

ENDO PHARMACEUTICALS HOLDINGS INC

Form 10-Q

May 10, 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 MARCH 31, 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**  
(State or other jurisdiction of  
incorporation or organization)

**13-4022871**  
(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 periods 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 the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date:

Common Stock, \$.01 par value: 131,930,671 shares as of May 5, 2005.

---

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**INDEX**

<u>Forward-Looking Statements</u>	<b>Page</b> 3
-----------------------------------	------------------

**PART I. FINANCIAL INFORMATION**

<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets (Unaudited) March 31, 2005 and December 31, 2004</u>	6
<u>Condensed Consolidated Statements of Operations (Unaudited) Three Months Ended March 31, 2005 and 2004</u>	7
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) Three Months Ended March 31, 2005 and 2004</u>	8
<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
<u>Overview</u>	21
<u>Critical Accounting Policies</u>	22
<u>Results of Operations</u>	24
<u>Three Months Ended March 31, 2005 Compared to the Three Months Ended March 31, 2004</u>	25
<u>Liquidity and Capital Resources</u>	26
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	30
<u>Item 4. Controls and Procedures</u>	31

**PART II. OTHER INFORMATION**

<u>Item 1. Legal Proceedings</u>	31
<u>Item 2. Changes in Securities and Use of Proceeds</u>	33
<u>Item 3. Defaults Upon Senior Securities</u>	33
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits and Reports on Form 8-K</u>	33

**SIGNATURES**

EX-10.41: POLICY RELATING TO INSIDER TRADING

EX-31.1: CERTIFICATION

EX-31.2: CERTIFICATION

EX-32.1: CERTIFICATION

EX-32.2: CERTIFICATION

**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, 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

**Table of Contents**

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.

Most of our net sales come from a small number of products. Net sales of Lidoderm®, Endocet®, Percocet® and generic morphine sulfate accounted for 50%, 19%, 14% and 10% of our net sales for the year ended December 31, 2004, respectively. 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.

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

**Table of Contents**

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 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 license 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 our current products and products in development and, as a result, our quota of these active ingredients may not be sufficient to meet commercial demand or complete clinical trials.

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>March 31, 2005</b>	<b>December 31, 2004</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 304,713	\$ 278,034
Accounts receivable, net	128,549	139,039
Inventories	65,839	71,415
Prepaid expenses and other current assets	11,621	11,867
Deferred income taxes	62,097	67,222
Total current assets	572,819	567,577
PROPERTY AND EQUIPMENT, Net	31,199	28,875
GOODWILL	181,079	181,079
OTHER INTANGIBLES, Net	110,302	117,258
DEFERRED INCOME TAXES	3,773	
NOTE RECEIVABLE	45,991	45,047
OTHER ASSETS	8,285	7,655
TOTAL ASSETS	\$ 953,448	\$ 947,491
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 83,431	\$ 83,259
Accrued expenses	137,351	145,214
Accrued tax sharing payments due to Endo Pharma LLC	42,965	42,939
Income taxes payable	1,909	1,836
Total current liabilities	265,656	273,248
DEFERRED INCOME TAXES		1,664
OTHER LIABILITIES	16,892	16,629
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS EQUITY		

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

Preferred Stock, \$0.01 par value; 40,000,000 shares authorized; none issued		
Common Stock, \$0.01 par value; 175,000,000 shares authorized; 131,916,704 and 131,856,014 issued and outstanding at March 31, 2005 and December 31, 2004, respectively	1,319	1,319
Additional paid-in capital	636,709	635,915
Retained earnings	32,512	18,697
Accumulated other comprehensive income	360	19
Total stockholders' equity	670,900	655,950
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 953,448	\$ 947,491

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)**

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
NET SALES	\$ 137,754	\$ 153,489
COST OF SALES	29,585	32,873
GROSS PROFIT	108,169	120,616
COSTS AND EXPENSES:		
Selling, general and administrative	53,594	38,742
Research and development	30,748	9,756
Depreciation and amortization	3,596	1,827
Loss on disposal of other intangible, including license termination fee of \$3,000		3,800
OPERATING INCOME	20,231	66,491
INTEREST (INCOME) EXPENSE, Net of interest (expense) income of (\$474) and \$205, respectively	(1,859)	10
INCOME BEFORE INCOME TAX	22,090	66,481
INCOME TAX	8,275	25,307
NET INCOME	\$ 13,815	\$ 41,174
NET INCOME PER SHARE:		
Basic	\$ 0.10	\$ 0.31
Diluted	\$ 0.10	\$ 0.31
WEIGHTED AVERAGE SHARES:		
Basic	131,871	131,779
Diluted	132,829	132,720

See Notes to Condensed Consolidated Financial Statements.

