

ENDO PHARMACEUTICALS HOLDINGS INC

Form 424B5

August 05, 2004

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PROSPECTUS SUPPLEMENT

(To prospectus dated August 3, 2004)

11,000,000 Shares

**Endo Pharmaceuticals Holdings Inc.
Common Stock**

The selling stockholders are offering 11,000,000 shares of our common stock, \$.01 par value per share, by this prospectus supplement and the accompanying prospectus. Our common stock is quoted on the Nasdaq National Market under the symbol "ENDP." On August 3, 2004, the last reported sale price of our common stock was \$18.72 per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 2 of the accompanying prospectus.

	Per Share	Total
Public Offering Price	\$17.70	\$ 194,700,000
Underwriting Discount	\$ 0.24	\$ 2,640,000
Proceeds to Selling Stockholders, Before Expenses	\$17.46	\$ 192,060,000

In addition to the underwriting discount, the underwriter will receive a commission equivalent from investors in the amount of \$0.05 for each share of common stock sold to those investors in the offering.

The selling stockholders have granted the underwriter a 30-day option to purchase up to 1,650,000 additional shares of our common stock on the same terms and conditions as set forth above, solely to cover over-allotments, if any.

Delivery of shares will be made on or about August 9, 2004.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Bear, Stearns & Co. Inc.

The date of this prospectus supplement is August 3, 2004.

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Prospectus

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This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information, some of which may not apply to this offering.

You should rely only on the information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. We are not, and the underwriters are not, making an offer of these securities in any state where the offer is not permitted. You should assume that the information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate only as of its respective date or on the date which is specified in those documents.

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FORWARD-LOOKING STATEMENTS

This prospectus supplement and the accompanying prospectus may contain or incorporate by reference information that includes or is based on "forward looking statements" within the meaning of Section 27A of the Securities Act 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations," which is included in documents incorporated by reference 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 "Risk Factors," beginning on page 2 of the accompanying prospectus and elsewhere in this prospectus supplement, the accompanying prospectus and in documents incorporated by reference 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 prospectus supplement and the accompanying prospectus. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this prospectus supplement and the accompanying prospectus include, among others:

- our ability to successfully develop, commercialize and market new products;
- results of pre-clinical or clinical trials on new products;
- our ability to obtain regulatory approval of any of our pipeline products;
- competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;
- market acceptance of our future products;
- government regulation of the pharmaceutical industry;
- our dependence on a small number of products;
- our dependence on outside manufacturers for the manufacture of our products;
- our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;
- new regulatory action or lawsuits relating to our use of narcotics in most of our core products;
- our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;
- our ability to protect our proprietary technology;
- our ability to successfully implement our acquisition and in-licensing strategy;
- the availability of controlled substances that constitute the active ingredients of some of our products and products in development;
- the availability of third-party reimbursement for our products; and
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our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this prospectus supplement for any reason, even if new information becomes available or other events occur in the future.

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THE COMPANY

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$16.6 billion in 2003. This represents an approximately 20% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were \$5.6 billion in 2003, representing a compounded annual growth rate of 25% since 1998.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Percodan® and Zydane®. Branded products comprised approximately 70% of our net sales in 2003. Our non-branded generic portfolio, which accounted for 30% of our net sales in 2003, currently consists of products that cover a variety of indications, most of which are focused in pain management. We focus on generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded products pipeline includes two filed new drug applications, or NDAs, one product in phase III clinical trials and three products in Phase II clinical trials. Through a dedicated sales force of approximately 230 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, surgery, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company, which was subsequently purchased by the Bristol-Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997.

Our executive offices are located at 100 Painters Drive, Chadds Ford, Pennsylvania 19317. Our telephone number is (610) 558-9800. The address of our website is www.endo.com (this is an inactive textual reference only). The information on our website is not part of this prospectus.

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RECENT DEVELOPMENTS

Financial Results

On July 14, 2004, we reported financial results for the three months and six months ended June 30, 2004. Net sales for the three months ended June 30, 2004 were \$144.0 million, compared to \$152.0 million in 2003. Net income for the three months ended June 30, 2004 was \$31.5 million compared to \$45.2 million in the same period in 2003. Diluted earnings per share for the three months ended June 30, 2004 was \$0.24 compared to \$0.34 in the same period in 2003.

For the six months ended June 30, 2004, our net sales were \$297.5 million compared to \$304.3 million in the same period in 2003. Net income for the six months ended June 30, 2004 was \$72.7 million compared to \$61.5 million in the same period in 2003. Diluted earnings per share for the six months ending June 30, 2004 was \$0.55 compared to \$0.46 in the same period in 2003.

Frova

On July 14, 2004, we entered into a license agreement and a loan agreement, each dated as of July 14, 2004, with Vernalis Development Limited, or Vernalis, under which Vernalis agreed to exclusively license to us rights to market Frova (frovatriptan) in North America. Launched in the U.S. in June 2002, Frova is indicated for the acute treatment of migraine headaches in adults. Net sales of Frova in the U.S. were \$37.5 million in 2003.

One of a class of compounds known as triptans (selective serotonin receptor agonists), Frova is also being studied as a potential prophylactic treatment for menstrually associated migraines. If approved for this indication, we believe that Frova would be the first triptan to be indicated for the prevention of any type of migraine. Vernalis anticipates filing a supplemental NDA for this indication following its completion of the second of two Phase III clinical trials.

Under the terms of the license agreement, we will pay Vernalis an upfront fee of \$30 million, anniversary payments for the first two years at \$15 million each year, and a \$40 million milestone payment upon U.S. Food and Drug Administration, or FDA, approval for the menstrually associated 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.

We expect to expand our primary and specialty sales force in early 2005 by approximately one-third to ensure the commercial success of Frova in the U.S., with the possibility for additional expansion in the future based on the product's growth and the potential approval by the FDA for the menstrually associated migraine indication. Vernalis has retained rights to co-promote frovatriptan in the U.S. Upon Vernalis exercising its co-promotion option, Endo will establish, train and fund a Vernalis sales force for a period of up to five years.

In addition, the license agreement also contains customary terms and conditions, including representations, warranties, indemnities and termination rights. The term of the license agreement is for the shorter of the time (i) that there are valid claims on the Vernalis patents covering Frova or there is market exclusivity granted by a regulatory authority, whichever is longer, or (ii) until the date on which a generic version of Frova is first offered, but in no event longer than 20 years. We can terminate the license agreement under certain circumstances, including upon one years' written notice. The license agreement is subject to a number of closing conditions, including obtaining clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

We will provide Vernalis with a loan of \$50 million at closing. The loan will primarily be used to pay in full the amounts currently due to Elan Corporation from Vernalis in connection with Vernalis' reacquisition of the North American rights to Frova. The balance of the loan will be available for Vernalis' general corporate purposes.

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The loan will be 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 monthly associated migraine indication approval milestone and fifty percent of all royalties to be paid under the license agreement to Vernalis to repay the loan. The loan is due in full in five years to the extent it is not previously repaid. Interest is at the rate of five percent 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.

DepoDur

During the second quarter of 2004, DepoDur received FDA approval which triggered a milestone payment of \$5.0 million to our development partner SkyePharma plc. This milestone is included in research and development expense in the second quarter. We expect to deploy a 25-person hospital sales force during the third quarter of 2004 to begin our commercialization efforts for DepoDur. This sales force will target selected institutions and continue to educate and build support, awareness and advocacy for this novel single shot sustained-release injectable formulation of morphine. We expect to be in a position to begin shipping the product before the end of 2004 and anticipate deploying 45 additional hospital sales representatives in the beginning of 2005 to promote DepoDur.

Generic Oxycodone Extended-Release

During the second quarter of 2004, we manufactured an additional \$4.5 million of our generic oxycodone extended-release product. We did not record a reserve for this inventory. Although there can be no assurance, we remain confident that the decision of the U.S. District Court for the Southern District of New York declaring Purdue's OxyContin patents unenforceable will be affirmed by the U.S. Court of Appeals for the Federal Circuit.

Oxymorphone Extended-Release

On July 7, 2004, we announced that we had reached an agreement with the FDA as to the design of a new clinical trial to provide additional safety and efficacy data of oxymorphone extended-release tablets in support of our NDA for this developmental product. We submitted the trial protocol to the FDA under the special protocol assessment, or SPA, process. Under the terms of the SPA, we will initiate a 12-week, multicenter, double-blinded, placebo-controlled trial of oxymorphone ER.

Propofol IDD-D

During the second quarter of 2004, Propofol IDD-D advanced into Phase III clinical development, which triggered a milestone payment of \$5.0 million to our development partner SkyePharma plc. This milestone payment is included in research and development expense in the second quarter. If the Phase III clinical trial results are positive, we currently expect that SkyePharma will submit an NDA for Propofol IDD-D to the FDA in the second half of 2006.

CHRONOGESIC

On July 21, 2004, our development partner DURECT Corporation announced that it would not be resuming human clinical trials of the CHRONOGESIC product in 2004. DURECT had initiated the process of clinical manufacturing of CHRONOGESIC following a series of promising results of in vitro studies and in vivo animal studies of the most recent CHRONOGESIC system design. However, they learned recently from a further animal study that they have not yet solved the premature shutdown problem (a stoppage in the delivery of drug before the intended full duration of delivery). DURECT continues to work to address this issue in order to bring this product to market.

2004 Stock Incentive Plan

In May 2004, our stockholders approved the Endo Pharmaceuticals Holdings Inc. 2004 Stock Incentive Plan. The maximum number of shares of our 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

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restricted stock, performance shares, performance units or other share-based awards that may be granted to our executive officers and other employees, including officers and directors who are employees, to our non-employee directors and consultants. 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. 2004 Stock Incentive Plan will dilute our public stockholders. No awards have been granted pursuant to this plan.

Product Review

Lidoderm®. For the three months ended June 30, 2004, net sales of Lidoderm® were \$58.2 million compared to \$50.6 million in the same period in 2003. For the first half of 2004, net sales of Lidoderm® were \$123.6 million compared with \$92.1 million in the same period in 2003. Due to the buying patterns of our customers during the second quarter of 2004, we estimate that inventory levels at our customers are currently below historic levels, which adversely impacted net sales of Lidoderm® in the second quarter of 2004.

Percocet®. Net sales of Percocet® were \$13.6 million for the three months ended June 30, 2004 compared to \$52.4 million in the same period in 2003. Net sales of Percocet® were \$44.4 million for the first half of 2004 compared to \$107.9 million in the same period in 2003. Net sales of Percocet® have been adversely affected during 2004 due to the introduction of generic versions of Percocet® 7.5/325 and 10/325 during the fourth quarter of 2003. In addition, due to the generic erosion of Percocet®, inventory levels of our customers increased above normal levels. Inventory levels at our customers are being brought back to normal levels, which adversely impacted net sales of Percocet® in the second quarter of 2004. We anticipate that our customers will be back to normal inventory levels during the third quarter of 2004.

Other branded products. Combined sales of all other branded products were \$3.1 million for the three months ended June 30, 2004 compared to \$8.1 million in the same period in 2003. Combined sales of all other branded products were \$7.5 million for the six months ended June 30, 2004 compared to \$15.5 million in the same period in 2003.

Generic products. Led by growth in Endocet®, net sales from our generic products rose to \$69.0 million for the three months ended June 30, 2004 compared to \$40.9 million in 2003. Net sales from our generic products rose to \$122.0 million for the six months ended June 30, 2004 compared to \$88.8 million in the same period in 2003. During 2004, we have experienced a decrease in net sales of our morphine sulfate extended-release tablets due to generic competition that was introduced in the third quarter of 2003; however, this was offset by our launch in the fourth quarter of 2003 of two new strengths of Endocet®. During the second quarter of 2004, another competitor announced that it had received approval to market two of the five strengths of morphine sulfate extended-release tablets. In addition, during the second quarter of 2004, another company received approval for a product that competes with Endocet® 7.5/325, 7.5/500, 10.0/325 and 10.0/650. We expect this additional competition to adversely impact the market share and price of both Endocet® and our morphine sulfate extended-release tablets.

Tax Sharing Agreement □ Liquidity Event

Under our amended tax sharing agreement, the sale of the 11 million shares of our common stock pursuant to this prospectus when added to the 16.6 million shares sold by the selling stockholders in July 2003 will cause a liquidity event to occur and, accordingly, we will be required to pay to Endo Pharma LLC the tax benefit amounts. Once a liquidity event occurs, we will be obligated to pay to Endo Pharma LLC, within 30 business days of the liquidity event, the tax benefit amounts attributable to 2001 and 2002 of approximately \$2 million and \$1 million, respectively. We will also be obligated to pay to Endo Pharma LLC 50% of the estimated tax benefit amount of approximately \$9 million attributable to 2003 within 30 business days of the liquidity event, and the remaining 50% of the tax benefit amount attributable to 2003 within 30 business days of the date on which we file our 2003 tax return with the Internal Revenue Service (which we estimate will occur in September 2004). In addition, since 3.8 million shares underlying stock options granted under the Endo Pharma LLC stock option plans are being exercised into common stock and sold in this offering, at a price of \$17.46, at a weighted average exercise price of \$2.44, an assumed tax rate of 38.3%

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and assuming the attributable compensation charge deductions are usable to reduce our taxes in 2004, we will be obligated to pay to Endo Pharma LLC a tax benefit amount of approximately \$22 million. If the over-allotment option is exercised, resulting in the exercise of 0.6 million additional options at an average exercise price of \$2.44, and assuming a tax rate of 38.3% and that the attributable compensation charge deductions are useable to reduce our taxes in 2004, we will be obligated to pay to Endo Pharma LLC an additional tax benefit of approximately \$3 million. Fifty percent of the tax benefit amount attributable to this offering and any additional offering in 2004 will be due within 15 business days of the date we receive an opinion on our final audited 2004 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 days of our fiscal year-end of December 31, 2004) 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). This estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised in 2004 may increase if certain holders of Endo Pharma LLC stock options exercise stock options in addition to those registered on the accompanying prospectus.

The following table presents our unaudited condensed consolidated statements of operations for the three months and six months ended June 30, 2004 and June 30, 2003:

**Endo Pharmaceuticals Holdings Inc.
Consolidated Statements of Operations (unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
	(in thousands, except per share data)			
NET SALES	\$ 143,968	\$ 152,027	\$ 297,457	\$ 304,301
COST OF SALES	28,915	26,258	61,788	53,835
GROSS PROFIT	115,053	125,769	235,669	250,466
COSTS AND EXPENSES:				
Selling, general and administrative	43,017	41,801	81,759	77,917
Research and development	19,245	9,438	29,001	21,502
Depreciation and amortization	2,262	1,365	4,089	2,717
Loss on disposal of other intangible, including license termination fee of \$3,000			3,800	
Compensation related to stock options <input type="checkbox"/> primarily selling, general and administrative				48,514
OPERATING INCOME	50,529	73,165	117,020	99,816
INTEREST (INCOME) EXPENSE, Net	(228)	22	(218)	153
INCOME BEFORE INCOME TAX	50,757	73,143	117,238	99,663
INCOME TAX	19,209	27,975	44,516	38,136
NET INCOME	\$ 31,548	\$ 45,168	\$ 72,722	\$ 61,527
NET INCOME PER SHARE:				
Basic	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.49
Diluted	\$ 0.24	\$ 0.34	\$ 0.55	\$ 0.46
WEIGHTED AVERAGE SHARES:				
Basic	131,792	131,734	131,786	125,014
Diluted	132,789	132,667	132,759	132,419

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Net sales for the six months ended June 30, 2004 decreased to \$297.5 million from \$304.3 million in the comparable 2003 period. This decrease in net sales was primarily due to the reduction in the net sales of Percocet® offset by the increase in the net sales of Lidoderm®, the first FDA-approved product for the treatment of the pain of post-herpetic neuralgia, and certain generic products. Net sales of Lidoderm®

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increased to \$123.6 million from \$92.1 million in the comparable 2003 period. Net sales of our generic products increased 37% to \$122.0 million from \$88.8 million in the comparable 2003 period primarily due to the growth of Endocet®. We experienced a decrease in net sales of our morphine sulfate extended release tablets due to generic competition introduced in the third quarter of 2003; however, this was offset by our launch in the fourth quarter of 2003 of two new strengths of Endocet®. During the second quarter of 2004, another competitor announced that they had received approval to market two of the five strengths of morphine sulfate extended-release tablets. In addition, during the second quarter of 2004, another competitor received approval for a product that competes with Endocet® 7.5/325, 7.5/500, 10.0/325 and 10.0/650. We expect this additional competition to adversely impact our market share and price of both Endocet® and our morphine sulfate extended-release. Percocet® net sales decreased to \$44.4 million from \$107.9 million in the comparable 2003 period due to the introduction of generic versions of Percocet® 7.5/ 325 and 10/325 during the fourth quarter of 2003. Generic competition with our products may have a material impact on our results of operations and cash flows in the future.

