaintiffs in other jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against us.

### *Pricing Litigation*

A number of cases, brought by local and state government entities, are pending that allege generally that EPI and numerous other pharmaceutical companies reported false pricing information in connection with certain drugs that are reimbursable under Medicaid. These cases generally seek damages, treble damages, disgorgement of profits, restitution and attorneys' fees. The federal court cases have been or are in the process of being consolidated in the United States District Court for the District of Massachusetts under the Multidistrict Litigation Rules as *In re:*

*Pharmaceutical Industry Average Wholesale Price Litigation, MDL 1456*. The following previously reported cases have been consolidated into one consolidated complaint in *MDL 1456*: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Albany v. Abbott Laboratories, Inc., et al.*; *County of Allegany v. Abbott Laboratories, Inc., et al.*; *County of Broome v. Abbott Laboratories, Inc., et al.*; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*; *County of Cayuga v. Abbott Laboratories, Inc., et al.*; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*; *County of Chenango v. Abbott Laboratories, Inc., et al.*; *County of Columbia v. Abbott Laboratories, Inc., et al.*; *County of Cortland v. Abbott Laboratories, Inc., et al.*; *County of Dutchess v. Abbott Laboratories, Inc., et al.*; *County of Essex v. Abbott Laboratories, Inc., et al.*; *County of Fulton v. Abbott Laboratories, Inc., et al.*; *County of Genesee v. Abbott Laboratories, Inc., et al.*; *County of Greene v. Abbott Laboratories, Inc., et al.*; *County of Herkimer v. Abbott Laboratories, Inc., et al.*; *County of Jefferson v. Abbott Laboratories, Inc., et al.*; *County of Lewis v. Abbott Laboratories, Inc., et al.*; *County of Madison v. Abbott Laboratories, Inc., et al.*; *County of Monroe v. Abbott Laboratories, Inc., et al.*; *County of Niagara v. Abbott Laboratories, Inc., et al.*; *County of Oneida v. Abbott Laboratories, Inc., et al.*; *County of Onondaga v. Abbott Laboratories, Inc., et al.*; *County of Ontario v. Abbott Laboratories, Inc., et al.*; *County of Orleans v. Abbott Laboratories, Inc., et al.*; *County of Putnam v. Abbott Laboratories, Inc., et al.*; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*; *County of Saratoga v. Abbott Laboratories, Inc., et al.*; *County of Schuyler v. Abbott Laboratories, Inc., et al.*; *County of Seneca v. Abbott Laboratories, Inc., et al.*; *County of Steuben v. Abbott Laboratories, Inc., et al.*; *County of Suffolk v. Abbott Laboratories, Inc., et al.*; *County of Tompkins v. Abbott Laboratories, Inc., et al.*; *County of Warren v. Abbott Laboratories, Inc., et al.*; *County of Washington v. Abbott Laboratories, Inc., et al.*; *County of Wayne v. Abbott Laboratories, Inc., et al.*; *County of Westchester v. Abbott Laboratories, Inc., et al.*; and *County of Yates v. Abbott Laboratories, Inc., et al.* One previously reported case filed in state court and removed to federal court has been transferred to *MDL 1456: County of Erie v. Abbott Laboratories, Inc., et al.*

There is a previously reported case pending in state court in Alabama against EPI and numerous other pharmaceutical companies: *State of Alabama v. Abbott Laboratories, Inc., et al.*, filed in January 2005 in the Circuit Court of Montgomery County.

The State of Mississippi filed a complaint similar to the complaint filed by the State of Alabama against EPI and numerous other pharmaceutical companies: State of Mississippi v. Abbott Laboratories, Inc., et al., filed in October, 2005 in the Chancery Court of Hinds County, Mississippi.

The Company intends to contest all of these cases vigorously. Litigation similar to that described above may also be brought by other plaintiffs in various jurisdictions. However, we cannot predict the timing or outcome of any such litigation, or whether any such litigation will be brought against the Company.

**Table of Contents**

*Other Legal Proceedings*

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

**Item 2.     *Unregistered Sales of Equity 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.***

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

Table of Contents

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.