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

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>OPERATING ACTIVITIES:</b>		
Net income	\$ 13,815	\$ 41,174
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,596	1,827
Accretion of interest on note receivable	(310)	
Deferred income taxes	(845)	(7,450)
Tax benefits of stock options exercised	322	491
Amortization of deferred financing costs	96	100
Loss on disposal of other intangible		3,800
Gain on disposal of property and equipment	(5)	(23)
Changes in assets and liabilities which provided (used) cash:		
Accounts receivable	15,490	(14,952)
Inventories	5,576	(17,344)
Note receivable	(634)	
Other assets	72	122
Accounts payable	172	10,365
Accrued expenses	(7,802)	22,465
Income taxes payable	73	26,386
Net cash provided by operating activities	29,616	66,961
<b>INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	(3,271)	(2,294)
Proceeds from the sale of property and equipment	1	109
Payment of license termination fee		(3,000)
Acquisitions of license rights		(7,250)
Net cash used in investing activities	(3,270)	(12,435)
<b>FINANCING ACTIVITIES:</b>		
Capital lease obligations repayments	(487)	(189)
Exercise of Endo Pharmaceutical Holdings Inc. Stock Options	820	158
Net cash provided by (used in) financing activities	333	(31)
NET INCREASE IN CASH AND CASH EQUIVALENTS	26,679	54,495
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	278,034	229,573
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 304,713	\$ 284,068

**SUPPLEMENTAL INFORMATION:**

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

Interest paid	\$ 91	\$ 91
Income taxes paid	\$ 8,802	\$ 5,999
<b>SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Purchase of property and equipment financed by capital leases	\$ 689	\$ 801

See Notes to Condensed Consolidated Financial Statements.

**Table of Contents**

**ENDO PHARMACEUTICALS HOLDINGS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
(UNAUDITED)  
FOR THE THREE MONTHS ENDED MARCH 31, 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 March 31, 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. Certain prior period amounts have been reclassified to conform to the current period presentation.

**2. RECENT ACCOUNTING PRONOUNCEMENTS**

In March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued FASB Staff Position EITF 03-1-1, which delays the effective date until additional guidance is issued for the application of the recognition and measurement provisions of EITF 03-1 to investments in securities that are impaired; however, the disclosure requirements are effective for annual periods ending after June 15, 2004. Although the Company will continue to evaluate the application of EITF 03-1, management does not currently believe adoption will have a material impact on its results of operations or financial position.

In November 2004, the FASB issued Statement of Financial Accounting Standards 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 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 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 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. 123R, *Share-Based Payments (revised 2004)*, (SFAS No. 123R). 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).

**Table of Contents**

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.

**3. INVENTORIES**

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

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
Raw Materials	\$ 12,605	\$ 14,936
Work-in-Process	9,951	16,294
Finished Goods	43,283	40,185
Total	\$ 65,839	\$ 71,415

**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 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 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 (10<sup>th</sup>) 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.*

**Table of Contents**

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, previously referred to as DepoMorphine, 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 three months ended March 31, 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.

**5. GOODWILL AND OTHER INTANGIBLES**

Our goodwill and other intangible assets consist of the following at March 31, 2005 and December 31, 2004, respectively (in thousands):

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 118,600	\$ 123,600
Patents	3,200	3,200
	121,800	126,800
Less accumulated amortization	(11,498)	(9,542)
Other Intangibles, net	\$ 110,302	\$ 117,258

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of March 31, 2005, goodwill and other intangibles comprised approximately 31% of our total assets and 43% of our stockholders' equity. SFAS No. 142, Goodwill and Other Intangible Assets (SFAS No. 142), 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 eleven 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

**Table of Contents**

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 three months ended March 31, 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.

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

2005	\$ 7,826
2006	7,826
2007	7,826
2008	7,826
2009	7,826

**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® (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®. 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 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 2005, Vernalis elected to defer payment of the first semi-annual interest payment otherwise due January 31, 2005.

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 months ended March 31, 2005 and 2004 (in thousands):

	<b>March 31, 2005</b>	<b>March 31, 2004</b>
Net income	\$ 13,815	\$ 41,174
Other comprehensive income:		
Unrealized gains on securities, net of tax	341	843
Total comprehensive income	\$ 14,156	\$ 42,017

## **8. COMPENSATION RELATED TO STOCK OPTIONS**

### **Endo Pharma LLC 1997 Executive and Employee Stock Option Plans and Endo Pharma LLC 2000 Supplemental Executive**

## **Table of Contents**

### **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.

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.