Gross profit for the six months ended June 30, 2004 decreased by 6% to \$235.7 million from \$250.5 million in the comparable 2003 period. Gross profit margins decreased to 79% from 82% due to the shift in revenues from higher-margin Percocet® to generic Endocet® combined with the impact of pricing pressure on our generic morphine sulfate product and the introduction of child-resistant packaging for Lidoderm® during the second quarter of 2004. We expect gross profit margins to continue to decrease in 2004.

Selling, general and administrative expenses for the six months ended June 30, 2004 increased by 5% to \$81.8 million from \$77.9 million in the comparable 2003 period. This increase was primarily due to the increase in educational and promotional efforts in 2004 over the comparable 2003 period to support our products, as well as support provided to our new product pipeline in anticipation of product launches.

Research and development expenses for the six months ended June 30, 2004 increased by 35% to \$29.0 million from \$21.5 million in the comparable 2003 period. This increase is primarily attributable to \$10 million in milestone payments, incurred in the second quarter of 2004, to SkyePharma related to the FDA approval of DepoDur® and the advance of Propofol IDD-D® into Phase III clinical development.

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The following table presents our unaudited condensed consolidated balance sheet data at June 30, 2004 and December 31, 2003:

Endo Pharmaceuticals Holdings Inc.
Condensed Consolidated Balance Sheet Data (unaudited)

	June 30, 2004	December 31, 2003
	(in thousands)	
ASSETS		
Cash and cash equivalents	\$ 231,687	\$ 229,573
Accounts receivable, net	139,437	101,284
Inventories	98,964	50,450
Other current assets	87,449	92,289
	557,537	473,596
Property and equipment, net	23,144	20,246
Goodwill	181,079	181,079
Other intangibles, net	46,918	42,043
Deferred income taxes	24,381	31,045
Other assets	7,112	5,871
	\$ 840,171	\$ 753,880
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 197,356	\$ 185,674
Other liabilities	1,335	589
Total stockholders' equity	641,480	567,617
	\$ 840,171	\$ 753,880

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The following table presents our unaudited condensed consolidated cash flow data for the six months ended June 30, 2004 and June 30, 2003:

Endo Pharmaceuticals Holdings Inc.
Condensed Consolidated Cash Flow Data (unaudited)

	Six Months Ended	
	June 30,	
	2004	2003
	(in thousands)	
Net cash provided by operating activities	\$ 15,148	\$ 139,122
Net cash used in investing activities	(12,668)	(27,309)
Net cash used in financing activities	(366)	(241)
Net increase in cash and cash equivalents	\$ 2,114	\$ 111,572
Cash and cash equivalents, beginning of period	\$ 229,573	\$ 56,902
Cash and cash equivalents, end of period	\$ 231,687	\$ 168,474

Cash flow from operating activities was \$15.1 million for the six months ended June 30, 2004 compared to \$139.1 million for the same period in 2003. This decrease primarily reflects both an increase in accounts receivable and an increase in our inventory levels.

The increase in accounts receivable is substantially attributable to an increase in the proportion of revenues of our generic products, which have payment terms of 60 days, compared to our branded products, which have payment terms of 30 days, as well as the timing of purchases by our customers during the quarter.

During the second quarter, our inventory levels increased as well. This increase was substantially due to an increase in our inventory of Lidoderm®. Historically, we have carried low inventory levels of Lidoderm® due to our manufacturing not being able to keep up with the product demand. This year, additional capacity has been added and our manufacturing of Lidoderm® has not only been able to keep up with demand, but we have been able to build a safety stock of Lidoderm® inventory. We are at this time, however, carrying more Lidoderm® inventory than we would like. Although we do not believe that there is a risk of obsolescence with this inventory, we and our manufacturer will be working together over the remainder of 2004 to bring the Lidoderm® inventory to more appropriate levels. In addition, during the second quarter of 2004, we made the decision to manufacture an additional \$4.5 million of our generic oxycodone extended-release tablets. We did not reserve for this inventory and, although there can be no assurance, we remain confident that the decision of the U.S. District Court for the Southern District of New York declaring Purdue's OxyContin patents unenforceable will be affirmed by the U.S. Court of Appeals for the Federal Circuit.

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THE OFFERING

Common Stock Offered	11,000,000 shares
Underwriter's Over-Allotment Option	1,650,000 shares
Nasdaq National Market Symbol	ENDP

USE OF PROCEEDS

All of the shares of common stock offered hereby are being sold by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

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SELLING STOCKHOLDERS

The following table provides information regarding the beneficial ownership of our common stock by the selling stockholders, as of August 2, 2004. Footnote (a) below provides a brief explanation of what is meant by the term "beneficial ownership." No offer or sale under this prospectus supplement and the accompanying prospectus may be made by a holder of the securities unless that holder is listed in the table in this prospectus supplement or until that holder has notified us and an amendment to the related registration statement has become effective.

We have prepared the table based on information given to us by, or on behalf of, the selling stockholders on or before August 2, 2004. Pursuant to the terms of our stockholder agreements, executive and employee stockholders cannot directly or indirectly sell, assign, mortgage, transfer, pledge, hypothecate or otherwise dispose of any of their shares of our common stock acquired in connection with our formation in 1997 or the shares of our common stock underlying their stock options granted pursuant to the Endo Pharma LLC stock option plans, in each case, without the consent of Endo Pharma LLC's Board of Managers, except to Endo Pharma LLC, Kelso Investment Associates V, L.P. and Kelso Equity Partners V, L.P. in accordance with the terms of the stockholders agreement. Furthermore, under this prospectus supplement and the accompanying prospectus, executive and employee stockholders can only sell such shares or shares of our common stock underlying such options in connection with a sale of shares by Endo Pharma LLC.

This table assumes the over-allotment option granted to the underwriter is not exercised. To the extent the underwriter exercises the over-allotment option, the selling stockholders will sell additional shares of common stock in approximately the same proportion as their participation in this offering.

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Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned Prior to the Offering*	Number of Shares That Will Be Offered	Number of Shares of Common Stock Beneficially Owned Following the Offering	Percentage of Shares of Common Stock to be Beneficially Owned After Completion of the Offering
Directors and Executive Officers:				
Carol A. Ammon(b)(d)	11,057,131(c)	1,354,279	9,702,852	7.4%
Brian T. Clingen (e)	15,000	□	15,000	**
Michael B. Goldberg(f)(g)				
Michael Hyatt(h)	1,171,494	91,667(h)	1,079,827	**
Roger H. Kimmel(i)	692,525	64,533	627,992	**
Frank J. Loverro(f)(g)				
Clive A. Meanwell, M.D., Ph.D(j)	15,000	□	15,000	**
Michael W. Mitchell(k)	30,000	□	30,000	**
Joseph T. O'Donnell, Jr.(l)	30,000	□	30,000	**
David I. Wahrhaftig(f)(g)				
Peter A. Lankau(b)	1,061,223(m)	54,764	1,006,459	**
David A. H. Lee, M.D., Ph.D.(b)(d)	4,057,882(n)	499,043	3,558,839	2.7%
Jeffrey R. Black(b)(d)	3,607,918(o)	443,575	3,164,343	2.4%
Caroline B. Manogue(b)	364,364(p)	31,723	332,641	**
All current directors and executive officers of Endo Pharmaceuticals Holdings Inc. as a group (14 persons)	21,611,344(q)	2,502,917(r)	19,108,427(s)	14.4%
Other Selling Stockholders:				
Endo Pharma LLC(d)(f)	82,219,380	10,820,392(t)	71,398,988	54.2%
Kelso Investment Associates V, L.P.(d)(f)(u)	38,321,689	5,379,007	32,942,682	25.0%
Kelso Equity Partners V, L.P.(d)(f)(u)	3,224,525	452,609	2,771,916	2.1%
Joseph S. Schuchert(f)(g)	□	□	□	□
Frank T. Nickell(f)(g)	□	□	□	□
Thomas R. Wall, IV(f)(g)	□	□	□	□
George E. Matelich(f)(g)	□	□	□	□
Frank K. Bynum, Jr.(f)(g)	□	□	□	□
Philip E. Berney(f)(g)	□	□	□	□
Michael B. Lazar(f)(g)	□	□	□	□
Greenwich Street Capital Partners, L.P.(d)(v)	4,910,225	689,221	4,221,004	3.2%
Greenwich Street Capital Offshore Fund, Ltd.(d)(v)	304,764	42,778	261,986	**
Citigroup GSP Employees Fund, L.P.(d)(v)	1,193,313	167,499	1,025,814	**
The Travelers Insurance Company(d)(v)	253,312	35,556	217,756	**
The Travelers Life and Annuity Company(d)(v)	124,765	17,513	107,252	**
Mariann T. MacDonald(b)(d)	9,301,159(w)	1,140,533	8,160,626	6.2%
Other selling stockholders representing less than 1% owners of our common stock(x)	5,383,706	572,367(y)	4,811,339	3.6%
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- * Number of shares assumes the exercise of all options reserved pursuant to the Endo Pharma LLC 1997 Stock Option Plans and Endo Pharma LLC 2000 Supplemental Stock Option Plans.
- ** The percentage of the class to be owned by such security holder after completion of the offering represents less than 1%.
- (a) "Beneficial ownership" is a term broadly defined by the Securities and Exchange Commission in Rule 13d-3 under the Exchange Act, and includes more than the typical form of stock ownership, that is, stock held in the person's name. The term also includes what is referred to as "indirect ownership," meaning ownership of shares as to which a person has or shares investment power. For purposes of this table, a person or group of persons is deemed to have "beneficial ownership" of any shares as of a given date that such person has the right to acquire within 60 days after such date.
- (b) The business address for this person is c/o Endo Pharmaceuticals Holdings Inc., 100 Painters Drive, Chadds Ford, Pennsylvania 19317.
- (c) Ms. Ammon is our Chairman and Chief Executive Officer. The shares to be sold by Ms. Ammon include 25,402 shares, which represent Ms. Ammon's pro rata portion of Endo Pharma LLC's shares that will be offered, and 1,328,877 shares, which represent the shares of common stock underlying her Endo Pharma LLC employee stock options that she will exercise and sell pursuant to this prospectus. Ms. Ammon owns 0.36% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. Ammon shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. Ammon's beneficial ownership after the offering includes 155,569 shares and 9,547,283 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she will not exercise and sell in an offering pursuant to this prospectus.
- (d) Members of Endo Pharma LLC will receive a pro rata distribution of the net proceeds from one or more offerings pursuant to this prospectus received by Endo Pharma LLC based on the number of Endo Pharma LLC units held by each such member. Affiliates of Kelso & Company own 83.6% of Endo Pharma LLC; Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd., Citigroup GSP Employees Fund, L.P., The Travelers Insurance Company and The Travelers Life and Annuity Company together own 13.7% of Endo Pharma LLC; our management, in the aggregate, owns .770% of Endo Pharma LLC; and certain other outside investors own 2.0% of Endo Pharma LLC. The number of shares shown that may be offered by Endo Pharma LLC does not include shares of common stock underlying the Endo Pharma LLC employee stock options that may be exercised and sold in one or more offerings pursuant to this prospectus.
- (e) Mr. Clingen is a director of Endo. The business address for Mr. Clingen is c/o BP Capital Management, 2215 York Rd, Suite 510, Oak Brook, Illinois 60523. Mr. Clingen's beneficial ownership represents options to purchase 15,000 shares of Common Stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (f) The business address for this person is c/o Kelso & Company, 320 Park Avenue, 24th Floor, New York, New York 10022.
- (g) Messrs. Goldberg, Loverro and Wahrhaftig are directors of Endo. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of Kelso Investment Associates V, L.P., or KIA V, and Kelso Equity Partners V, L.P., or KEP V, as members of Endo Pharma LLC. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar may be deemed to share beneficial ownership of securities owned of record by KIA V and KEP V, by virtue of the status of each of them as a general partner of the general partner of KIA V and as a general partner of KEP V. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar share investment and voting power along with the other general partners with respect to securities owned by KIA V and KEP V, but disclaim beneficial ownership of such securities except to the extent of each individual's pecuniary interest.
- (h) Mr. Hyatt is a director of Endo. The business address for Mr. Hyatt is c/o Bear, Stearns & Co. Inc., 383 Madison Avenue, New York, New York 10179. Mr. Hyatt's beneficial ownership includes (i) 629,551 shares of common stock owned directly by Mr. Hyatt, (ii) 511,943 shares held in trusts for which Mr. Hyatt serves as trustee and as to which shares Mr. Hyatt holds either the sole or the shared power of

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disposition or the power to vote (including 491,193 shares with respect to which beneficial ownership is shared with Mr. Kimmel) and (iii) options to purchase 30,000 shares of common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. 36,667 of the 491,193 shares with respect to which beneficial ownership is shared with Mr. Kimmel are included in Mr. Hyatt's number of shares that will be offered and are not to be accounted for in addition to the shares listed for Mr. Kimmel herein. Mr. Hyatt's beneficial ownership excludes 171,332 shares of common stock held in a trust for the benefit of the children of Mr. Hyatt, as to which shares Mr. Hyatt has neither the power of disposition nor the power to vote.

