ENDO PHARMACEUTICALS HOLDINGS INC
Form 10-Q
May 10, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

þ 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

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM ___TO ___.

Commission file number: 001-15989

ENDO PHARMACEUTICALS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-4022871**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

100 Endo Boulevard
Chadds Ford, Pennsylvania 19317
(Address of Principal Executive Offices)

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

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter 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 þ NO o

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

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.

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Forward Looking Statements

We have made forward-looking statements in this document within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. These statements, including estimates of future net sales, 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

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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

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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.

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PART I. FINANCIAL INFORMATION

Item 1. *Financial Statements*

ENDO PHARMACEUTICALS HOLDINGS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
(In thousands, except share data)

	March 31, 2005	December 31, 2004
ASSETS		
CURRENT ASSETS:		
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
LIABILITIES AND STOCKHOLDERS EQUITY		
CURRENT LIABILITIES:		
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		

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.

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ENDO PHARMACEUTICALS HOLDINGS INC.

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

	Three Months Ended March 31,	
	2005	**2004**
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.

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ENDO PHARMACEUTICALS HOLDINGS INC.

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

	Three Months Ended March 31,	
	2005	**2004**
OPERATING ACTIVITIES:		
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
INVESTING ACTIVITIES:		
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)
FINANCING ACTIVITIES:		
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:		

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

See Notes to Condensed Consolidated Financial Statements.

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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).

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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):

	March 31, 2005	December 31, 2004
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^{th}) 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.

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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):

	March 31, 2005	December 31, 2004
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

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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):

	March 31, 2005	March 31, 2004
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

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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):

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	Three Months Ended March 31,	
	2005	2004
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