(Registrant)

/s/ PETER A. LANKAU  
Name: **Peter A. Lankau**  
Title: *President and Chief Executive Officer*

/s/ JEFFREY R. BLACK  
Name: **Jeffrey R. Black**  
Title: *Executive Vice President and Chief Financial Officer*

Date: November 9, 2005

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

<b>Exhibit No</b>	<b>Title</b>
3.1	Amended and Restated Certificate of Incorporation of Endo Pharmaceuticals Holdings Inc. ( Endo ) (incorporated herein by reference to Exhibit 3.1 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
3.2	Amended and Restated By-laws of Endo (incorporated herein by reference to Exhibit 3.2 of the Form 10-Q for the Quarter ended March 31, 2003 filed with the Commission on May 14, 2003)
4.1	Amended and Restated Executive Stockholders Agreement, dated as of July 7, 2003, by and among Endo, Endo Pharma LLC ( Endo LLC ), Kelso Investment Associates V, L.P. ( KIA V ), Kelso Equity Partners V, L.P. ( KEP V ) and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended June 30, 2003 filed with the Commission on August 14, 2003)
4.1.2	Amendment to Amended and Restated Executive Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, 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 September 30, 2004 filed with the Commission on November 5, 2004) the Commission on July 1, 2003)
4.1.3	Amendment 2 to the Amended and Restated Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.2	Amended and Restated Employee Stockholders Agreement, dated as of June 5, 2003, by and among Endo, Endo LLC, KIA V, KEP V and the Employee Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.2 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
4.2.2	Amendment to Amended and Restated Employee Stockholders Agreement, dated as of June 28, 2004, by and among Endo, Endo LLC, KIA V, KEPV and the Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.1 of the Form 10-Q for the Quarter ended September 30, 2004 filed with the Commission on November 5, 2004)
4.2.3	Amendment 2 to the Amended and Restated Employee Stockholders Agreement, dated September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Amending Stockholders (as defined therein) (incorporated herein by reference to Exhibit 4.2.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.3	Employee Stockholders Consent and Release, effective September 20, 2005, by and among the Company, Endo LLC, Kelso and certain Employee Stockholders (as defined therein) signatory thereto (incorporated herein by reference to Exhibit 4.3 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	Shelf Registration Agreement, dated September 21, 2005, by and between Endo, Endo LLC and certain Management Stockholders (as defined therein) (incorporated herein by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the Commission on September 22, 2005)
10.2	Shelf Registration Agreement, dated April 30, 2004, between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.2 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)
10.3	Amendment to Shelf Registration Agreement, dated June 10, 2004 between Endo Pharmaceuticals Holdings Inc. and Endo Pharma LLC (incorporated herein by reference to Exhibit 10.3 of Amendment No. 1 to the Form S-3 Registration Statement (Registration No. 333-115032) filed with the Commission on June 10, 2004)