- (i) Mr. Kimmel is a director of Endo. The business address for Mr. Kimmel is c/o Rothschild, Inc., 1251 Avenue of the Americas, New York, New York 10022. Mr. Kimmel's beneficial ownership includes (i) 662,525 shares held in trusts for which Mr. Kimmel serves as trustee and as to which shares Mr. Kimmel holds either the sole or the shared power of disposition and power to vote (including 491,193 shares with respect to which beneficial ownership is shared with Mr. Hyatt) and (ii) options to purchase 30,000 shares of common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. Mr. Kimmel's beneficial ownership excludes a total of 201,530 shares of common stock held in trusts for the benefit of Mr. Kimmel's adult children, as to which shares Mr. Kimmel has neither the power of disposition nor the power to vote.
- (j) Dr. Meanwell is a director of Endo. The business address for Dr. Meanwell is c/o The Medicines Company, 5 Sylvan Way, Parsippany, New Jersey 07054. Dr. Meanwell's beneficial ownership represents options to purchase 15,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (k) Mr. Mitchell is a director of Endo. The business address for Mr. Mitchell is c/o Skadden, Arps, Slate, Meagher & Flom LLP, Four Times Square, New York, NY 10036. Mr. Mitchell's beneficial ownership represents options to purchase 30,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (l) Mr. O'Donnell is a director of Endo. The business address for Mr. O'Donnell is Van Beuren Capital, L.L.C., Van Beuren Road, Morristown, New Jersey 07960. Mr. O'Donnell's beneficial ownership represents options to purchase 30,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (m) Mr. Lankau is our President and Chief Operating Officer. The 54,764 shares to be sold by Mr. Lankau represent the shares of common stock underlying Mr. Lankau's Endo Pharma LLC employee stock options that he will exercise and sell pursuant to this prospectus. Mr. Lankau's beneficial ownership after the offering include 179,940 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans and 826,519 shares underlying options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan that he will not exercise and sell in an offering pursuant to this prospectus.
- (n) Dr. Lee is our Executive Vice President and Chief Scientific Officer. The shares to be sold by Dr. Lee include 1,588 shares, which represent Dr. Lee's pro rata portion of Endo Pharma LLC's shares that will be offered, and 497,455 shares, which represent the shares of common stock underlying his Endo Pharma LLC employee stock options that he will exercise and sell pursuant to this prospectus. Dr. Lee owns .02% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of his status as a member of Endo Pharma LLC. Dr. Lee shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest. Dr. Lee's beneficial ownership after the offering includes 9,723 shares and 3,549,116 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he will not exercise and sell in an offering pursuant to this prospectus.
- (o) Mr. Black is our Executive Vice President, Chief Financial Officer and Treasurer. The shares to be sold by Mr. Black include 3,175 shares, which represent Mr. Black's pro rata portion of Endo Pharma LLC's shares that will be offered, and 440,400 shares, which represent his shares of common stock underlying his Endo Pharma LLC employee stock options that he will exercise and sell pursuant to this prospectus. Mr. Black owns .05% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of his status as a member of Endo Pharma LLC. Mr. Black shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities

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except to the extent of his pecuniary interest. Mr. Black's beneficial ownership after the offering includes 19,446 shares and 3,144,897 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he will not exercise and sell in an offering pursuant to this prospectus.

- (p) Ms. Manogue is our Executive Vice President, Chief Legal Officer and Secretary. The 31,723 shares that will be sold by Ms. Manogue represent the shares of common stock underlying Ms. Manogue's Endo Pharma LLC employee stock options that she will exercise and sell pursuant to this prospectus. Ms. Manogue's beneficial ownership after the offering includes 202,981 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans and 129,660 shares underlying options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan that she will not exercise and sell in an offering pursuant to this prospectus.
- (q) This number excludes 491,193 shares held in trust for which Mr. Hyatt serves as trustee and for which he shares beneficial ownership with Mr. Kimmel and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (r) This number excludes 36,667 of the 491,193 shares with respect to which Mr. Hyatt shares beneficial ownership with Mr. Kimmel which are included in Mr. Hyatt's number of shares that may be offered and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (s) This number excludes 454,526 shares held in trust for which Mr. Hyatt serves as trustee and for which he shares beneficial ownership with Mr. Kimmel and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (t) This number represents the aggregate number of shares beneficially owned by all selling stockholders with the exception of Roger H. Kimmel and Michael Hyatt and 60,075 shares owned directly by current and former employees and are therefore not to be accounted for in addition to the shares individually listed herein.
- (u) KIA V and KEP V share investment and voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaim beneficial ownership of such securities except to the extent of its pecuniary interest. Kelso Partners V, L.P., or KP V, may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of its status as a general partner of KIA V, which is a member of Endo Pharma LLC. KP V shares investment and voting power along with its general partners with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of its pecuniary interest.
- (v) The business address for Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Employees Fund, L.P. is 500 Campus Drive, Suite 220, Florham Park, New Jersey 07932. The business address for Travelers Insurance Company and The Travelers Life and Annuity Company is One City Place, Hartford, CT 06103-3415. Greenwich Street Investments, L.P. is the general partner of Greenwich Street Capital Partners, L.P. Greenwich Street Investments, L.L.C. is the general partner of Greenwich Street Investments, L.P. The Travelers Insurance Company is the sole member of Greenwich Street Investments, L.L.C. Andrew Wagner and Woodbourne Corporation (BVI) Limited are the directors of Greenwich Street Capital Offshore Fund, Ltd. TRV Employees Investments, Inc. is the general partner of Citigroup GSP Employees Fund, L.P. and is a wholly-owned subsidiary of Citigroup Inc. GSCP (NJ), L.P. is the manager of Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Employees Fund, L.P. GSCP, Inc. is the general partner of GSCP (NJ), L.P. Each of Keith W. Abell, Alfred C. Eckert III, Robert A. Hamwee, Richard M. Hayden, Thomas V. Inglesby, Matthew C. Kaufman, Christine K. Vanden Beukel and Andrew Wagner is an executive officer and stockholder of GSCP (NJ), Inc. and a limited partner of GSCP (NJ), L.P. Greenwich Street Investments, L.P., Greenwich Street Investments, L.L.C. and The Travelers Insurance Company, because of their relationships with Greenwich Street Capital Partners, L.P., may be deemed to beneficially own the securities held by Greenwich Street Capital Partners, L.P. Notwithstanding the foregoing, the above entities disclaim beneficial ownership of the securities held by Greenwich Street Capital Partners, L.P. except to the extent of their pecuniary interest in the securities. Andrew Wagner and Woodbourne Corporation (BVI) Limited, because of their relationships to Greenwich Street Capital Offshore Fund, Ltd., may be deemed to beneficially own the securities held by Greenwich Street Capital Offshore Fund, Ltd. Notwithstanding the foregoing, the above individual and entity disclaim beneficial ownership of the securities held by Greenwich Street Capital Offshore Fund, Ltd. except to the extent of their pecuniary

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interest in the securities. TRV Employees Investments, Inc. and Citigroup Inc., because of their relationships with Citigroup Employees GSP Fund, L.P., may be deemed to beneficially own the securities held by Citigroup Employees GSP Fund, L.P. Notwithstanding the foregoing, the above entities disclaim beneficial ownership of the securities held by Citigroup Employees GSP Fund, L.P. except to the extent of their pecuniary interest in the securities. GSCP (NJ), L.P., GSCP (NJ), Inc., Keith W. Abell, Alfred C. Eckert III, Robert A. Hamwee, Richard M. Hayden, Thomas V. Inglesby, Matthew C. Kaufman, Christine K. Vanden Beukel and Andrew Wagner, because of their relationships with Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P., may be deemed to beneficially own the securities held by Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P. Notwithstanding the foregoing, the above entities and individuals disclaim beneficial ownership of the securities held by Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P. except to the extent of their pecuniary interest in the securities. The Travelers Life and Annuity Company is a wholly-owned subsidiary of The Travelers Insurance Company, which is a subsidiary of Citigroup Inc. The Travelers Insurance Company and Citigroup Inc. may be deemed to be the beneficial owner of the securities held by The Travelers Life and Annuity Company. The above entities and individuals may be deemed to share beneficial ownership of the shares of common stock owned of record by Endo Pharma LLC because they are members of Endo Pharma LLC or affiliates of members of Endo Pharma LLC. The above entities and individuals disclaim beneficial ownership of the securities owned by Endo Pharma LLC, except to the extent of their pecuniary interest.

- (w) Until December 31, 2003, Ms. MacDonald was our Executive Vice President of Operations, at which time she resigned from her executive office, while remaining an employee. The shares to be sold by Ms. MacDonald include 19,051 shares, which represent Ms. MacDonald's pro rata portion of her Endo Pharma LLC's shares that will be offered, and 1,121,482 shares, which represent the shares of common stock underlying Endo Pharma LLC employee stock options that she will exercise and sell pursuant to this prospectus. Ms. MacDonald owns .27% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. MacDonald shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. MacDonald's beneficial ownership after the offering includes 116,676 shares and 8,043,950 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she will not exercise and sell in an offering pursuant to this prospectus.
- (x) The 572,367 shares that will be sold by the other selling stockholders represent (1) the shares of common stock underlying Endo Pharma LLC employee stock options that they will exercise and sell pursuant to this prospectus; (2) shares which represent the selling stockholders pro rata portion of Endo Pharma LLC's shares that will be offered; and (3) other shares of common stock owned outright by the selling stockholders. Certain of the selling stockholders own 2.0% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of their status as members of Endo Pharma LLC. Each selling stockholder's shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but each disclaims beneficial ownership of such securities except to the extent of each selling stockholder's pecuniary interest.
- (y) This number is comprised of 60,075 shares and 371,312 shares underlying Endo Pharma LLC stock options beneficially owned by our current and former employees and 140,980 shares beneficially owned by members of Endo Pharma LLC.

[Back to Contents](#)**UNDERWRITING**

We and the selling stockholders have entered into an underwriting agreement, dated August 3, 2004, with Bear, Stearns & Co. Inc. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase 11,000,000 shares of common stock from the selling stockholders.

The underwriter has advised us that, initially, the underwriter proposes to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus supplement. If all the shares are not sold at the public offering price, the underwriter may change the offering price and the other selling terms. The shares are offered by the underwriter as stated herein, subject to receipt and acceptance by the underwriter and subject to the underwriter's right to reject any order in whole or in part.

The underwriting agreement provides that the obligations of the underwriter are conditional and may be terminated at its discretion based on its assessment of the state of the financial markets. The obligations of the underwriter may also be terminated upon the occurrence of the events specified in the underwriting agreement. The underwriter is committed to purchase all of the shares offered if any shares are purchased, other than those shares covered by the over-allotment option described below.

The selling stockholders have granted to the underwriter an option, exercisable within 30 days after the date of this prospectus supplement, to purchase up to a total of 1,650,000 additional shares of common stock to cover over-allotments, if any, at the public offering price less the underwriting discount. If the underwriter exercises the over-allotment option to purchase any of the additional 1,650,000 shares of common stock, these additional shares will be sold by the underwriter on the same terms as those on which the shares offered hereby are being sold. The underwriter may exercise the over-allotment option only to cover over-allotments made in connection with the sale of the shares of common stock offered in this offering.

The following table shows the public offering price, underwriting discount and proceeds to the selling stockholders from the sale of common stock. Such amounts are shown assuming both no exercise and full exercise of the underwriter's over-allotment option to purchase additional shares.

	Per Share	Total	
		Without over-allotment	With over-allotment
Public offering price	\$ 17.70	\$ 194,700,000	\$ 223,905,000
Underwriting discount	\$ 0.24	\$ 2,640,000	\$ 3,036,000
Proceeds, before expenses, to the selling stockholders	\$ 17.46	\$ 192,060,000	\$ 220,869,000

In addition to the underwriting discount, the underwriter will receive a commission equivalent from investors in the amount of \$0.05 for each share of common stock sold to those investors in the offering.

The expenses of the offering, other than the underwriting discount referred to above, are estimated at approximately \$0.9 million and are payable entirely by us.

We and the selling stockholders have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act of 1933 or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

We, our executive officers, our directors and Endo Pharma LLC have agreed, subject to limited exceptions, that, for a period of 45 days from the date of this prospectus, we and they will not, without the prior written consent of the underwriter, offer, sell, contract to sell, pledge or otherwise dispose of any shares of our common stock or any securities convertible into or exchangeable for our common stock. The underwriter in its sole discretion may release any of the securities subject to these lock-up agreements at any time without notice.

Our common stock trades on the Nasdaq National Market under the symbol "ENDP." On August 3, 2004, the last reported sale price of our common stock was \$18.72 per share.

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In connection with the offering, the underwriter may purchase and sell shares of common stock in the open market. These transactions may include short sales, syndicate covering transactions and stabilizing transactions. Short sales involve syndicate sales of common stock in excess of the number of shares to be purchased by the underwriter in the offering, which creates a syndicate short position. "Covered" short sales are sales of shares made in an amount up to the number of shares represented by the underwriter's over-allotment option. In determining the source of shares to close out the covered syndicate short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which the underwriter may purchase shares through the over-allotment option. Transactions to close out the covered syndicate short involve either purchases of the common stock in the open market after the distribution has been completed or the exercise of the over-allotment option. The underwriter may also make "naked" short sales of shares in excess of the over-allotment option. The underwriter must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriter is concerned that there may be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of bids for or purchases of shares in the open market while the offering is in progress.

Any of these activities may have the effect of preventing or retarding a decline in the market price of the common stock. They may also cause the price of the common stock to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriter may conduct these transactions on the Nasdaq National Market or otherwise. If the underwriter commences any of these transactions, the underwriter may discontinue them at any time.

The underwriter and certain of its affiliates have in the past provided, and may in the future provide, investment banking and other financial and banking services to us for which they have in the past received, and may in the future receive, customary fees. Mr. Hyatt, one of our directors, is a Senior Managing Director of Bear, Stearns & Co. Inc. In addition, Mr. Nickell, President and Chief Executive Officer of Kelso & Company, is an outside director of The Bear Stearns Companies, Inc.

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LEGAL MATTERS

Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York is acting as legal counsel to Endo Pharmaceuticals Holdings Inc. Skadden, Arps, Slate, Meagher & Flom LLP represents Kelso & Company and its affiliates from time to time. Debevoise & Plimpton LLP, New York, New York is acting as legal counsel to the underwriter. Debevoise & Plimpton LLP also represents Kelso and its affiliates from time to time.

EXPERTS

The financial statements and the related financial statement schedule incorporated in this prospectus supplement by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003 have been audited by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's change in method of accounting for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, effective January 1, 2002), which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INTERESTS OF EXPERTS

Mr. Michael Mitchell, of counsel to Skadden, Arps, Slate, Meagher & Flom LLP, which provides legal services to us from time to time, is a director of Endo Pharmaceuticals Holdings Inc. and beneficially owns 30,000 options exercisable into shares of Endo Pharmaceuticals Holdings Inc.'s common stock.

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PROSPECTUS

30,000,000 Shares

**Endo Pharmaceuticals Holdings Inc.
Common Stock**

This prospectus relates to the sale by selling stockholders of up to 30,000,000 shares of our common stock. We will not receive any proceeds from the sale of shares offered by the selling stockholders.

The shares are being registered to permit the selling stockholders to sell the shares from time to time in the public market. The selling stockholders will only sell their shares through underwriters. See "Plan of Distribution."

You should read this prospectus and any accompanying prospectus supplement carefully before you make your investment decision. The prospectus supplement will describe, among other things, the means of distribution for any shares of our common stock sold by the selling stockholders.

Our common stock is quoted on the Nasdaq National Market under the symbol "ENDP." The last reported sale price of our common stock on the Nasdaq National Market on August 3, 2004 was \$18.72 per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 2.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is August 3, 2004.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, the SEC, using a "shelf" registration or continuous offering process. Under this shelf process, selling stockholders may from time to time sell the securities described in this prospectus in one or more offerings.

This prospectus provides you with a general description of the securities that the selling stockholders may offer. Each time a selling stockholder sells securities, the selling stockholders are required to provide you with a prospectus and/or a prospectus supplement containing specific information about the selling stockholder, the terms of the securities being offered and the means of distribution. A prospectus supplement may include other special considerations applicable to those securities. The prospectus supplement may also add, update or change information in this prospectus. If there is any inconsistency between the information in this prospectus and any prospectus supplement, you should rely on the information in that prospectus supplement. You should read carefully both this prospectus and any prospectus supplement together with the additional information described under the heading "Where You Can Find More Information."

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THE COMPANY

We are a specialty pharmaceutical company with market leadership in pain management. We are engaged in the research, development, sale and marketing of branded and generic prescription pharmaceuticals used primarily to treat and manage pain. According to IMS Health data, the total U.S. market for pain management pharmaceuticals, excluding over-the-counter products, totaled \$16.6 billion in 2003. This represents an approximately 20% compounded annual growth rate since 1998. Our primary area of focus within this market is in the opioid analgesics segment. Total U.S. sales for this segment were \$5.6 billion in 2003, representing a compounded annual growth rate of 25% since 1998.