### **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 December 31, 2004, only stock options have been awarded under both plans. Stock options granted under the 2000 and 2004 Stock Incentive Plans generally vest over four years 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 to the Endo Pharmaceuticals Holdings Inc. 2000 and 2004 Stock Incentive Plans will dilute our public stockholders. During the three months ended March 31, 2005, 65,829 stock options were granted pursuant to these plans.

### **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 59% in 2005 and 70% in 2004; risk-free interest rate of 4.0% 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):

**Table of Contents**

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Net income, as reported	\$ 13,815	\$ 41,174
Deduct: Total stock-based employee compensation expense determined under fair value based methods for all awards	(1,700)	(1,438)
Add: Tax effect of stock-based employee compensation expense under fair value based methods	637	548
Pro forma net income	\$ 12,752	\$ 40,284
Basic earnings per share, as reported	\$ 0.10	\$ 0.31
Basic earnings per share, pro forma	\$ 0.10	\$ 0.31
Diluted earnings per share, as reported	\$ 0.10	\$ 0.31
Diluted earnings per share, pro forma	\$ 0.10	\$ 0.30
Weighted average shares outstanding		
Basic	131,871	131,779
Diluted	132,829	132,720

**9. RELATED PARTY TRANSACTIONS**

**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 a significant portion 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 upon the occurrence of a liquidity event, which occurred on August 9, 2004 as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of March 31, 2005, approximately 10.5 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 March 31, 2005, approximately \$147 million), which is estimated to result in a tax benefit amount of approximately \$57 million. Under the tax sharing agreement, we are required to pay this \$57 million 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.

Using a weighted average exercise price of \$2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 10.5 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the

**Table of Contents**

occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments had been made or accrued prior to August 9, 2004. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. That offering could, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement.

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 once a liquidity event has occurred. The amendment provides that upon the occurrence of a liquidity event (which occurred on August 9, 2004), we are required pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. In addition, the amended tax sharing agreement provides that with respect to all taxable years following the occurrence of a liquidity event, 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. Finally, the amendment also clarified two matters related to determining the occurrence of when a liquidity event has occurred: (i) the amendment establishes a formula for calculating when a sale of 20% of the common equity of Endo has occurred, and (ii) the amendment specifies that secondary sales of Endo common stock include sales pursuant to a shelf registration statement.

A secondary sale of 11 million shares by Endo Pharma LLC closed on August 9, 2004. This offering, when combined with the 16.6 million shares sold in July 2003, constituted a liquidity event and thus triggered a payment obligation. 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.

In 2004, we paid \$13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on August 9, 2004, at a price of \$17.46, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes related to 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately \$22 million. In addition, since 2.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on November 29, 2004, at a price of \$20.02, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes related to 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately \$19 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and any other Endo Pharma LLC stock option exercises in 2004 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 is due within 30 business days of the date on which we file our 2004 tax return with the Internal Revenue Service (which we estimate will occur in September 2005). As of March 31, 2005, approximately \$43 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. We paid \$21.4 million to Endo Pharma LLC in April 2005 to satisfy 50% of the obligation related to 2004. 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 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering would most likely trigger an additional tax sharing payment to Endo Pharma LLC, would not

## **Table of Contents**

increase the number of our outstanding shares of common stock and we would not receive any proceeds from any offering covered by this shelf registration.

***Settlement of Contingent Obligation.*** During the three months ended March 31, 2005, the Company reached a tentative agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was subsequently finalized on May 10, 2005, and the \$2 million has been recorded in selling, general and administrative expenses for the three months ended March 31, 2005. It is anticipated that Endo Pharma LLC will make these payments totaling \$2 million on behalf of the Company, and it will be treated as a capital contribution by Endo Pharma LLC once payments are made.

## **10. COMMITMENTS AND CONTINGENCIES**

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

#### *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.

#### *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 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.*

In addition to a share of each product's sales revenue that may increase from 20% initially, to a maximum of 60%, of net sales as the products' combined sales achieve certain thresholds, future milestone payments may be due SkyePharma under the terms of the agreement as follows (in thousands):

**Table of Contents**

Milestone Event	Milestone Payment
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
Total contingent sales milestones for DepoDur	\$ 35,000
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
Total contingent regulatory milestones for Propofol IDD-D	\$ 45,000

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 the 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. Additionally, we are bearing a portion of the risk of loss related to inventory costs associated with the fentanyl patch that have been incurred by us and by Noven. If final regulatory approval of the product is denied or delayed, our risk of loss is approximately \$3.4 million. No amounts have been expensed as of March 31, 2005 related to our risk of loss based upon our judgment of probable future commercial use.