**Table of Contents**

10.4	[Intentionally Omitted.]
10.5	Tax Sharing Agreement, dated as of July 17, 2000, by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.5 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
10.6	Amended and Restated Tax Sharing Agreement, dated as of April 30, 2004 by and among Endo, Endo Inc. and Endo LLC (incorporated herein by reference to Exhibit 10.6 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.7	Amended and Restated Credit Agreement, dated as of December 21, 2001, by and between Endo, Endo Pharmaceuticals, the Lenders Party Thereto and JPMorgan Chase Bank (incorporated by reference to Exhibit 10.7 of the Annual Report on Form 10-K for the Year Ended December 31, 2001 filed with the Commission on March 29, 2002)
10.8	Amendment No.1, dated as of April 30, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.8 of the Form 10-Q for the Quarter ended March 31, 2004 filed with the Commission on May 10, 2004)
10.9	Amendment No.2, dated as of July 13, 2004, to the Amended and Restated Credit Agreement dated as of December 21, 2001, among Endo, Endo Pharmaceuticals Inc., the Lenders thereto and JP Morgan Chase. (incorporated herein by reference to Exhibit 10.9 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.10	Sole and Exclusive License Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals Inc. ( 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	[Intentionally Omitted.]
10.12	[Intentionally Omitted.]
10.13	[Intentionally Omitted.]
10.14	Supply and Manufacturing Agreement, dated as of November 23, 1998, by and between Endo Pharmaceuticals and Teikoku Seiyaku Co., Ltd (incorporated herein by reference to Exhibit 10.14 of the Registration Statement filed with the Commission on June 9, 2000)
10.15	Supply Agreement, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt Inc. ( Mallinckrodt ) (incorporated herein by reference to Exhibit 10.15 of the Registration Statement filed with the Commission on June 9, 2000)
10.16	Supply Agreement for Bulk Narcotics Raw Materials, dated as of July 1, 1998, by and between Endo Pharmaceuticals and Mallinckrodt(incorporated herein by reference to Exhibit 10.16 of the Registration Statement filed with the Commission on June 9, 2000)
10.17	Manufacture and Supply Agreement, dated as of August 26, 1997, by and among Endo Pharmaceuticals, DuPont Merck Pharmaceutical and DuPont Merck Pharma (n/k/a Bristol-Myers Squibb Pharma Company) (incorporated herein by reference to Exhibit 10.17 of the Registration Statement filed with the Commission on June 9, 2000)
10.17.2	Amendment Agreement effective August 27, 2002 by and between Endo Pharmaceuticals and Bristol-Myers Squibb Pharma Company as successor-in-interest to DuPont Pharmaceuticals Company formerly known as The DuPont Merck Pharmaceutical Company (incorporated herein by reference to Exhibit 10.17.2 of the Current Report on Form 8-K dated August 27, 2002)
10.18	Amended and Restated Strategic Alliance Agreement, dated as of April 2, 2002, by and between Endo Pharmaceuticals and Penwest Pharmaceuticals Co. (incorporated herein by reference to Exhibit 10.18 of the Quarterly Report on Form 10-Q for the Quarter Ended March 31, 2002 filed with the Commission on May 14, 2002)

**Table of Contents**

10.19	Agreement, dated as of February 1, 2000, by and between Endo Pharmaceuticals and UPS Supply Chain Solutions, Inc. (f/d/b/a Livingston Healthcare Services Inc.) (incorporated herein by reference to Exhibit 10.19 of the Registration Statement filed with the Commission on June 9, 2000)
10.20	Medical Affairs Support Services Agreement, dated as of June 1, 1999, by and between Endo Pharmaceuticals and Kunitz and Associates, Inc. (incorporated herein by reference to Exhibit 10.20 of the Registration Statement filed with the Commission on June 9, 2000)
10.21	Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.21 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.22	Endo LLC Amended and Restated 1997 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.22 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	[Intentionally Omitted.]
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)
10.27.1	Letter Agreement, dated as of January 21, 2005, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27.1 of the Current Report on Form 8-K dated January 24, 2005)
10.27.2	Letter Agreement, dated as of May 19, 2005, by and between the Registrant and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27.2 of the Current Report on Form 8-K dated May 23, 2005)
10.28	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28 of the Current Report on Form 8-K dated August 31, 2001)
10.28.1	Letter Agreement, dated as of January 21, 2005, by and between Endo Pharmaceuticals and Jeffrey R. Black (incorporated herein by reference to Exhibit 10.28.1 of the Current Report on Form 8-K dated January 24, 2005)
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)
10.29.1	Letter Agreement, dated as of January 21, 2005, by and between Endo Pharmaceuticals and David Allen Harvey Lee, MD, Ph.D. (incorporated herein by reference to Exhibit 10.29.1 of the Current Report on Form 8-K dated January 24, 2005)
10.30	Amended and Restated Employment Agreement, dated as September 1, 2001, by and between Endo Pharmaceuticals and Mariann T. MacDonald (incorporated herein by reference to Exhibit 10.30 of the Current Report on Form 8-K dated August 31, 2001)
10.31	[Intentionally Omitted.]
10.32	[Intentionally Omitted.]