We have a portfolio of branded products that includes established brand names such as Lidoderm®, Percocet®, Percodan® and Zydone®. Branded products comprised approximately 70% of our net sales in 2003. Our non-branded generic portfolio, which accounted for 30% of our net sales in 2003, currently consists of products that cover a variety of indications, most of which are focused in pain management. We focus on generics that have one or more barriers to market entry, such as complex formulation, regulatory or legal challenges or difficulty in raw material sourcing.

We have established research and development expertise in analgesics and devote significant resources to this effort so that we can maintain and develop our product pipeline. Our late-stage branded products pipeline includes two filed new drug applications, or NDAs, one product in phase III clinical trials and three products in Phase II clinical trials. Through a dedicated sales force of approximately 230 sales representatives in the United States, we market our branded pharmaceutical products to high-prescribing physicians in pain management, surgery, oncology and primary care. Our sales force also targets retail pharmacies and other healthcare professionals throughout the United States.

Our wholly-owned subsidiary, Endo Pharmaceuticals Inc., commenced operations in 1997 by acquiring certain pharmaceutical products, related rights and assets of The DuPont Merck Pharmaceutical Company, which subsequently became DuPont Pharmaceuticals Company, which was subsequently purchased by the Bristol-Myers Squibb Pharma Company in 2001. Endo Pharmaceuticals Inc. was formed by some members of the then-existing management of DuPont Merck and an affiliate of Kelso & Company who were also parties to the purchase agreement, under which we acquired these initial assets. We were incorporated in Delaware as a holding company on November 18, 1997. Our common stock is quoted on the Nasdaq National Market under the symbol **ENDP**.

Our executive offices are located at 100 Painters Drive, Chadds Ford, Pennsylvania 19317. Our telephone number is (610) 558-9800. The address of our website is www.endo.com (this is an inactive textual reference only). The information on our website is not part of this prospectus.

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RISK FACTORS

You should carefully consider the following risk factors in addition to the other information in this prospectus before investing in our common stock.

Risks Related to Our Business

We face intense competition, in particular from companies that develop rival products to our branded products and from companies with which we compete to acquire rights to intellectual property assets.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully in any of these areas, our business, profitability and cash flows could be adversely affected. Our competitors include the major brand name and generic manufacturers of pharmaceuticals, especially those doing business in the United States, and include Abbott Laboratories, Elan Corporation plc, Johnson & Johnson, Ligand Pharmaceuticals Incorporated, Mallinckrodt Inc., Mylan Laboratories Inc., Pfizer, Inc., The Purdue Frederick Company, Roxane Laboratories, Inc., Teva Pharmaceutical Industries Ltd. and Watson Pharmaceuticals, Inc.

In the market for branded pharmaceutical products, our competitors vary depending on product category, dosage strength and drug-delivery systems. In addition to product safety, development and efficacy, other competitive factors in the branded pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. Because we are smaller than many of our national competitors in the branded pharmaceutical products sector, we may lack the financial and other resources needed to maintain our profit margins and market share in this sector.

The intensely competitive environment of the branded products business requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products to healthcare professionals in private practice, group practices and managed care organizations.

Our branded products face competition from generic versions. Generic versions 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. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, introduced measures intended to speed the process by which generic versions of brand name drugs are introduced to the market. Additionally, this legislation limits regulatory delays of generic drug applications and penalizes companies that reach agreements with makers of brand name drugs to delay the introduction of generic versions. The entrance of generic competition to our branded products generally reduces our market share and adversely affects our profitability and cash flows. According to the IMS National Prescription Audit, in 2003, generic versions of Percocet® were used to fill approximately 83% of the approximately 16.0 million new prescriptions for this drug. Percocet® 10/325 and Percocet® 7.5/325, which prior to the introduction of generic competition then represented approximately 75% of our dispensed Percocet® prescriptions, currently face generic competition. Generic competition with our products will have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows in 2004.

We compete to acquire the intellectual property assets that we require to continue to develop and broaden our product range. In addition to our in-house research and development efforts, we seek to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. Competitors with greater resources may acquire assets that we seek, and even where we are successful, competition may increase the acquisition price of such assets. If we fail to compete successfully, our growth may be limited.

We face intense competition from other manufacturers of generic versions of our generic products.

Our generic products compete with generic versions made by other manufacturers, such as Mallinckrodt Inc., Mylan Laboratories Inc., Roxane Laboratories, Inc., Teva Pharmaceutical Industries Ltd. and Watson Pharmaceuticals, Inc. When additional versions of one of our generic products enter the market, we generally lose market share and our margins on the product decline. Because we are smaller than many of our national competitors in the generic pharmaceutical products sector, we may lack the financial and other resources

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needed to maintain our profit margins and market share in this sector. A generic competitor to one of our generic products, morphine sulfate extended-release tablets was introduced in the third quarter of 2003 and another generic competitor was introduced in the second quarter of 2004. In addition, during the second quarter of 2004, another competitor received approval for a product that competes with Endocet. The introduction of these third-party generic versions of our products will have a material adverse effect on our net sales, gross profit, operating income, net income and cash flows in 2004.

We entered into a tax sharing agreement with Endo Pharma LLC in July 2000, pursuant to which we may have to make large cash payments to Endo Pharma LLC.

Upon the exercise of the stock options granted under the Endo Pharma LLC stock option plans, only currently outstanding shares of our common stock held by Endo Pharma LLC will be issued. Endo Pharma LLC was formed in connection with the acquisition of Algos Pharmaceutical Corporation in July 2000 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. Because Endo Pharma LLC, and not us, will provide the shares upon the exercise of these options, we entered into a tax sharing agreement with Endo Pharma LLC under which we will be required to pay to Endo Pharma LLC upon the occurrence of a liquidity event, 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 June 30, 2004, approximately 3.8 million of these stock options had been exercised by former employees into shares of our common stock held by Endo Pharma LLC. The exercise of any of these Endo Pharma LLC stock options generally will permit us to deduct as a compensation charge, for 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 June 30, 2004, approximately \$38 million, which is estimated to result in a tax benefit amount of approximately \$15 million). Under the tax sharing agreement, we are required to pay this \$15 million to Endo Pharma LLC upon the occurrence of a liquidity event, as described further below, to the extent that a compensation charge deduction is usable to reduce our taxes and based upon the assumption that all other deductions of Endo are used prior thereto.

Under the tax sharing agreement, payments to Endo Pharma LLC are required to be made only 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) primary offerings by us, (ii) secondary sales by Endo Pharma LLC or other holders of common stock 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. No liquidity event has yet occurred and therefore no payments have been made or accrued to date.

On April 30, 2004, we amended the tax sharing agreement to clarify when a liquidity event has occurred and 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. Upon the occurrence of a liquidity event, we will 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. Moreover, with respect to all taxable years for which we file our federal income tax return after 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 generally be paid within 15 business days of our receipt from our independent registered public accounting firm of an opinion on our final audited financial statements, and (ii) the remaining amount shall be paid within 30 business days of the filing of our federal income tax return. In addition, the amendment established a formula for calculating when a sale of 20% of the common equity of Endo has occurred and specified that secondary sales of Endo common stock include sales pursuant to a shelf registration statement.

In general, under the amended tax sharing agreement, a liquidity event will occur and we will be required to pay to Endo Pharma LLC the tax benefit amounts upon the sale of approximately 10.5 million additional shares of our common stock under a shelf registration agreement. Accordingly, if approximately 10.5 million shares of our common stock are sold pursuant to this prospectus, a liquidity event will have occurred. Once a liquidity event occurs, we will be obligated to pay to Endo Pharma LLC, within 30 business

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days of the time of such liquidity event, the tax benefit amounts attributable to 2001 and 2002 of approximately \$2 million and \$1 million, respectively. After a liquidity event occurs, we will also be obligated to pay to Endo Pharma LLC 50% of the estimated tax benefit amount of approximately \$9 million attributable to 2003 within 30 business days of the liquidity event, and the remaining 50% of the tax benefit amount attributable to 2003 within 30 business days of the date on which we file our 2003 tax return with the Internal Revenue Service (which we estimate will occur in September 2004). In addition, if the approximately 10.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans that are registered on this prospectus are exercised into common stock and sold in 2004, assuming a price of \$18.72 (the last reported stock price of our common stock on the NASDAQ National Market on August 3, 2004), an exercise price of \$2.60, an assumed tax rate of 38.3% and assuming that the attributable compensation charge deductions are usable to reduce our taxes in 2004, we will be obligated to pay to Endo Pharma LLC a tax benefit amount of approximately \$65 million. 50% of the tax benefit amount attributable to 2004 is due within 15 business days of the date we receive an opinion on our final audited 2004 financial statements from our independent registered public accounting firm (which we estimate will occur within 60 days of our fiscal year-end of December 31, 2004) and the remaining 50% 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). This estimated tax benefit amount payment to Endo Pharma LLC attributable to Endo Pharma LLC stock options exercised in 2004 may increase if certain holders of Endo Pharma LLC stock options exercise stock options in addition to those registered on this prospectus.

Assuming the approximately 10.5 million shares underlying stock options granted under the Endo Pharma LLC stock option plans that are registered on this prospectus are exercised into common stock and sold (and assuming no additional stock options under the Endo Pharma LLC stock option plans are exercised), there will be approximately 22 million stock options remaining to be exercised under the Endo Pharma LLC stock option plans. Using a weighted average exercise price of \$2.60 per share and an assumed tax rate of 38.3%, if all of these remaining stock options under the Endo Pharma LLC stock options plans were vested and exercised, and assuming the price of our common stock was \$18.72 per share, we generally would be able to deduct, for income tax purposes, compensation of approximately \$355 million, which could result in a tax benefit amount of approximately \$136 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.

We were successful in our patent challenge against Purdue Frederick for our generic OxyContin product. Purdue has appealed, and if we receive an unfavorable ruling by the appeals court, we may be liable for damages and the price of our common stock may decline.

The Purdue Frederick Company filed suit against us in October 2000 (and again in March 2001 and August 2001) alleging that our 10mg, 20mg, 40mg and 80mg bioequivalent versions of OxyContin, for which we have filed an ANDA, violate three of their patents. The trial of the patent claims concluded in June 2003. The U.S. District Court for the Southern District of New York issued an Opinion and Order on January 5, 2004 holding that, while Endo infringes the three Purdue patents, the patents are unenforceable due to Purdue's inequitable conduct. Accordingly, the district court 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 stay the injunction against the enforcement of their patents pending the outcome of the appeal and to expedite the appeal. 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, and oral argument is expected to take place by the end of 2004. We can make no prediction as to how the appellate court will rule in any such appeal, nor can we predict the timing or effect of the ruling on the price of our common stock or on our generic strategy. As disclosed on May 17, 2004, we have decided to wait until appellate review of the district court's decision to launch our 10mg, 20mg and 40mg bioequivalent versions of generic OxyContin. If we receive an unfavorable ruling from the appeals court, we may be unable to sell our generic OxyContin, and the price of our stock may decline. However, if upon further examination we determine that it is in our best interest to launch one or more of our bioequivalent versions of OxyContin in advance of the appellate court decision and the district court's ruling is overturned on appeal, we may be

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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.

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.

Most of our core products contain narcotic ingredients. Misuse or abuse of such drugs can lead to physical or other harm. In the past two years, reportedly widespread misuse or abuse of OxyContin, a Purdue Frederick product containing the narcotic oxycodone, resulted in the strengthening of warnings on its labeling. In addition, the manufacturer of OxyContin faces numerous lawsuits, including class action lawsuits, related to OxyContin misuse or abuse. On March 23, 2004, we received final approval from the FDA for bioequivalent versions of the 10mg, 20mg and 40mg strengths of OxyContin and confirmation of tentative approval from the FDA for a bioequivalent version of 80mg strength OxyContin. Following the favorable decision we received from the court on January 5, 2004 in our patent litigation with Purdue Frederick, we are awaiting the outcome of Purdue Frederick's appeal. We may be subject to litigation similar to the OxyContin suits related to our generic version of OxyContin or any other narcotic-containing product we market.

The FDA or the DEA may impose new regulations concerning the manufacture and sale of prescription narcotics. Such regulations may include new labeling requirements, the development and implementation of risk management programs, restrictions on prescription and sale of these products and mandatory reformulation of our products in order to make abuse more difficult. In addition, state health departments and boards of pharmacy have authority to regulate distribution and may modify their regulations with respect to prescription narcotics in an attempt to curb abuse. In either case, any such new regulations may be difficult and expensive for us to comply with, may adversely affect our net sales and may have a material adverse effect on our business, 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. Failure to comply with applicable regulatory requirements 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.

The submission of an NDA to the FDA alone does not guarantee that the FDA will grant approval to market the product. Satisfaction of FDA requirements typically takes a number of years, varies substantially based upon the type, complexity and novelty of the pharmaceutical product and is subject to uncertainty. The NDA approval process for a new product varies in time but generally takes from eight months to four years from the date of application. NDA approvals, if granted, may not include all uses for which a company may seek to market a product. The FDA actively enforces regulations prohibiting marketing of products for non-indicated uses.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone ER or oxymorphone IR, 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. In particular, on May 6, 2004, we announced that we will initiate a new clinical trial for oxymorphone ER to provide additional safety and efficacy data in response to

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meetings we had with the FDA in the first half of 2004. On July 7, 2004, we announced that we had reached an agreement with the FDA as to the design of this new clinical trial for oxymorphone ER, which will be a 12-week, multicenter, double-blinded, placebo-controlled trial. In addition, in March 2004, we announced that more safety and efficacy information from patients receiving repeated doses of oxymorphone IR will be required. We do not know what the FDA will require for final approval of oxymorphone ER and oxymorphone IR. There can be no assurance that the FDA will approve oxymorphone ER and oxymorphone IR or if the FDA will require significant additional testing which could result in a substantial delay in launching these products, if at all. Any delay of this nature in obtaining, or failure to obtain, these approvals would adversely affect the marketing of our products and our ability to generate product revenue.

The current FDA standards of approving new pharmaceutical products are more stringent than those that were applied in the past. These standards were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. Accordingly, we believe the FDA has recently expressed an intention to develop such databases for certain of these products, including many opioids.

In particular, the FDA has expressed interest in specific chemical structures that may be present as impurities in a number of opioid narcotic active pharmaceutical ingredients, such as oxycodone, which based on certain structural characteristics and laboratory tests may indicate the potential for having mutagenic effects. More stringent controls of the levels of these impurities have been required and may continue to be required for FDA approval of products containing these impurities, such as oxymorphone. Also, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary for new or existing products containing such impurities. The FDA's more stringent requirements together with any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development. Although we do not believe that the FDA would seek to remove a currently marketed product from the market unless such mutagenic effects are believed to indicate a significant risk to patient health, we cannot make any such assurance.

The FDA and the Drug Enforcement Administration, or DEA, have important and complementary responsibilities with respect to our business. The FDA administers an application process to assure that marketed products are safe, effective and consistently of uniform, high quality. The DEA administers registration, drug allotment and accountability systems to assure against loss and diversion of controlled substances. Both agencies have trained investigators that routinely, or for cause, conduct inspections, and both have authority to enforce their statutory authority and regulations using administrative remedies as well as civil and criminal sanctions.

The FDA regulates the facilities and procedures used to manufacture pharmaceutical products in the United States or for sale in the United States. Such facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with "current good manufacturing practices," or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects our third-party manufacturing facilities and procedures to assure compliance. The FDA may cause a recall or withdrawal of product approvals if regulatory standards are not maintained. The FDA approval to manufacture a drug is site-specific. In the event an approved manufacturing facility for a particular drug is required by the FDA to cease or curtail operations, or otherwise becomes inoperable, or the manufacturing contract applicable thereto terminates, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business, profitability and cash flows.