*EpiCept Corp.*

The license agreement 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 the license agreement, we will make anniversary payments for the first two years of \$15 million in 2005 and 2006, 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®.

*Orexo AB*

The agreement 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. 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.

*ProEthic Pharmaceuticals, Inc.*

## **Table of Contents**

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 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 (10<sup>th</sup>) 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 March 31, 2005, we have invested \$1 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**

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 March 31, 2005.

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

*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,

**Table of Contents**

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.

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. We are awaiting the outcome of this appeal.

At this time we have decided to launch our bioequivalent versions of OxyContin® after appellate review of the district court's decision. We will continue to monitor the situation and may in the future decide to launch our bioequivalent versions of OxyContin® in advance of the appellate decision. If we do launch our bioequivalent versions of OxyContin® in advance of the appellate decision and the district court's ruling is overturned, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. Our payment of those amounts may materially adversely affect our business, financial condition and cash flows. Whether or not we have launched our bioequivalent versions of OxyContin®, if we receive an unfavorable ruling from the appeals court, we may be unable to sell our generic OxyContin®.

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

**Table of Contents**

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 now been transferred to *MDL 1456: City of New York v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; and *County of Westchester v. Abbott Laboratories, Inc., et al.* One previously reported federal case is in the process of being transferred to *MDL 1456: County of Onondaga v. Abbott Laboratories, Inc., et al.* One previously reported case filed in state court was removed to federal court and is in the process of being transferred to *MDL 1456: County of Erie v. Abbott Laboratories, Inc., et al.* Twenty-two new federal cases naming EPI in addition to numerous other pharmaceutical companies have been filed and are in the process of being transferred to *MDL 1456: County of Albany v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern Western District of New York; *County of Allegany v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Broome v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Cayuga v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Western District of New York; *County of Chenango v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Northern District of New York; *County of Fulton v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Genesee v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Greene v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Herkimer v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Monroe v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Oneida v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Saratoga v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Steuben v. Abbott Laboratories, Inc., et al.*, filed in May 2005 in the United States District Court for the Western District of New York; *County of Tompkins v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Northern District of New York; *County of Warren v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Washington v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Wayne v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Western District of New York; and *County of Yates v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York. EPI also believes it will be named in the as yet not filed second amended complaint in *County of Suffolk v. Abbott Laboratories, Inc., et al.*, which is currently pending in *MDL 1456*.

There is also a similar case pending in a state court 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, Alabama.

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.

## **11. Earnings Per Share**

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

20

---

**Table of Contents**

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Numerator:		
Net income available to common stockholders	\$ 13,815	\$ 41,174
Denominator:		
For basic per share data    weighted average shares	131,871	131,779
Effect of dilutive stock options	958	941
For diluted per share data    weighted average shares	132,829	132,720
Basic earnings per share	\$ 0.10	\$ 0.31
Diluted earnings per share	\$ 0.10	\$ 0.31

During the first quarter of 2005, employees exercised stock options to acquire 60,690 shares of common stock at exercise prices ranging from \$8.49 to \$15.40.

**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 73% of net sales for the years ended December 31, 2003 and 2004 and the three months ended March 31, 2005. 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.

On March 9, 2005, we announced that Peter A. Lankau, the current president and chief operating officer of Endo, has 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 current chief executive officer, will continue to serve Endo as Chairman of the Board of Directors. In addition, Endo's Board of Directors has appointed Lankau to the Endo Board of Directors, effective immediately. This appointment expands 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 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.

## **Table of Contents**

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.

## **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 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 also include costs associated with certain products prior to regulatory approval and/or resolution of patent infringement litigation based on management's judgment of probable future commercial use and net realizable value.

***Goodwill and Other Intangibles***

**Table of Contents**

Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of March 31, 2005, goodwill and other intangibles comprised approximately 31% of our total assets and 43% of our stockholders' equity. SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142) 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 eleven 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 three months ended March 31, 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* (SFAS No. 144), 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.

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

23

---

**Table of Contents**

	<b>March 31, 2005</b>	<b>December 31, 2004</b>
Goodwill	\$ 181,079	\$ 181,079
Amortizable Intangibles:		
Licenses	\$ 118,600	\$ 123,600
Patents	3,200	3,200
	121,800	126,800
Less accumulated amortization	(11,498)	(9,542)
Other Intangibles, net	\$ 110,302	\$ 117,258

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

2005	\$ 7,826
2006	7,826
2007	7,826
2008	7,826
2009	7,826

***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.

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. 123R). 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. 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.