**Table of Contents**

10.33	[Intentionally Omitted.]
10.34	Lease Agreement, dated as of May 5, 2000, by and between Endo Pharmaceuticals and Painters Crossing One Associates, L.P. (incorporated herein by reference to Exhibit 10.34 of the Registration Statement filed with the Commission on June 9, 2000)
10.35	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35 of the Current Report on Form 8-K dated August 31, 2001)
10.35.1	Letter Agreement, dated as of January 21, 2005, by and between Registrant and Caroline B. Manogue (formerly Berry) (incorporated herein by reference to Exhibit 10.35.1 of the Current Report on Form 8-K dated January 24, 2005)
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)
10.36.1	Letter Agreement, dated as of January 21, 2005, by and between Registrant and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36.1 of the Current Report on Form 8-K dated January 24, 2005)
10.36.2	Letter Agreement, dated as of May 19, 2005, by and between the Registrant and Peter A. Lankau (incorporated herein by reference to Exhibit 10.36.2 of the Current Report on Form 8-K dated May 23, 2005)
10.37	Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.37 of the Form 10-Q for the Quarter ended June 30, 2004 filed with the Commission on August 9, 2004)
10.38	[Intentionally Omitted.]
10.39	Master Development and Toll Manufacturing Agreement, dated as of May 3, 2001, by and between Novartis Consumer Health, Inc. and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.39 of the Form 10-Q for the Quarter Ended June 30, 2001 filed with the Commission on August 14, 2001)
10.39.1	First Amendment, effective February 1, 2003, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.1 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.39.2	Second Amendment, effective as of December 1, 2004, to the Master Development and Toll Manufacturing Agreement between Endo Pharmaceuticals and Novartis Consumer Health, Inc. (incorporated herein by reference to Exhibit 10.39.2 of the Form 10-Q for the Quarter Ended June 30, 2005 filed with the Commission on August 8, 2005)
10.40	[Intentionally Omitted.]
10.41	Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information (incorporated herein by reference to Exhibit 10.41 of the Form 10-Q for the Quarter ended March 31, 2005 filed with the Commission on May 10, 2005)
10.42	Development, Commercialization and Supply License Agreement, dated as of November 8, 2002, by and between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42 of the Current Report on Form 8-K dated November 14, 2002)
10.42.2	Amendment to Development, Commercialization and Supply License Agreement, dated January 28, 2004, between DURECT Corporation and Endo Pharmaceuticals (incorporated herein by reference to Exhibit 10.42.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.43	Development and Marketing Strategic Alliance Agreement, dated as of December 31, 2002, by and among Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43 of the Current Report on Form 8-K dated January 8, 2003)
10.43.2	Amendment to Development and Marketing Strategic Alliance Agreement, dated March 2, 2004, between Endo Pharmaceuticals, SkyePharma, Inc. and SkyePharma Canada, Inc. (incorporated herein by reference to Exhibit 10.43.2 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)

**Table of Contents**

10.44	Lease Agreement, dated as of January 6, 2003, by and between Endo Pharmaceuticals and Dawson Holding Company (incorporated by reference to Exhibit 10.44 of the Annual Report on Form 10-K for the Year Ended December 31, 2002 filed with the Commission on March 27, 2003)
10.45	Lease Agreement, dated as of November 13, 2003, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45 of the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on March 15, 2004)
10.45.1	Amendment to Lease Agreement, dated as of February 16, 2005, by and between Endo Pharmaceuticals and Painters Crossing Two Associates, L.P. (incorporated herein by reference to Exhibit 10.45.1 of the Current Report on Form 8-K dated February 18, 2005)
10.46	License Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.46 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.47	Supply Agreement, dated as of February 25, 2004, by and between Endo Pharmaceuticals and Noven Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.47 of Amendment No. 2 to the Annual Report on Form 10-K for the Year Ended December 31, 2003 filed with the Commission on June 25, 2004)
10.48	License and Co-Promotion Rights Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
10.48.1	Co-Promotion Agreement, dated as of July 1, 2005, by and between Endo Pharmaceuticals Inc. and Vernalis Development Limited (incorporated by reference to Exhibit 10.48.1 of the Current Report on Form 8-K dated July 8, 2005)
10.49	Loan Agreement, dated as of July 14, 2004, by and between Endo Pharmaceuticals and Vernalis Development Limited (incorporated herein by reference to Exhibit 10.49 of the Current Report on Form 8-K dated July 19, 2004)
31.1	Certification of the President and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the President and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002