The stringent DEA regulations on our use of controlled substances include restrictions on their use in research, manufacture, distribution and storage. A breach of these regulations could result in imposition of civil and criminal penalties, refusal to renew or action to revoke necessary registrations, or other restrictions on operations involving controlled substances.

In addition to FDA and DEA regulations, federal anti-kickback and false claims laws and similar state laws have been in recent years applied to restrict certain marketing practices in the pharmaceutical industry

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and to assure that reported data used to establish or determine government reimbursement for pharmaceutical products are accurate and complete. The Federal Healthcare Program Anti-kickback Law prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. The Federal False Claims Act prohibits knowingly or with reckless disregard for the truth presenting or causing to be presented to the federal government a false or fraudulent claim for payment. Various federal and state governmental and regulatory agencies have recently increased their focus on, and investigations of, possible violations within the pharmaceutical industry of the federal anti-kickback law and False Claims Act and similar state laws, including the manner by which pharmaceutical companies have reported average wholesale price and the promotion of off-label product use.

Doctors commonly prescribe pharmaceutical products for indications other than those for which the products have been approved by the FDA. While it is not illegal for doctors to prescribe pharmaceutical products for off-label uses, it is illegal for pharmaceutical companies to promote off-label uses of their products. Although it is our policy to market and promote our products only in accordance with their FDA-approved labeling, we believe that Lidoderm® is at times prescribed by doctors for uses other than Lidoderm®'s FDA- approved indication.

Violations of the federal anti-kickback statute and the Federal False Claims Act may result in substantial civil monetary penalties, imposition of corporate integrity agreements and exclusion from participation in federal healthcare programs. In addition, violation of the anti-kickback statute may also result in substantial criminal fines and imprisonment.

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.

The rate of patient enrollment sometimes delays completion of clinical studies. There is substantial competition to enroll patients in clinical trials for pain management products, and such competition has delayed clinical development of our products in the past. Delays in planned patient enrollment can result in increased development costs and delays in regulatory approval. We presently have three products in Phase II of clinical trials, including Lidoderm® for chronic low back pain. We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, including oxymorphone ER or oxymorphone IR, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. In particular, on May 6, 2004, we announced that we will initiate a new clinical trial for oxymorphone ER to provide additional safety and efficacy data in response to meetings we had with the FDA in the first half of 2004. In addition, we announced in March 2004, that more safety and efficacy information from patients receiving repeated doses of oxymorphone IR will be required. We do not know what the FDA will require for final approval of oxymorphone ER and oxymorphone IR. There can be no assurance that the FDA will approve oxymorphone ER and oxymorphone IR or if the FDA will require significant additional testing which could result in a substantial delay in launching these products, if at all. Any delay or limitation in obtaining, or failing to obtain approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock. In addition, we rely on collaboration partners that may control or make changes in trial protocol and design enhancements that may also delay clinical trials. We cannot assure you that we will not experience delays or undesired results in these or any other of our clinical trials.

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Before obtaining regulatory approvals for certain generic products, we must conduct limited clinical trials to show comparability to the branded products. A failure to obtain satisfactory results in these trials would prevent us from obtaining required regulatory approvals.

Our growth and development will depend on developing, commercializing and marketing 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.

Our future revenues and profitability will depend, to a significant extent, upon our ability to successfully commercialize new branded and generic pharmaceutical products in a timely manner. As a result, we must continually develop, test and manufacture new products, and these new products must meet regulatory standards and receive requisite regulatory approvals. Products we are currently developing may or may not receive the regulatory approvals necessary for us to market them. Furthermore, the development and commercialization process is time-consuming and costly, and we cannot assure you that any of our products, if and when developed and approved, can be successfully commercialized. Some of our collaboration partners may decide to make substantial changes to a product's formulation or design, may experience financial difficulties or have limited financial resources, any of which may delay the development, commercialization and/or marketing of new products. In addition, if a co-developer on a new product terminates our collaboration agreement or does not perform under the agreement, we may experience delays and, possibly, additional costs in developing and marketing that product.

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. Our policy is to seek patent protection and enforce the intellectual property rights we own and license. We cannot assure you that patent applications we submit, and have submitted, will result in patents being issued. If an advance is made that qualifies as a joint invention, the joint inventor or his or her employer may have rights in the invention. We cannot assure you that a third party will not infringe upon, design around or develop uses not covered by any patent issued or licensed to us or that these patents will otherwise be commercially viable. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the U.S. Patent and Trademark Office, or PTO, or in legal proceedings. Moreover, we believe that obtaining foreign patents may be more difficult than obtaining domestic patents because of differences in patent laws and, accordingly, our patent position may be stronger in the United States than abroad. Foreign patents may be more difficult to protect and/or the remedies available may be less extensive than in the United States. Various countries limit the subject matter that can be patented and limit the ability of a patent owner to enforce patents in the medical field. This may limit our ability to obtain or utilize those patents internationally. Patent applications in the United States are maintained in secrecy until at least 18 months after the filing of the application with the PTO and, since publication of discoveries in the scientific or patent literature tends to lag behind actual discoveries, we cannot be certain that we were the first creator of the inventions covered by pending patent applications or the first to file patent applications on those inventions. Several drug companies and research and academic institutions have developed technologies, filed patent applications or received patents for technologies that may be related to our business. Others may file patent applications and may receive patents that may conflict with patents or patent applications we have obtained or licensed for our use, either by claiming the same methods or compounds or by claiming methods or compounds that could dominate those owned by or licensed to us. We cannot assure you that any of our pending patent applications will be allowed, or, if allowed, whether the scope of the claims allowed will be sufficient to protect our products. We also cannot assure you that our existing patents will be sufficient to protect our products. Litigation to establish the validity of patents, to defend against patent infringement claims of others and to assert patent infringement claims against others can be expensive and time-consuming even if the outcome is favorable to us. If the outcome is unfavorable to us, this could have a material adverse effect on our business. We have taken and may, in the future, take steps to enhance our patent protection, but we cannot assure you that any such steps will be successful or that, if unsuccessful, our patent protection will be adequate. We periodically review the portfolio of patents protecting our products. As a result of that

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review, we may determine that a patent or patents protecting our products can be strengthened through further proceedings in the PTO, such as reissue or reexamination. Consequently, we may occasionally seek to have the PTO review one or more issued patents, where we believe we have a reasonable likelihood of strengthening that patent, or the protection of a product as a whole.

We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We attempt to protect our proprietary technology in large part by confidentiality agreements with our employees, consultants and other contractors. We cannot assure you, however, that these agreements will not be breached, that we would have adequate remedies for any breach or that competitors will not know of, or independently discover, our trade secrets. We cannot assure you that others will not independently develop substantially equivalent proprietary information or be issued patents that may prevent the sale of our products or know-how or require licensing and the payment of significant fees or royalties by us in order to produce our products. Moreover, we cannot assure you that our technology does not infringe upon any valid claims of patents that other parties own.

In the future, if we were found to be infringing on a patent, we might have to seek a license to use the patented technology. We cannot assure you that, if required, we would be able to obtain such a license on terms acceptable to us, if at all. If a third party brought a legal action against us or our licensors, we could incur substantial costs in defending ourselves, and we cannot assure you that such an action would be resolved in our favor. If such a dispute were to be resolved against us, we could be subject to significant damages, and the testing, manufacture or sale of one or more of our technologies or proposed products, if developed, could be enjoined.

We cannot assure you as to the degree of protection any patents will afford, whether the PTO will issue patents or whether we will be able to avoid violating or infringing upon patents issued to others or that others will not manufacture and distribute our patented products upon expiration of the applicable patents. Despite the use of confidentiality agreements and non-compete agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.

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 products for which we are developing generic versions may be claimed by their manufacturer to be protected by one or more patents. If we file an abbreviated new drug application, or an ANDA, to seek FDA approval of our generic version of such a drug, we are required to certify that any patent or patents listed as covering the approved listed drug are invalid, unenforceable or will not be infringed by our generic version. Similar certification and notification requirements apply to new drug applications filed under [section 505(b)(2)] of the Federal Food, Drug and Cosmetic Act, where we rely on information to which we do not have a right of reference. Once the FDA accepts our ANDA or section 505(b)(2) NDA filing, we are required to notify the brand manufacturer of this fact. The brand manufacturer then has 45 days from the receipt of the notice in which to sue us for patent infringement. If it does so, the FDA is generally prevented from granting approval of the ANDA or section 505(b)(2) NDA until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in favor of us or expiration of the patent(s).

In some cases, we may qualify for the 180-day market exclusivity period for generic products. Given the recent passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the 2003 Medicare Act, with accompanying amendments to the Hatch-Waxman Act, marketing exclusivity for our extended-release oxycodone product would begin to run upon the earlier of our commercial launch of this product or upon an appellate court decision in our favor. However, we cannot assure you that we will be prepared, authorized or willing (depending on the circumstances) to commercialize our product prior to an appellate decision in our favor.

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On January 6, 2004, we received a favorable decision from the U.S. District Court for the Southern District of New York in our patent litigation with respect to our extended-release oxycodone product. This litigation was instituted by Purdue Pharma, the manufacturer of the brand OxyContin, and resulted in a delay in our ability to obtain final FDA approval for our extended-release oxycodone product. Purdue filed an appeal as well as motions to stay the injunction against the enforcement of their patents pending the outcome of the appeal and to expedite the appeal. Both motions were denied on March 18, 2004. On March 23, 2004, we received the final FDA approval of the 10mg, 20mg and 40mg strengths of this product and confirmation of tentative FDA approval of the 80mg strength of this product. We have decided at this time not to launch this product until the appeals court has ruled on the district court's decision. However, upon further examination, we may determine that it is in our best interest to launch one or more of our bioequivalent versions of OxyContin in advance of the appellate court decision.

We may be the subject of product liability claims or product recalls, and we may be unable to obtain or maintain insurance adequate to cover 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.

We cannot assure you that a product liability claim or series of claims brought against us would not have an adverse effect on our business, financial condition, profitability and cash flows. If any claim is brought against us, regardless of the success or failure of the claim, we cannot assure you that we will be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities or the cost of a recall.

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.

On December 8, 2003, President Bush signed into law the 2003 Medicare Act. The 2003 Medicare Act provides for a new system of private market insurance providers to be instituted in 2006, which may result in an increased use of formularies (listings of prescription drugs approved for use) such that, in the event a Medicare beneficiary's medications are not listed on the applicable formulary, such Medicare beneficiary may not receive reimbursement for all of his/her medications. Moreover, once these formularies are established, Medicare will not be obligated to pay for drugs omitted from a formulary, and the cost of these non-covered drugs will not be counted towards the \$3,600 out-of-pocket deductible established by the 2003 Medicare Act. Further, beginning in 2006, Medicare prescription drug program beneficiaries will not be permitted to purchase private insurance policies, known as "Medigap" policies, to cover the cost of these off-formulary medications. If our products are excluded from these new formularies resulting in Medicare beneficiaries not being reimbursed for the purchase of our medications, this may result in a reduced demand and thereby lower prices for our products, which may adversely affect our business and our results of operation.

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If government and third-party payers do not provide adequate coverage and reimbursement levels for users of our products, the market acceptance of these products could be adversely affected. In addition, the following factors could significantly influence the purchase of pharmaceutical products, which would result in lower prices and a reduced demand for our products:

- ☐ the trend toward managed health care in the United States;
- ☐ the growth of organizations such as HMOs and managed care organizations;
- ☐ legislative proposals to reform health care and government insurance programs; and
- ☐ price controls and non-reimbursement of new and highly priced medicines for which the economic therapeutic rationales are not established.

Once approved, 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.

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third-party reimbursement and the extent of marketing efforts by third-party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. In addition, many of our products contain narcotic ingredients that carry stringent record-keeping obligations, strict storage requirements and other limitations on these products' availability, which could limit the commercial usage of these products.

Most of our net sales come from a small number of products.

For the year ended December 31, 2003, 36% of our net sales came from sales of our Percocet® franchise, 16% came from sales of morphine sulfate extended-release tablets and 30% came from sales of Lidoderm®. 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 sell our products to a limited number of wholesale drug distributors and large pharmacy chains, the loss of whose business could materially affect our 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 32%, 26%, 18% and 8% respectively, of net sales for the three months ended March 31, 2004, 26%, 26%, 19% and 11% respectively, of net sales in 2003, 24%, 24%, 23% and 11% respectively, of net sales in 2002, and 28%, 24%, 19% and 10%, respectively, of net sales in 2001. 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 are dependent on outside manufacturers for the manufacture of our products; therefore, we will have limited control of the manufacturing process and related costs.

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

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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.

In May 2001, we entered into a long-term manufacturing and development agreement with Novartis Consumer Health, Inc., pursuant to which Novartis has agreed to manufacture certain of our commercial products in addition to products in development. In addition, we may consider entering into additional manufacturing arrangements with third-party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to begin commercial production by these manufacturers.

In addition, we have entered into minimum purchase requirement contracts with some of our third party manufacturers. If the market for the products manufactured by these third parties substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

We are dependent on third parties to supply all raw materials used in our products and to provide 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.

We rely on third parties to supply all raw materials used in our products. In addition, we rely on third-party suppliers, distributors and collaboration partners to provide services for the core aspects of our business, including manufacturing, warehousing, distribution, customer service support, medical affairs services, clinical studies, sales and other technical and financial services. All third-party suppliers and contractors are subject to FDA, and very often DEA, requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third-party manufacturers, distributors and collaboration partners. 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, financial condition, profitability and cash flows.

In addition, we have entered into minimum purchase requirement contracts with some of our third party suppliers. If the market for the products that utilize these raw materials substantially contracts or disappears, we will continue to be financially obligated under these contracts, an obligation which could have a material adverse effect on our business.

The DEA limits the availability of the active ingredients used in our current products and products in development and, as a result, our quota may not be sufficient to meet commercial demand or complete clinical trials.

The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. The active ingredients in some of our current products and products in development, including oxycodone, oxymorphone, morphine, fentanyl and hydrocodone, are listed by the DEA as Schedule II or III substances under the Controlled Substances Act of 1970. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of scheduled substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to meet commercial demand or complete clinical trials. DEA regulations may limit the supply of the drugs used in our clinical trials, and in the future, our ability to produce and distribute our products in the volume needed to meet commercial demand.

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Sales of our products may be adversely affected by the consolidation of the wholesale drug distribution and retail pharmacy industries, a trend which may continue.

The network through which we sell our products has undergone significant consolidation marked by mergers and acquisitions among wholesale distributors and the growth of large retail drug store chains. As a result, a small number of large wholesale distributors control a significant share of the market, and the number of independent drug stores and small drug store chains has decreased. We expect that consolidation of drug wholesalers and retailers will increase pricing and place other competitive pressures on drug manufacturers, including us.

We may not be able to maintain our current insurance policies covering our business, assets, directors and officers and product liability claims and we may not be able to obtain new policies in the future.

Property, product liability, directors' and officers' and general liability insurance represent significant costs to us. Since the events of September 11, 2001, and due to recent concerns over corporate governance in the U.S., corporate accounting scandals and product liability lawsuits related to pharmaceuticals, liability and other types of insurance have become more difficult and costly to obtain. Unanticipated additional insurance costs could have a material adverse effect on our results of operations and cash flows. There can be no assurance that we will be able to maintain our existing insurance policies or obtain new policies in meaningful amounts or at a reasonable cost. Any failure to obtain or maintain any necessary insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

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 look to continue to enrich our product line by acquiring rights to additional products and compounds. Such acquisitions may be carried out through the purchase of assets, joint ventures and licenses or by acquiring other companies. However, we cannot assure you that we will be able to complete acquisitions that meet our target criteria on satisfactory terms, if at all. In particular, we may not be able to identify suitable acquisition candidates, and we may have to compete for acquisition candidates. Our competitors may have greater resources than us and therefore be better able to complete acquisitions or may cause the ultimate price we pay for acquisitions to increase. If we fail to achieve our acquisition goals, our growth may be limited.