## Results of Operations

### *Net Sales*

**Table of Contents**

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.

The following table presents our net sales by product category for the three months ended March 31, 2005 and 2004.

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
	<b>(in thousands)</b>	
Lidoderm®	\$ 64,100	\$ 65,356
Percocet®	27,419	30,744
Frova®	6,131	
Other brands	2,821	4,350
<b>Total brands</b>	<b>100,471</b>	<b>100,450</b>
<b>Total generics</b>	<b>37,283</b>	<b>53,039</b>
<b>Total net sales</b>	<b>\$ 137,754</b>	<b>\$ 153,489</b>

The following table presents our net sales as a percentage of total net sales for select products for the three months ended March 31, 2005 and 2004.

	<b>Three Months Ended March 31,</b>	
	<b>2005</b>	<b>2004</b>
Lidoderm®	47%	43%
Percocet®	20	20
Frova®	4	
Other brands	2	3
<b>Total brands</b>	<b>73</b>	<b>66</b>
<b>Total generics</b>	<b>27</b>	<b>34</b>
<b>Total</b>	<b>100%</b>	<b>100%</b>

*Three Months Ended March 31, 2005 Compared to the Three Months Ended March 31, 2004*

**Net Sales.** Net sales for the three months ended March 31, 2005 decreased to \$137.8 million from \$153.5 million in the comparable 2004 period. This decrease is primarily due to a decrease in net sales of our generic products. Net sales of our morphine sulfate extended release tablets and Endocet® both 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. In addition, during



the first quarter of 2005, Lidoderm<sup>®</sup> net sales were essentially unchanged from the comparable period in 2004 due to certain of our customers reducing their inventory levels. The prescription demand for Lidoderm<sup>®</sup> remains strong, and, for the full year we expect net sales of Lidoderm<sup>®</sup> to be approximately \$390 to \$400 million. We expect total net sales for the full year of 2005 to be approximately \$650 to \$660 million.

**Gross Profit.** Gross profit for the three months ended March 31, 2005 decreased by 10% to \$108.2 million from \$120.6 million in the comparable 2004 period. Gross profit margins stayed relatively constant at 79%. We expect gross profit margins to decrease in 2005 versus 2004 due to our product mix as well as competition with our products.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses for the three months ended March 31, 2005 increased by 39% to \$53.6 million from \$38.7 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>. In the three months ended March 31, 2005, we increased our specialty and community based sales forces from approximately 230 sales representatives to approximately 300 sales representatives. In addition, during the three months ended March 31, 2005, we have a hospital based sales force of approximately 70 sales representatives. During the three months ended March 31, 2004, we did not have a hospital based sales force. The increase is also due to the support provided to our new product pipeline in anticipation of product launches.

**Table of Contents**

**Research and Development Expenses.** Research and development expenses for the three months ended March 31, 2005 increased to \$30.7 million from \$9.8 million in the comparable 2004 period. This increase is primarily related to \$20 million expensed during the three months ended March 31, 2005 related to the upfront payments to license the topical ketoprofen patch and the transdermal sufentanil patch.

**Depreciation and Amortization.** Depreciation and amortization for the three months ended March 31, 2005 increased to \$3.6 million from \$1.8 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 since March 31, 2004. We expect depreciation and amortization to continue to increase as we increase our capital expenditures for new office and laboratory space and automobiles for our newly hired sales representatives, and as we continue to acquire products and technologies.

**Loss on Disposal of Other Intangible.** The loss on disposal of other intangible in the three months ended March 31, 2004 is due to the termination of our collaboration agreement with Lavipharm Laboratories Inc. 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.

**Interest (Income) Expense, Net.** Interest (income) expense, net for the three months ended March 31, 2005 was \$1.9 million in interest income compared to \$10,000 in interest expense in the comparable 2004 period. This change is substantially due to the increased interest income earned as a result of higher cash balances during the first quarter of 2005 and interest income earned on our note receivable from Vernalis.

**Income Tax.** Income tax for the three months ended March 31, 2005 decreased to \$8.3 million from \$25.3 million in the comparable 2004 period. This decrease is due to the decrease in income before income tax for the three months ended March 31, 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 decreased to \$29.6 million for the three months ended March 31, 2005 from \$67.0 million for the three months ended March 31, 2004. This decrease is primarily due to a decrease in net sales and gross profit and an increase in operating expenses for the three months ended March 31, 2005 compared to the three months ended March 31, 2004.