Acquisitions may expose us to additional risks and may have a material adverse effect on our profitability and cash flows. Any acquisitions we make may:

- ☐ fail to accomplish our strategic objectives;
- ☐ not be successfully combined with our operations;
- ☐ not perform as expected; and
- ☐ expose us to cross border risks.

In addition, based on current acquisition prices in the pharmaceutical industry, acquisitions could decrease our income per share and add significant intangible assets and related amortization charges. Our acquisition strategy may require us to obtain additional debt or equity financing, resulting in leverage, or increased debt obligations as compared to equity, and dilution of ownership. We may not be able to finance acquisitions on terms satisfactory to us.

Further, if we are unable to maintain, on commercially reasonable terms, product, compound or other licenses that we have acquired, our ability to develop or commercially exploit our products may be inhibited.

If we are unable to retain our key personnel, and continue to attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors will remain highly dependent, in large part, upon our ability

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to attract and retain qualified scientific and technical personnel. The loss of key scientific and technical personnel or the failure to recruit additional key scientific and technical personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions and have employment agreements with our key executives, we cannot assure you that we will succeed in retaining this personnel or their services under existing agreements. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

We have significant goodwill and other intangible assets. Consequently, potential impairment of goodwill and other intangibles may significantly impact our profitability.

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, and no longer amortize goodwill. Goodwill and other intangibles represent a significant portion of our assets and stockholders' equity. As of March 31, 2004, goodwill and other intangibles comprised approximately 27% of our total assets and 38% of our stockholders' equity. 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. Other intangible assets are assessed periodically for impairment in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. 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. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should an impairment of goodwill or other intangible assets occur.

Our credit agreement limits our ability to conduct our business, which could negatively affect our ability to finance future capital needs and engage in other business activities.

The covenants in our existing credit agreement contain a number of significant limitations on our ability to, among other things:

- pay dividends;
- incur additional indebtedness;
- create liens on our assets; and
- acquire or dispose of assets.

These restrictive covenants could negatively affect our ability to finance our future capital needs, engage in other business activities or withstand a future downturn in our business or the economy.

Under our credit agreement, we are required to maintain certain specified financial ratios and meet financial tests, including maintaining a specific level of EBITDA, as defined therein. Our ability to comply with these may be affected by matters beyond our control. A breach of any of these covenants would prevent us from being able to draw under our revolving loan and will result in a default under our credit agreement.

We are a holding company with no operations.

We are a holding company with no direct operations. Our principal assets are the equity interests we hold in our operating subsidiaries. As a result, we are dependent on loans, dividends and other payments from our subsidiaries to generate the funds necessary to meet our financial obligations. Our subsidiaries are legally distinct from us and have no obligation to make funds available to us.

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Risks Related to Ownership of Our Common Stock

We caution readers of this prospectus not to place undue reliance on our forward-looking financial information.

Neither our independent registered public accounting firm, nor any other independent registered public accounting firms, have compiled, examined or performed any procedures with respect to any prospective financial information that may be contained or incorporated by reference in this prospectus, nor have they expressed any opinion or any other form of assurance on such information or its achievability, and assume no responsibility for, and disclaim any association with, any such prospective financial information.

Our assumptions and estimates underlying the prospective financial information contained in documents incorporated by reference in this prospectus are inherently uncertain and are subject to a wide variety of significant regulatory, business, economic, and competitive risks, uncertainties and conditions that could cause actual results to differ materially from those contained in the prospective financial information. In particular, our estimates are based on assumptions regarding the anticipated timing of generic competition and the continued growth in net sales of our products. Accordingly, we cannot assure you that the prospective results are indicative of our future performance or that actual results will not differ materially from those that the prospective financial information present. You should not regard inclusion of the prospective financial information in the documents incorporated by reference in this prospectus as a representation by any person that we will achieve the results the prospective financial information contains.

We have expressly disclaimed any obligations to update this prospective financial information for any reason, even if new information becomes available or other events occur in the future.

Our revenues and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock to decline.

Variations in our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. We cannot predict with certainty the timing or level of sales of our products in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Our operating results may fluctuate due to various factors including those set forth above in "Risk Factors" "Risks Related to Our Business." As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

Our controlling stockholder may continue to control us following one or more offerings pursuant to this prospectus.

Assuming that Endo Pharma LLC sells all shares it is entitled to sell under this prospectus, Endo Pharma LLC will own approximately 40% of our common stock. Endo Pharma LLC is, in turn, controlled by affiliates of Kelso & Company who currently own 83.6% of Endo Pharma LLC. Three of our directors, Mr. Goldberg, Mr. Wahrhaftig and Mr. Loverro, are Managing Directors of Kelso. Three of our directors, Mr. Goldberg, Mr. Wahrhaftig and Ms. Ammon, serve as members of the Board of Managers of Endo Pharma LLC. These individuals therefore direct how Endo Pharma LLC votes its shares on corporate matters. As a result, Endo Pharma LLC and Kelso may be able to control the outcome of stockholder votes, including votes concerning the election of the majority of directors, the adoption or amendment of provisions in our charter or by-laws, the approval of mergers, decisions affecting our capital structure and other significant corporate transactions. Kelso also has significant control over our management and policies. The interests of Endo Pharma LLC and Kelso may conflict with your interests. Their control could also have the effect of deterring hostile takeovers, delaying or preventing changes in control or changes in management or limiting the ability of our stockholders to approve transactions that they may deem to be in their best interests.

Our stock price may be volatile, and your investment in our common stock could decline in value.

The market prices for securities of healthcare companies in general have been highly volatile and may continue to be highly volatile in the future. Within the last 12 months, our stock has traded between \$27.15

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and \$14.50 per share. The following factors, in addition to other risk factors described in this section, may cause the market price of our common stock to change:

- ☐ FDA approval or disapproval of any of the drug applications we have submitted;
- ☐ the success or failure of our clinical trials;
- ☐ competitors announcing technological innovations or new commercial products;
- ☐ introduction of generic substitutes for our products;
- ☐ developments concerning our or others' proprietary rights, including patents;
- ☐ competitors' publicity regarding actual or potential products under development;
- ☐ regulatory developments in the United States and foreign countries, or announcements relating to these matters;
- ☐ period-to-period fluctuations in our financial results;
- ☐ new legislation in the United States, such as the 2003 Medicare Act, relating to the sale or pricing of pharmaceuticals;
- ☐ litigation; and
- ☐ economic and other external factors, including disasters and other crises.

If our stockholders sell substantial amounts of our common stock, the market price of our common stock may fall.

If our stockholders sell substantial amounts of our common stock, including shares issued upon the exercise of outstanding options, the market price of our common stock may fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem appropriate.

At August 2, 2004, approximately 83.5 million shares of common stock, representing approximately 63.4% of our common stock outstanding after the offering, were eligible for sale, subject to compliance with Rule 144 or Rule 145(d) under the Securities Act of 1933, or the Securities Act.

Of the 3,256,830 shares that may be issued upon the exercise of options outstanding as of August 2, 2004, 940,095 are vested, currently exercisable and eligible for sale. The sale of these shares is unrestricted, subject to any lock-up agreements that may be entered into with underwriters in connection with any underwritten offering of such shares covered by this prospectus.

We have not paid, and may not pay, dividends and therefore, unless our stock appreciates in value, investors in our stock may not benefit from holding our stock.

We have not paid any cash dividends since our inception. Furthermore, our existing credit facility limits our ability to pay dividends. We may not pay cash dividends in the future. As a result, investors in our stock will not be able to benefit from owning our stock unless the shares that these investors acquire appreciate in value.

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FORWARD-LOOKING STATEMENTS

This prospectus and any related prospectus supplement may contain or incorporate by reference information that includes or is based on “forward looking statements” within the meaning of Section 27A of the Securities Act 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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” which is included in documents incorporated by reference 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 “Risk Factors,” and elsewhere in this prospectus and in documents incorporated by reference 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 prospectus. Important factors that could cause our actual results to differ materially from the expectations reflected in the forward-looking statements in this prospectus include, among others:

- our ability to successfully develop, commercialize and market new products;
- results of pre-clinical or clinical trials on new products;
- our ability to obtain regulatory approval of any of our pipeline products;
- competition for the business of our branded and generic products, and in connection with our acquisition of rights to intellectual property assets;
- market acceptance of our future products;
- government regulation of the pharmaceutical industry;
- our dependence on a small number of products;
- our dependence on outside manufacturers for the manufacture of our products;
- our dependence on third parties to supply raw materials and to provide services for certain core aspects of our business;
- new regulatory action or lawsuits relating to our use of narcotics in most of our core products;
- our exposure to product liability claims and product recalls and the possibility that we may not be able to adequately insure ourselves;
- our ability to protect our proprietary technology;
- our ability to successfully implement our acquisition and in-licensing strategy;
- the availability of controlled substances that constitute the active ingredients of some of our products and products in development;
- the availability of third-party reimbursement for our products; and
- our dependence on sales to a limited number of large pharmacy chains and wholesale drug distributors for a large portion of our total net sales.

We do not undertake any obligation to update our forward-looking statements after the date of this prospectus for any reason, even if new information becomes available or other events occur in the future.

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All of the shares of common stock offered hereby are being sold by the selling stockholders. We will not receive any proceeds from such sales.

PRICE RANGE OF OUR COMMON STOCK

Our common stock is listed for trading on the Nasdaq National Market under the symbol "ENDP." The following table sets forth the quarterly high and low share price information for the periods indicated.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2004		
1st Quarter	\$ 25.00	\$ 18.78
2nd Quarter	\$ 27.15	\$ 20.34
3rd Quarter (through August 3, 2004)	\$ 23.59	\$ 18.52
Year Ending December 31, 2003		
1st Quarter	\$ 14.10	\$ 7.49
2nd Quarter	19.45	12.72
3rd Quarter	22.26	13.99
4th Quarter	24.00	14.50
Year Ending December 31, 2002		
1st Quarter	\$ 13.31	\$ 8.80
2nd Quarter	13.05	4.98
3rd Quarter	9.56	5.81
4th Quarter	9.50	5.90

DIVIDEND POLICY

We have never paid cash dividends on our common stock. Furthermore, the payment of cash dividends from earnings is currently restricted by our credit facility. Assuming removal of this restriction, the payment of cash dividends is subject to the discretion of our board of directors and will be dependent on many factors, including our earnings, capital needs and general financial condition. We anticipate that, for the foreseeable future, we will retain our earnings in order to finance the expansion of our business.

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DESCRIPTION OF CAPITAL STOCK

Authorized Capital Stock

Under our current charter, we have the authority to issue up to 175,000,000 shares of common stock and 40,000,000 shares of preferred stock.

Common Stock

Common Stock Outstanding. As of August 2, 2004, there were 131,799,203 shares of common stock outstanding. As of August 2, 2004, we had approximately 130 shareholders of record of our common stock.

Shares of our common stock are listed on the Nasdaq National Market and trade under the symbol "ENDP."

Dividends. Owners of shares of common stock are entitled to receive dividends when, as and if declared by our board of directors, out of funds legally available for their payment, subject to the rights of holders of any outstanding shares of preferred stock.

Voting Rights. Owners of shares of common stock are entitled to one vote per share. Subject to the rights of the holders of any preferred stock pursuant to applicable law or the provision of any future certificate of designations creating a specific series of preferred stock, all voting rights are vested in the owners of shares of common stock. Owners of shares of common stock have non-cumulative voting rights, which means that the holders of more than 50% of the shares voting for the election of directors can elect 100% of the directors.

Rights Upon Liquidation. In the event of our voluntary or involuntary liquidation, dissolution or winding up, the owners of shares of common stock will be entitled to share equally in any assets available for distribution after the payment in full of all debts and distributions and after the owners of any of our outstanding preferred stock have received their liquidation preferences in full.

Other Rights. Owners of shares of common stock are not entitled to pre-emptive rights with respect to the future issuances of common stock. We may, however, enter into contracts with stockholders to grant holders pre-emptive rights. Shares of common stock are not convertible into shares of any other class of capital stock. If we merge or consolidate with or into another company and, as a result, the shares of common stock are converted into or exchangeable for other securities or property including cash, all owners of shares of common stock will be entitled to receive the same kind and amount of such consideration for each share of common stock.

Preferred Stock

No shares of preferred stock are outstanding. Our board of directors may, without further action by our stockholders, issue a series of preferred stock and fix the rights and preferences of those shares, including the dividend rights, dividend rates, conversion rights, exchange rights, voting rights, terms of redemption, redemption price or prices, liquidation preferences, the number of shares constituting any series and the designation of such series.

Warrants

Warrants Issued to Endo Stockholders Immediately Prior to our Merger with Algos Pharmaceutical Corporation

General. Immediately prior to our merger with Algos, our then stockholders received, for each of their common shares, one warrant exercisable, for \$.01 per share, into a specified number of shares of common stock if the FDA did not approve MorphiDex® for any pain indication prior to December 31, 2002.

Exercisability and Expiration. As the FDA did not approve MorphiDex® before December 31, 2002, these warrants became exercisable. Each of these outstanding 71.3 million warrants was exercisable into 0.416667 shares of our common stock. These warrants were exercisable at an exercise price of \$.01 per share

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into a maximum of 29.7 million shares of our common stock. The warrants were exercisable until July 8, 2003, at which time they would have expired. All of these warrants were exercised in a timely manner.

Directors' Liability

Our certificate of incorporation allows us to eliminate the personal liability of our directors and to indemnify directors and officers to the fullest extent authorized by Delaware Law.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and transferable warrants is American Stock Transfer & Trust Company. Its address is 40 Wall Street, New York, New York 10005.

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CERTAIN U.S. FEDERAL TAX CONSEQUENCES TO NON-U.S. HOLDERS OF COMMON STOCK

The following is a general discussion of the principal United States federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. holder. As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States or any political subdivision of the United States;
- a partnership;
- an estate whose income is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, in general, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust.

An individual may be treated as a resident of the United States in any calendar year for U.S. federal income tax purposes, instead of a nonresident, by among other ways, being present in the United States on at least 31 days in that calendar year and for an aggregate of at least 183 days during the current calendar year and the two immediately preceding calendar years. For purposes of this calculation, you would count all of the days present in the current calendar year, one-third of the days present in the immediately preceding calendar year and one-sixth of the days present in the second preceding calendar year. Residents are treated for U.S. federal income tax purposes as if they were U.S. citizens.

This discussion does not consider:

- U.S. state and local or non-U.S. tax consequences;
- specific facts and circumstances that may be relevant to a particular non-U.S. holder's tax position;
- the tax consequences for the stockholders, partners or beneficiaries of a non-U.S. holder;
- special tax rules that may apply to particular non-U.S. holders, such as financial institutions, insurance companies, tax-exempt organizations, U.S. expatriates, broker-dealers, and traders in securities; or
- special tax rules that may apply to a non-U.S. holder that holds our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or other integrated investment.

The following discussion is based on provisions of the U.S. Internal Revenue Code of 1986, as amended, applicable U.S. Treasury regulations and administrative and judicial interpretations, all as in effect on the date of this prospectus, and all of which are subject to change, retroactively or prospectively. The following discussion also assumes that a non-U.S. holder holds our common stock as a capital asset. **EACH NON-U.S. HOLDER SHOULD CONSULT ITS TAX ADVISOR REGARDING THE U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. INCOME AND OTHER TAX CONSEQUENCES OF ACQUIRING, HOLDING, AND DISPOSING OF OUR COMMON STOCK.**

Dividends

Distributions on common stock constitute dividends for U.S. federal income tax purposes to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. We may not pay cash dividends on our common stock in the foreseeable future. See "Dividend Policy." In the event, however, that we pay dividends on our common stock, we will have to withhold U.S. federal withholding tax at a rate of 30%, or at a lower rate if provided by an applicable income tax treaty and we have received proper certification of the application of such income tax treaty, from the gross amount of the dividends paid to a non-U.S. holder unless such dividends are effectively connected with a non-U.S. holder's conduct of a trade or business, as described below.

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Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under an applicable income tax treaty and the manner of claiming the benefits of such treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the U.S. Internal Revenue Service.

Dividends that are effectively connected with a non-U.S. holder's conduct of a trade or business in the United States are not subject to the U.S. withholding tax, but, unless otherwise provided in an applicable income tax treaty, are instead taxed in the manner applicable to U.S. persons. In that case, we will not have to withhold U.S. federal withholding tax if the non-U.S. holder complies with applicable certification and disclosure requirements. In addition, dividends received by a foreign corporation that are effectively connected with the conduct of a trade or business in the United States may be subject to a branch profits tax at a 30% rate, or at a lower rate if provided by an applicable income tax treaty.

Gain on Disposal of Common Stock

A non-U.S. holder generally will not be taxed on gain recognized on a disposition of our common stock unless:

- ☐ the non-U.S. holder is an individual who holds our common stock as a capital asset, is present in the United States for 183 days or more during the taxable year of the disposition and meets certain other conditions (though any such person will generally be treated as a resident of the U.S.);
- ☐ the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States or, in some instances if an income tax treaty applies, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; or
- ☐ we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes, and such non-U.S. holder held more than 5 percent of our common stock at any time during the shorter of the five-year period ending on the date of disposition or the period that such non-U.S. holder held our common stock.

We have determined that we are not, and we do not anticipate that we will become, a U.S. real property holding corporation.

An individual non-U.S. holder who is subject to U.S. tax because the holder was present in the U.S. for 183 days or more during the year of disposition is taxed on the amount by which capital gains allocated to U.S. sources (including gains from sale of our common stock) exceed capital losses allocated to U.S. sources incurred during the year at a flat rate of 30%, or at a lower rate if provided by an applicable income tax treaty. Other non-U.S. holders that are subject to U.S. federal income tax on gain from the disposition of our common stock will be taxed on such gain in the same manner in which citizens or residents of the U.S. would be taxed, and if such non-U.S. holder is a foreign corporation such gain may also be subject to a branch profits tax at a 30% rate, or at a lower rate if provided by an applicable income tax treaty.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise.

Recently enacted U.S. federal legislation provides for reductions in the U.S. federal estate tax through 2009 and the elimination of the tax entirely in 2010. Under the legislation, the estate tax would be fully reinstated, as in effect prior to the reductions, in 2011.

Information Reporting and Backup Withholding Tax

We must report annually to the U.S. Internal Revenue Service and to each non-U.S. holder the amount of dividends paid to that holder and the tax withheld from those dividends. Copies of the information returns reporting those dividends and withholding may also be made available by the U.S. Internal Revenue Service

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to the tax authorities in the country in which the non-U.S. holder is a resident under the provisions of an applicable income tax treaty or agreement.

Under some circumstances, U.S. Treasury regulations require additional information reporting and backup withholding on payments made with respect to or on our common stock. Under currently applicable law, the gross amount of dividends paid to a non-U.S. holder that fails to certify its non-U.S. holder status in accordance with applicable U.S. Treasury regulations generally will be subject to additional information reporting and backup withholding.

The payment of proceeds on the disposition of common stock by a non-U.S. holder to or through a U.S. office of a broker or a non-U.S. office of a U.S. broker generally will be reported to the U.S. Internal Revenue Service and, if to or through U.S. offices of a broker, reduced by backup withholding, unless the non-U.S. holder either certifies its status as a non-U.S. holder under penalties of perjury or otherwise establishes an exemption and certain other conditions are met. The payment of proceeds on the disposition of common stock by a non-U.S. holder to or through a non-U.S. office of a non-U.S. broker will not be reduced by backup withholding or reported to the U.S. Internal Revenue Service unless the non-U.S. broker has certain enumerated connections with the United States.

Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder will be refunded, or credited against the holder's U.S. federal income tax liability, if any, provided that certain required information is furnished to the U.S. Internal Revenue Service.

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SELLING STOCKHOLDERS

The following table provides information regarding the beneficial ownership of our common stock by the selling stockholders, as of August 2, 2004. Footnote (a) below provides a brief explanation of what is meant by the term "beneficial ownership." No offer or sale under this prospectus may be made by a holder of the securities unless that holder is listed in the table in this prospectus or until that holder has notified us and a supplement to this prospectus has been filed or an amendment to the related registration statement has become effective.

We have prepared the table based on information given to us by, or on behalf of, the selling stockholders on or before August 2, 2004. Pursuant to the terms of our stockholder agreements, executive and employee stockholders cannot directly or indirectly sell, assign, mortgage, transfer, pledge, hypothecate or otherwise dispose of any of their shares of our common stock acquired in connection with our formation in 1997 or the shares of our common stock underlying their stock options granted pursuant to the Endo Pharma LLC stock option plans, in each case, without the consent of Endo Pharma LLC's Board of Managers, except to Endo Pharma LLC, Kelso Investment Associates V, L.P. and Kelso Equity Partners V, L.P. in accordance with the terms of the stockholders agreement. Furthermore, under this prospectus, executive and employee stockholders can only sell such shares or shares of our common stock underlying such options in connection with a sale of shares by Endo Pharma LLC.

Information about the selling stockholders may change over time. Any changed information given to us by the selling stockholders will be set forth in prospectus supplements or amendments to this prospectus if and when necessary. The registration of these shares does not necessarily mean that the selling stockholders will sell all or any of the shares.

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Name of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned Prior to the Offering*	Number of Shares That May Be Offered	Number of Shares of Common Stock Beneficially Owned Following the Offering	Percentage of Shares of Common Stock to be Beneficially Owned After Completion of the Offering
Directors and Executive Officers:				
Carol A. Ammon(b)(d)	11,057,131(c)	3,693,488	7,363,643	5.6%
Brian T. Clingen (e)	15,000	□	15,000	**
Michael B. Goldberg(f)(g)				
Michael Hyatt(h)	1,171,494	250,000(h)	921,494	**
Roger H. Kimmel(i)	692,525	176,000	516,525	**
Frank J. Loverro(f)(g)				
Clive A. Meanwell, M.D., Ph.D(j)	15,000	□	15,000	**
Michael W. Mitchell(k)	30,000	□	30,000	**
Joseph T. O'Donnell, Jr.(l)	30,000	□	30,000	**
David I. Wahrhaftig(f)(g)				
Peter A. Lankau(b)	1,061,223(m)	149,354	911,869	**
David A. H. Lee, M.D., Ph.D.(b)(d)	4,057,882(n)	1,361,026	2,696,856	2.0%
Jeffrey R. Black(b)(d)	3,607,918(o)	1,209,751	2,398,167	1.8%
Caroline B. Manogue(b)	364,364(p)	86,515	277,849	**
All current directors and executive officers of Endo Pharmaceuticals Holdings Inc. as a group (14 persons)	21,611,344(q)	6,826,134(r)	14,785,210(s)	11.1%
Other Selling Stockholders:				
Endo Pharma LLC(d)(f)	82,219,380	29,674,000(t)	52,545,380	39.9%
Kelso Investment Associates V, L.P.(d)(f)(u)	38,321,689	14,670,018	23,651,671	17.9%
Kelso Equity Partners V, L.P.(d)(f)(u)	3,224,525	1,234,388	1,990,137	1.5%
Joseph S. Schuchert(f)(g)	□	□	□	□
Frank T. Nickell(f)(g)	□	□	□	□
Thomas R. Wall, IV(f)(g)	□	□	□	□
George E. Matelich(f)(g)	□	□	□	□
Frank K. Bynum, Jr.(f)(g)	□	□	□	□
Philip E. Berney(f)(g)	□	□	□	□
Michael B. Lazar(f)(g)	□	□	□	□
Greenwich Street Capital Partners, L.P.(d)(v)	4,910,225	1,879,695	3,030,530	2.3%
Greenwich Street Capital Offshore Fund, Ltd.(d)(v)	304,764	116,667	188,097	**
Citigroup GSP Employees Fund, L.P.(d)(v)	1,193,313	456,815	736,498	**
The Travelers Insurance Company(d)(v)	253,312	96,971	156,341	**
The Travelers Life and Annuity Company(d)(v)	124,765	47,761	77,004	**
Mariann T. MacDonald(b)(d)	9,301,159(w)	3,110,546	6,190,613	4.7%
Other selling stockholders representing less than 1% owners of our common stock(x)	5,383,706	1,561,001(y)	3,822,705	2.9%

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- * Number of shares assumes the exercise of all options reserved pursuant to the Endo Pharma LLC 1997 Stock Option Plans and Endo Pharma LLC 2000 Supplemental Stock Option Plans.
- ** The percentage of the class to be owned by such security holder after completion of the offering represents less than 1%.
- (a) [Beneficial ownership] is a term broadly defined by the Securities and Exchange Commission in Rule 13d-3 under the Exchange Act, and includes more than the typical form of stock ownership, that is, stock held in the person's name. The term also includes what is referred to as [indirect ownership,] meaning ownership of shares as to which a person has or shares investment power. For purposes of this table, a person or group of persons is deemed to have [beneficial ownership] of any shares as of a given date that such person has the right to acquire within 60 days after such date.
- (b) The business address for this person is c/o Endo Pharmaceuticals Holdings Inc., 100 Painters Drive, Chadds Ford, Pennsylvania 19317.
- (c) Ms. Ammon is our Chairman and Chief Executive Officer. The shares to be sold by Ms. Ammon include up to 69,277 shares, which represent Ms. Ammon's pro rata portion of Endo Pharma LLC's shares that may be offered, and up to 3,624,211 shares, which represent the shares of common stock underlying her Endo Pharma LLC employee stock options that she may exercise and sell in one or more offerings pursuant to this prospectus. Ms. Ammon owns 0.36% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. Ammon shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. Ammon's beneficial ownership after the offering includes 111,693 shares and 7,251,950 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she will not exercise and sell in an offering pursuant to this prospectus.
- (d) Members of Endo Pharma LLC will receive a pro rata distribution of the net proceeds from one or more offerings pursuant to this prospectus received by Endo Pharma LLC based on the number of Endo Pharma LLC units held by each such member. Affiliates of Kelso & Company own 83.6% of Endo Pharma LLC; Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd., Citigroup GSP Employees Fund, L.P., The Travelers Insurance Company and The Travelers Life and Annuity Company together own 13.7% of Endo Pharma LLC; our management, in the aggregate, owns .770% of Endo Pharma LLC; and certain other outside investors own 2.0% of Endo Pharma LLC. The number of shares shown that may be offered by Endo Pharma LLC does not include shares of common stock underlying the Endo Pharma LLC employee stock options that may be exercised and sold in one or more offerings pursuant to this prospectus.
- (e) Mr. Clingen is a director of Endo. The business address for Mr. Clingen is c/o BP Capital Management, 2215 York Rd, Suite 510, Oak Brook, Illinois 60523. Mr. Clingen's beneficial ownership represents options to purchase 15,000 shares of Common Stock under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (f) The business address for this person is c/o Kelso & Company, 320 Park Avenue, 24th Floor, New York, New York 10022.
- (g) Messrs. Goldberg, Loverro and Wahrhaftig are directors of Endo. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of the status of Kelso Investment Associates V, L.P., or KIA V, and Kelso Equity Partners V, L.P., or KEP V, as members of Endo Pharma LLC. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar may be deemed to share beneficial ownership of securities owned of record by KIA V and KEP V, by virtue of the status of each of them as a general partner of the general partner of KIA V and as a general partner of KEP V. Messrs. Schuchert, Nickell, Wall, Matelich, Goldberg, Wahrhaftig, Bynum, Berney, Loverro and Lazar share investment and voting power along with the other general partners with respect to securities owned by KIA V and KEP V, but disclaim beneficial ownership of such securities except to the extent of each individual's pecuniary interest.

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- (h) Mr. Hyatt is a director of Endo. The business address for Mr. Hyatt is c/o Bear, Stearns & Co. Inc., 383 Madison Avenue, New York, New York 10179. Mr. Hyatt's beneficial ownership includes (i) 629,551 shares of common stock owned directly by Mr. Hyatt, (ii) 511,943 shares held in trusts for which Mr. Hyatt serves as trustee and as to which shares Mr. Hyatt holds either the sole or the shared power of disposition or the power to vote (including 491,193 shares with respect to which beneficial ownership is shared with Mr. Kimmel) and (iii) options to purchase 30,000 shares of common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. 100,000 of the 491,193 shares with respect to which beneficial ownership is shared with Mr. Kimmel are included in Mr. Hyatt's number of shares that may be offered and are not to be accounted for in addition to the shares listed for Mr. Kimmel herein. Mr. Hyatt's beneficial ownership excludes 171,332 shares of common stock held in a trust for the benefit of the children of Mr. Hyatt, as to which shares Mr. Hyatt has neither the power of disposition nor the power to vote.
- (i) Mr. Kimmel is a director of Endo. The business address for Mr. Kimmel is c/o Rothschild, Inc., 1251 Avenue of the Americas, New York, New York 10022. Mr. Kimmel's beneficial ownership includes (i) 662,525 shares held in trusts for which Mr. Kimmel serves as trustee and as to which shares Mr. Kimmel holds either the sole or the shared power of disposition and power to vote (including 491,193 shares with respect to which beneficial ownership is shared with Mr. Hyatt) and (ii) options to purchase 30,000 shares of common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan. Mr. Kimmel's beneficial ownership excludes a total of 201,530 shares of common stock held in trusts for the benefit of Mr. Kimmel's adult children, as to which shares Mr. Kimmel has neither the power of disposition nor the power to vote.
- (j) Dr. Meanwell is a director of Endo. The business address for Dr. Meanwell is c/o The Medicines Company, 5 Sylvan Way, Parsippany, New Jersey 07054. Dr. Meanwell's beneficial ownership represents options to purchase 15,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (k) Mr. Mitchell is a director of Endo. The business address for Mr. Mitchell is c/o Skadden, Arps, Slate, Meagher & Flom LLP, Four Times Square, New York, NY 10036. Mr. Mitchell's beneficial ownership represents options to purchase 30,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (l) Mr. O'Donnell is a director of Endo. The business address for Mr. O'Donnell is Van Beuren Capital, L.L.C., Van Beuren Road, Morristown, New Jersey 07960. Mr. O'Donnell's beneficial ownership represents options to purchase 30,000 shares of our common stock granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan.
- (m) Mr. Lankau is our President and Chief Operating Officer. The 149,354 shares to be sold by Mr. Lankau represent the shares of common stock underlying Mr. Lankau's Endo Pharma LLC employee stock options that he may exercise and sell in one or more offerings pursuant to this prospectus. Mr. Lankau's beneficial ownership after the offering include 85,350 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans and 826,519 shares underlying options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan that he will not exercise and sell in an offering pursuant to this prospectus.
- (n) Dr. Lee is our Executive Vice President and Chief Scientific Officer. The shares to be sold by Dr. Lee include 4,330 shares, which represent Dr. Lee's pro rata portion of Endo Pharma LLC's shares that may be offered, and 1,356,696 shares, which represent the shares of common stock underlying his Endo Pharma LLC employee stock options that he may exercise and sell in one or more offerings pursuant to this prospectus. Dr. Lee owns .02% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of his status as a member of Endo Pharma LLC. Dr. Lee shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest. Dr. Lee's beneficial ownership after the offering includes 6,981 shares and 2,689,875 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he will not exercise and sell in an offering pursuant to this prospectus.