**Net Cash Used in Investing Activities.** Net cash used in investing activities decreased to \$3.3 million for the three months ended March 31, 2005 from \$12.4 million for the three months ended March 31, 2004. During the three months ended March 31, 2005, the Company paid \$3.3 million for capital expenditures. During the three months ended March 31, 2004, the Company paid \$7.3 million in license fees, a termination penalty of \$3 million to Lavipharm and had capital expenditures of \$2.3 million primarily related to our new research and development facility in Long Island, New York.

**Net Cash Provided by (Used in) Financing Activities.** Net cash provided by (used in) financing activities increased to \$0.3 million for the three months ended March 31, 2005 from (\$31,000) for the three months ended March 31, 2004. The increase is primarily due to the proceeds from the exercise of employee stock options pursuant to the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.

**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. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3,

**Table of Contents**

which we initially filed on April 30, 2004, providing for the sale by Endo Pharma LLC and certain other selling stockholders to be 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. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. As of March 31, 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 a significant portion 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 upon the occurrence of a liquidity event, which occurred on August 9, 2004 as described further below, the amount of the tax benefits usable by us as a result of the exercise of these stock options into shares of our common stock held by Endo Pharma LLC. As of March 31, 2005, approximately 10.5 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 March 31, 2005, approximately \$147 million), which is estimated to result in a tax benefit amount of approximately \$57 million. Under the tax sharing agreement, we are required to pay this \$57 million 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.

Using a weighted average exercise price of \$2.60 per share and an assumed effective tax rate of 38.3%, if all 36.3 million stock options under the Endo Pharma LLC Stock Option Plans were vested and exercised (including the 10.5 million stock options already exercised as discussed above):

upon exercise, assuming the market price of our common stock is then \$20.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$632 million, which could result in a tax benefit amount of approximately \$242 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$25.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$813 million, which could result in a tax benefit amount of approximately \$311 million payable to Endo Pharma LLC.

upon exercise, assuming the market price of our common stock is then \$30.00 per share, we generally would be able to deduct, for federal income tax purposes, compensation of approximately \$994 million, which could result in a tax benefit amount of approximately \$381 million payable to Endo Pharma LLC.

Under the terms of the tax sharing agreement, we must pay all such tax benefit amounts to Endo Pharma LLC to the extent these tax benefits are usable by us, as described above. However, these payments need only be made to Endo Pharma LLC upon the occurrence of a liquidity event, which is generally defined as a transaction or series of transactions resulting in (a) a sale of greater than 20% on a fully diluted basis of our common equity (either through (i) a primary offering by us, (ii) a secondary sale by Endo Pharma LLC or other holders of common stock pursuant to a registration rights agreement or (iii) a combination of both such primary and secondary offerings), (b) a change in control of Endo or (c) a sale of all or substantially all of our assets. In accordance with the tax sharing agreement, no payments had been made or accrued prior to August 9, 2004. On July 8, 2003, a secondary sale by Endo Pharma LLC was closed which represented a sale of, on a fully diluted basis, approximately 12% of our common equity which did

not, by itself, trigger a payment under the tax sharing agreement, and was not a liquidity event. That offering could, however, be combined with future offerings to result in a series of transactions that will trigger a payment obligation pursuant to the tax sharing agreement.

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 once a liquidity event has occurred. The amendment provides that upon the occurrence of a liquidity event (which occurred on August 9, 2004), we are required pay to Endo Pharma LLC, within 30 business days, the amount of the tax benefits usable by us in each of the previous taxable years for which we have filed a federal income tax return. In addition, the amended tax sharing agreement provides that with respect to all taxable years following the occurrence of a liquidity event, the amount of the tax benefits usable by us in each such year will be paid to Endo Pharma LLC in two installments: (i)

**Table of Contents**

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. Finally, the amendment also clarified two matters related to determining the occurrence of when a liquidity event has occurred: (i) the amendment establishes a formula for calculating when a sale of 20% of the common equity of Endo has occurred, and (ii) the amendment specifies that secondary sales of Endo common stock include sales pursuant to a shelf registration statement.

A secondary sale of 11 million shares by Endo Pharma LLC closed on August 9, 2004. This offering, when combined with the 16.6 million shares sold in July 2003, constituted a liquidity event and thus triggered a payment obligation. 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.

In 2004, we paid \$13.5 million to Endo Pharma LLC to satisfy the tax sharing obligations attributable to 2001, 2002 and 2003. Since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on August 9, 2004, at a price of \$17.46, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes related to 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately \$22 million. In addition, since 2.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans were exercised into common stock and sold in the offering on November 29, 2004, at a price of \$20.02, with a weighted average exercise price of \$2.44, an assumed tax rate of 38.3% and assuming the attributable compensation charge deductions are usable to reduce our taxes related to 2004, we are obligated to pay Endo Pharma LLC a tax benefit of approximately \$19 million. Fifty percent of the tax benefit amount attributable to these two 2004 offerings and any other Endo Pharma LLC stock option exercises in 2004 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 is due within 30 business days of the date on which we file our 2004 tax return with the Internal Revenue Service (which we estimate will occur in September 2005). As of March 31, 2005, approximately \$43 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. We paid \$21.4 million to Endo Pharma LLC in April 2005 to satisfy 50% of the obligation related to 2004. 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 and November 29, 2004 offerings, which totaled 19 million shares, up to 11 million shares remain eligible for sale by Endo Pharma LLC under this shelf registration statement. The shelf registration statement enables one or more offerings of common stock, subject to market conditions. The nature and terms of any offering will be established at the time of the offering and set forth in a prospectus supplement. Any offering would most likely trigger an additional tax sharing payment to Endo Pharma LLC, would not increase the number of our outstanding shares of common stock and we would not receive any proceeds from any offering covered by this shelf registration.

***Settlement of Contingent Obligation.*** During the three months ended March 31, 2005, the Company reached a tentative agreement with an individual to compensate him a total of \$2 million for past services rendered to the Company. This agreement was subsequently finalized on May 10, 2005, and the \$2 million has been recorded in

selling, general and administrative expenses for the three months ended March 31, 2005. It is anticipated that Endo Pharma LLC will make these payments totaling \$2 million on behalf of the Company, and it will be treated as a capital contribution by Endo Pharma LLC once payments are made.

***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 three months ended March 31, 2005 follows:

*DURECT Corporation*

**Table of Contents**

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 been 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 (10<sup>th</sup>) 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, previously referred to as DepoMorphine, 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 three months ended March 31, 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.



**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.

## **Table of Contents**

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

### **Recent Accounting Pronouncements**

In March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued FASB Staff Position EITF 03-1-1, which delays the effective date until additional guidance is issued for the application of the recognition and measurement provisions of EITF 03-1 to investments in securities that are impaired; however, the disclosure requirements are effective for annual periods ending after June 15, 2004. Although the Company will continue to evaluate the application of EITF 03-1, management does not currently believe adoption will have a material impact on its results of operations or financial position.

In November 2004, the FASB issued Statement of Financial Accounting Standards 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 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 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 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. 123R, *Share-Based Payments (revised 2004)*, (SFAS No. 123R). 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 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.

**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. On April 30, 2004, we amended our credit facility to allow us to file a shelf registration statement on Form S-3, which we initially filed on April 30, 2004. On July 13, 2004, we amended our credit facility to allow us to enter in the transaction with Vernalis. 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

## **Table of Contents**

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 March 31, 2005 and 2004, we have no assets or liabilities that have significant interest rate sensitivity.

At March 31, 2005, we had publicly traded equity securities comprised of DURECT Corporation common stock at fair value totaling \$5.6 million in Other assets. The fair value of this investment is subject to significant fluctuations due to the volatility of the stock market, changes in general economic conditions and changes in the financial condition of DURECT. Based on the fair value of the publicly traded equity securities we held at March 31, 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 \$1.4 million, \$2.2 million and \$2.8 million, respectively.

We do not believe that inflation has had a significant impact on our revenues or operations.

### **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 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 first 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

## **Table of Contents**

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. We are awaiting the outcome of this appeal.

At this time we have decided to launch our bioequivalent versions of OxyContin® after appellate review of the district court's decision. We will continue to monitor the situation and may in the future decide to launch our bioequivalent versions of OxyContin® in advance of the appellate decision. If we do launch our bioequivalent versions of OxyContin® in advance of the appellate decision and the district court's ruling is overturned, we may be liable for lost profits and damages to Purdue and costs associated with the launching of our products. Our payment of those amounts may materially adversely affect our business, financial condition and cash flows. Whether or not we have launched our bioequivalent versions of OxyContin®, if we receive an unfavorable ruling from the appeals court, we may be unable to sell our generic OxyContin®.