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- (o) Mr. Black is our Executive Vice President, Chief Financial Officer and Treasurer. The shares to be sold by Mr. Black include 8,659 shares, which represent Mr. Black's pro rata portion of Endo Pharma LLC's shares that may be offered, and 1,201,092 shares, which represent his shares of common stock underlying his Endo Pharma LLC employee stock options that he may exercise and sell in one or more offerings pursuant to this prospectus. Mr. Black owns .05% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of his status as a member of Endo Pharma LLC. Mr. Black shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of his pecuniary interest. Mr. Black's beneficial ownership after the offering includes 13,962 shares and 2,384,205 shares underlying options that he holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that he will not exercise and sell in an offering pursuant to this prospectus.
- (p) Ms. Manogue is our Executive Vice President, Chief Legal Officer and Secretary. The 86,515 shares that may be sold by Ms. Manogue represent the shares of common stock underlying Ms. Manogue's Endo Pharma LLC employee stock options that she may exercise and sell in one or more offerings pursuant to this prospectus. Ms. Manogue's beneficial ownership after the offering includes 148,189 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans and 129,660 shares underlying options granted under the Endo Pharmaceuticals Holdings Inc. 2000 Stock Incentive Plan that she will not exercise and sell in an offering pursuant to this prospectus.
- (q) This number excludes 491,193 shares held in trust for which Mr. Hyatt serves as trustee and for which he shares beneficial ownership with Mr. Kimmel and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (r) This number excludes 100,000 of the 491,193 shares with respect to which Mr. Hyatt shares beneficial ownership with Mr. Kimmel which are included in Mr. Hyatt's number of shares that may be offered and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (s) This number excludes 391,193 shares held in trust for which Mr. Hyatt serves as trustee and for which he shares beneficial ownership with Mr. Kimmel and thus are not to be accounted for in addition to the shares listed for Mr. Kimmel herein.
- (t) This number represents the aggregate number of shares beneficially owned by all selling stockholders with the exception of Roger H. Kimmel and Michael Hyatt and are therefore not to be accounted for in addition to the shares individually listed herein.
- (u) KIA V and KEP V share investment and voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaim beneficial ownership of such securities except to the extent of its pecuniary interest. Kelso Partners V, L.P., or KP V, may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of its status as a general partner of KIA V, which is a member of Endo Pharma LLC. KP V shares investment and voting power along with its general partners with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of its pecuniary interest.
- (v) The business address for Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Employees Fund, L.P. is 500 Campus Drive, Suite 220, Florham Park, New Jersey 07932. The business address for Travelers Insurance Company and The Travelers Life and Annuity Company is One City Place, Hartford, CT 06103-3415. Greenwich Street Investments, L.P. is the general partner of Greenwich Street Capital Partners, L.P. Greenwich Street Investments, L.L.C. is the general partner of Greenwich Street Investments, L.P. The Travelers Insurance Company is the sole member of Greenwich Street Investments, L.L.C. Andrew Wagner and Woodbourne Corporation (BVI) Limited are the directors of Greenwich Street Capital Offshore Fund, Ltd. TRV Employees Investments, Inc. is the general partner of Citigroup GSP Employees Fund, L.P. and is a wholly-owned subsidiary of Citigroup Inc. GSCP (NJ), L.P. is the manager of Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Employees Fund, L.P. GSCP, Inc. is the general partner of GSCP (NJ), L.P. Each of Keith W. Abell, Alfred C. Eckert III, Robert A. Hamwee, Richard M. Hayden, Thomas V. Inglesby, Matthew C. Kaufman, Christine K. Vanden Beukel and Andrew Wagner is an executive officer and stockholder of GSCP (NJ), Inc. and a limited partner of GSCP (NJ), L.P. Greenwich Street Investments, L.P., Greenwich Street Investments, L.L.C. and The Travelers Insurance Company, because

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of their relationships with Greenwich Street Capital Partners, L.P., may be deemed to beneficially own the securities held by Greenwich Street Capital Partners, L.P. Notwithstanding the foregoing, the above entities disclaim beneficial ownership of the securities held by Greenwich Street Capital Partners, L.P. except to the extent of their pecuniary interest in the securities. Andrew Wagner and Woodbourne Corporation (BVI) Limited, because of their relationships to Greenwich Street Capital Offshore Fund, Ltd., may be deemed to beneficially own the securities held by Greenwich Street Capital Offshore Fund, Ltd. Notwithstanding the foregoing, the above individual and entity disclaim beneficial ownership of the securities held by Greenwich Street Capital Offshore Fund, Ltd. except to the extent of their pecuniary interest in the securities. TRV Employees Investments, Inc. and Citigroup Inc., because of their relationships with Citigroup Employees GSP Fund, L.P., may be deemed to beneficially own the securities held by Citigroup Employees GSP Fund, L.P. Notwithstanding the foregoing, the above entities disclaim beneficial ownership of the securities held by Citigroup Employees GSP Fund, L.P. except to the extent of their pecuniary interest in the securities. GSCP (NJ), L.P., GSCP (NJ), Inc., Keith W. Abell, Alfred C. Eckert III, Robert A. Hamwee, Richard M. Hayden, Thomas V. Inglesby, Matthew C. Kaufman, Christine K. Vanden Beukel and Andrew Wagner, because of their relationships with Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P., may be deemed to beneficially own the securities held by Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P. Notwithstanding the foregoing, the above entities and individuals disclaim beneficial ownership of the securities held by Greenwich Street Capital Partners, L.P., Greenwich Street Capital Offshore Fund, Ltd. and Citigroup GSP Fund, L.P. except to the extent of their pecuniary interest in the securities. The Travelers Life and Annuity Company is a wholly-owned subsidiary of The Travelers Insurance Company, which is a subsidiary of Citigroup Inc. The Travelers Insurance Company and Citigroup Inc. may be deemed to be the beneficial owner of the securities held by The Travelers Life and Annuity Company. The above entities and individuals may be deemed to share beneficial ownership of the shares of common stock owned of record by Endo Pharma LLC because they are members of Endo Pharma LLC or affiliates of members of Endo Pharma LLC. The above entities and individuals disclaim beneficial ownership of the securities owned by Endo Pharma LLC, except to the extent of their pecuniary interest.

- (w) Until December 31, 2003, Ms. MacDonald was our Executive Vice President of Operations, at which time she resigned from her executive office, while remaining an employee. The shares to be sold by Ms. MacDonald include 51,958 shares, which represent Ms. MacDonald's pro rata portion of her Endo Pharma LLC's shares that may be offered, and 3,058,588 shares, which represent the shares of common stock underlying Endo Pharma LLC employee stock options that she may exercise and sell in one or more offerings pursuant to this prospectus. Ms. MacDonald owns .27% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of her status as a member of Endo Pharma LLC. Ms. MacDonald shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but disclaims beneficial ownership of such securities except to the extent of her pecuniary interest. Ms. MacDonald's beneficial ownership after the offering includes 83,770 shares and 6,106,843 shares underlying options that she holds in the Endo Pharma LLC 1997 Stock Option Plans and the Endo Pharma LLC 2000 Supplemental Stock Option Plans that she will not exercise and sell in an offering pursuant to this prospectus.
- (x) The 1,561,001 shares that may be sold by the selling stockholders represent (1) the shares of common stock underlying Endo Pharma LLC employee stock options that they intend to exercise and sell in one or more offerings pursuant to this prospectus; (2) shares which represent the selling stockholders pro rata portion of Endo Pharma LLC's shares that may be offered; and (3) other shares of common stock owned outright by the selling stockholders. The selling stockholders own 2.0% of Endo Pharma LLC and may be deemed to share beneficial ownership of shares of common stock owned of record by Endo Pharma LLC by virtue of their status as members of Endo Pharma LLC. Each selling stockholder's shares voting power along with the other members of Endo Pharma LLC with respect to securities owned by Endo Pharma LLC, but each disclaims beneficial ownership of such securities except to the extent of each selling stockholder's pecuniary interest.
- (y) This number is comprised of 1,176,510 shares and shares underlying Endo Pharma LLC stock options beneficially owned by our current and former employees and 384,491 shares beneficially owned by members of Endo Pharma LLC.

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PLAN OF DISTRIBUTION

We are registering the shares of common stock covered by this prospectus for the selling stockholders. As used in this prospectus, "selling stockholders" includes the donees, transferees or others who may later hold the selling stockholders' interest. The common stock may be sold from time to time by the selling stockholders. Such sales may be made in the over-the-counter market at prices and at terms then prevailing or at prices related to the then current market price, or in negotiated transactions. The selling stockholders will act independently of Endo in making decisions with respect to the timing, manner and size of each sale.

The selling stockholders may negotiate and pay underwriters' or broker-dealers' commissions, discounts or concessions for their services as applicable. Underwriters or broker-dealers engaged by the selling stockholders may allow other underwriters or broker-dealers to participate in resales.

The common stock may be sold in one or more of the following types of transactions:

(a) A sale to one or more underwriters for resale to the public or to institutional investors in one or more transactions;

(i) If a selling stockholder notifies us of any material arrangement that it has entered into with an underwriter(s), we will execute an underwriting agreement with such underwriter(s) and file a supplemental prospectus, if required, pursuant to Rule 424(b) under the Securities Act of 1933. In that supplemented prospectus, we will disclose the name of each such underwriter, the number of shares to be sold, the price at which such shares were sold, the commissions paid or discounts or concessions allowed to such underwriter(s), where applicable, and any other facts material to the transaction.

(ii) The selling stockholders and any underwriters involved in the sale or resale of the common stock may qualify as "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. In addition, the underwriters' commissions, discounts or concessions may qualify as underwriters' compensation under the Securities Act. If a selling stockholder qualifies as an "underwriter," it will be subject to the prospectus delivery requirements of Section 5(b)(2) of the Securities Act.

(b) A block trade in which a selling stockholder will engage a broker-dealer as agent, who will then attempt to sell the common stock, or position and resell a portion of the block, as principal, in order to facilitate the transaction;

(c) Derivative transactions with third parties;

(i) If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by the selling shareholder or borrowed from the selling shareholder or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from the selling shareholder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

(d) Other hedging transactions, whereby the selling stockholder may:

(i) enter into transactions with a broker-dealer or affiliate thereof in connection with which such broker-dealer or affiliate will engage in short sales of the common stock pursuant to this prospectus, in which case such broker-dealer or affiliate may use shares of common stock received from the selling stockholders to close out its short positions;

(ii) sell common stock short itself and redeliver such shares to close out its short positions;

(iii) enter into option or other types of transactions that require the selling stockholder to deliver common stock to a broker-dealer or an affiliate thereof, who will then resell or transfer the common stock under this prospectus; or

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(iv) loan or pledge the common stock to a broker-dealer or an affiliate thereof, who may sell the loaned shares or, in an event of default in the case of a pledge, sell the pledged shares pursuant to this prospectus; or

(e) Sales to third parties who may deliver the common stock upon exchange of exchangeable securities issued by such third parties or their affiliates, which in either case may deliver this prospectus in connection with the sale of those exchangeable securities. Such transactions may be combined with other transactions of the types described above. In particular, such third parties or their affiliates may engage in sales of common stock (including short sales) to hedge their position prior to the exchange of their exchangeable securities, may deliver this prospectus in connection with some or all of those sales and may deliver shares of common stock covered by this prospectus to close out any short positions created in connection with those sales.

Pursuant to the terms of our stockholder agreements, executive and employee stockholders cannot directly or indirectly sell, assign, mortgage, transfer, pledge, hypothecate or otherwise dispose of any of their shares of our common stock acquired in connection with our formation in 1997 or the shares of our common stock underlying their stock options granted pursuant to the Endo Pharma LLC stock option plan, in each case, without the consent of Endo Pharma LLC's Board of Managers, except to Endo Pharma LLC, Kelso Investment Associates V, L.P. and Kelso Equity Partners V, L.P. or in accordance with the terms of the stockholders agreements. Furthermore, under this prospectus, executive and employee stockholders can only sell such shares or shares of our common stock underlying such options in connection with a sale of shares by Endo Pharma LLC.

Subject to the foregoing, in addition to selling its common stock under this prospectus, a selling stockholder may:

- (a) agree to indemnify any underwriter or broker-dealer against certain liabilities related to the selling of the common stock, including liabilities arising under the Securities Act;
- (b) transfer its common stock in other ways not involving market maker or established trading markets, including directly by gift, distribution, or other transfer;
- (c) sell its common stock under Rule 144 of the Securities Act rather than under this prospectus, if the transaction meets the requirements of Rule 144; or
- (d) sell its common stock by any other legally available means.

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LEGAL MATTERS

Skadden, Arps, Slate, Meagher & Flom LLP, New York, New York is acting as legal counsel to Endo Pharmaceuticals Holdings Inc. Skadden, Arps, Slate, Meagher & Flom LLP represents Kelso & Company and its affiliates from time to time. Debevoise & Plimpton LLP, New York, New York is acting as legal counsel to the underwriters. Debevoise & Plimpton LLP also represents Kelso and its affiliates from time to time.

EXPERTS

The financial statements and the related financial statement schedule incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003 have been audited by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's change in method of accounting for goodwill and other intangible assets upon adoption of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, effective January 1, 2002), which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

INTERESTS OF EXPERTS

Mr. Michael Mitchell, of counsel to Skadden, Arps, Slate, Meagher & Flom LLP, which provides legal services to us from time to time, is a director of Endo Pharmaceuticals Holdings Inc. and beneficially owns 30,000 options exercisable into shares of Endo Pharmaceuticals Holdings Inc.'s common stock.

WHERE YOU CAN FIND MORE INFORMATION

We file reports and other information with the SEC. We have filed a registration statement on Form S-3 with the SEC of which this prospectus is a part. This prospectus does not contain all of the information included in the registration statement, and you should refer to the registration statement and its exhibits and any related prospectus supplement to read that information. References in this prospectus and any related prospectus supplement to any of our contracts or other documents are not necessarily complete, and you should refer to the exhibits attached to or incorporated by reference in the registration statement for copies of the actual contract or document.

You may read and copy the registration statement, the related exhibits and the other material we file with the SEC at the SEC's public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549. You can also request copies of those documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file with the SEC. The site's address is www.sec.gov. You may also request a copy of these filings, at no cost, by writing or telephoning us as follows: 100 Painters Drive, Chadds Ford, Pennsylvania 19317, Attention: Chief Financial Officer or (610) 558-9800.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we later file with the SEC will automatically update and supersede the information contained or incorporated by reference in this prospectus. Accordingly, we incorporate by reference:

- our annual report on Form 10-K for the year ended December 31, 2003, as amended;

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- our quarterly report on Form 10-Q for the three months ended March 31, 2004;
- our information statement on Schedule 14C for our 2004 annual stockholders' meeting;
- our Form 8-A filed on July 12, 2000; and
- our current reports on Form 8-K filed on January 5, 2004, July 7, 2004, July 14, 2004, July 16, 2004 and July 19, 2004.

All documents which we subsequently file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the termination of an offering pursuant to this prospectus shall be deemed to be incorporated by reference into this prospectus from the date of filing of such documents. These documents are or will be available for inspection or copying at the locations identified above under the caption "Where You Can Find More Information."

We will provide without charge to each person, including any beneficial owner of common stock, to whom this prospectus is delivered, upon written or oral request, a copy of any and all of the documents that have been or may be incorporated by reference in this prospectus. You should direct requests for documents to 100 Painters Drive, Chadds Ford, Pennsylvania 19317, Attn: Chief Financial Officer. His telephone number is (610) 558-9800.

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus supplement. You must not rely on any unauthorized information or representations. This prospectus supplement is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus supplement is current only as of its date.

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11,000,000 shares

Common Stock

PROSPECTUS SUPPLEMENT

Bear, Stearns & Co. Inc.

August 3, 2004