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 now been transferred to MDL 1456: *City of New York v. Abbott Laboratories, Inc., et al.*; *County of Rockland v. Abbott Laboratories, Inc., et al.*; and *County of Westchester v. Abbott Laboratories, Inc., et al.* One previously reported federal case is in the process of being transferred to MDL 1456: *County of Onondaga v. Abbott Laboratories, Inc., et al.* One previously reported case filed in state court was removed to federal court and is in the process of being transferred to MDL 1456: *County of Erie v. Abbott Laboratories, Inc., et al.* Twenty-two new federal cases naming EPI in addition to numerous other pharmaceutical companies have been filed and are in the process of being transferred to MDL 1456: *County of Albany v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern Western District of New York; *County of Allegany v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Broome v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Cattaraugus v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States

**Table of Contents**

District Court for the Western District of New York; *County of Cayuga v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Chautauqua v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Western District of New York; *County of Chenango v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Northern District of New York; *County of Fulton v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Genesee v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Greene v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Herkimer v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Monroe v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York; *County of Oneida v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Rensselaer v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Saratoga v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of St. Lawrence v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Steuben v. Abbott Laboratories, Inc., et al.*, filed in May 2005 in the United States District Court for the Western District of New York; *County of Tompkins v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Northern District of New York; *County of Warren v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Washington v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Northern District of New York; *County of Wayne v. Abbott Laboratories, Inc., et al.*, filed in March 2005 in the United States District Court for the Western District of New York; and *County of Yates v. Abbott Laboratories, Inc., et al.*, filed in April 2005 in the United States District Court for the Western District of New York. EPI also believes it will be named in the as yet not filed second amended complaint in *County of Suffolk v. Abbott Laboratories, Inc., et al.*, which is currently pending in MDL 1456.

There is also a similar case pending in a state court 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, Alabama.

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.

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

None.

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



None.

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

None.

**Item 5. *Other Information.***

None.

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

**Table of Contents**

(a) *Exhibits.*

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

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

We filed the following Form 8-Ks in the quarter ended March 31, 2005:

	<b>Dates</b>	<b>Items</b>
January 24, 2005		1.01 and 9.01
February 18, 2005		1.01 and 9.01
March 11, 2005		5.02 and 9.01

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

**Table of Contents**

**SIGNATURES**

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

ENDO PHARMACEUTICALS HOLDINGS INC.  
(Registrant)

/s/ Carol A. Ammon

Name: Carol A. Ammon

Title: *Chairman and Chief Executive Officer*

/s/ Jeffrey R. Black

Name: Jeffrey R. Black

Title: *Executive Vice President and Chief Financial Officer*

Date: May 10, 2005

**Table of Contents**

**Exhibit Index**

**Exhibit**

No	Title
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)
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, 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)
4.3	[Intentionally Omitted.]
4.4	Registration Rights Agreement, dated as of July 17, 2000, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 4.4 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 15, 2000)
4.5	Amendment to Registration Rights Agreement, dated as of June 30, 2003, by and between Endo and Endo LLC (incorporated herein by reference to Exhibit 10.1 of Amendment No. 2 to the Form S-3 Registration Statement (Registration No. 333-105338) filed with the Commission on July 1, 2003)
10.1	[Intentionally Omitted.]
10.2	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	

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

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)

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)

**Table of Contents**

**Exhibit**

No	Title
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)
- 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

**Table of Contents**

**Exhibit**

<b>No</b>	<b>Title</b>
	the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.23	Endo LLC Amended and Restated 1997 Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.23 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.24	Endo LLC 2000 Amended and Restated Supplemental Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.24 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.25	Endo LLC 2000 Amended and Restated Supplemental Executive Stock Option Plan (incorporated herein by reference to Exhibit 10.25 of the Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2000 filed with the Commission on November 13, 2000)
10.26	Employment Agreement, dated as of July 17, 2000, by and between Endo and John W. Lyle (incorporated herein by reference to Exhibit 10.26 of the Form 10-Q for the Quarter ended June 30, 2000 filed with the Commission on August 14, 2000)
10.27	Amended and Restated Employment Agreement, dated as of September 1, 2001, by and between Endo Pharmaceuticals and Carol A. Ammon (incorporated herein by reference to Exhibit 10.27 of the Current Report on Form 8-K dated August 31, 2001)
10.27.1	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)
10.28	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.]
- 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)

**Table of Contents**

<b>Exhibit No</b>	<b>Title</b>
	(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)
10.37	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)
10.40	[Intentionally Omitted.]
10.41	Policy of Endo Pharmaceuticals Holdings Inc. Relating to Insider Trading in Company Securities and Confidentiality of Information
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)
10.44	

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

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

**Table of Contents**

**Exhibit**

<b>No</b>	<b>Title</b>
	Development Limited (incorporated herein by reference to Exhibit 10.48 of the Current Report on Form 8-K dated July 19, 2004)
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 Chairman and Chief Executive Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer of Endo pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certificate of the Chairman and Chief Executive Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certificate of the Chief Financial Officer of Endo pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002